Evidence-Based Management and Clinical Decision-Making in Temporomandibular Joint Disc Displacement without Reduction

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Abstract

Disc displacement without reduction (DDwoR), also known as “closed lock” (CL), is a temporomandibular disorder that may cause painful and limited mouth opening. Patients with DDwoR may present to any clinician in practice, but in the acute phase, patients often seek care immediately from clinicians at the frontline in emergency or primary care. There is, however, a lack of understanding on how frontline clinicians behave and what decisions they make when initially presented with a DDwoR patient. The suggested therapeutic interventions for DDwoR vary considerably in invasiveness with contradictory opinions about the appropriate conservative or surgical intervention, and their timing, for managing DDwoR. This may cause confusion for clinicians and lead management of DDwoR to become based more on experience than evidence. The aim of this project is to inform and facilitate the development of a virtually delivered, evidence-informed, behavioural intervention for clinicians to aid management of DDwoR, through the identification of: the best available evidence for timing of intervention, and the intervention itself, for DDwoR; the influences on clinicians’ decision-making processes in the management of DDwoR.

This project involved three separate, but sequential, studies. The first study was a systematic review of closed lock studies to investigate the effects of locking duration on DDwoR management. The second study was a systematic review of randomised trials to examine the therapeutic effects of interventions on DDwoR. The third study was a qualitative study interviewing clinicians at the frontline and specialist services in order to understand the decision-making processes in DDwoR management.

The two systematic reviews suggest that the best available evidence for managing DDwoR is by intervening early with the simplest and least invasive intervention. The qualitative data suggest that the main behavioural influences on frontline clinicians’ decision to refer DDwoR early were their lack of condition-specific knowledge, skills, and experience which represent the theoretically-based core targets for a future intervention to support their decisions.

Dedication

This thesis is dedicated to my parents and my wife.

Acknowledgment

The work of this thesis would not have been possible without the help and contribution of many people.

I would firstly like to thank Dr Justin Durham for his excellent supervision, enthusiasm, and thorough guidance throughout every step in this research project. I have been privileged working with him and I am very grateful to his constant support in different aspects of my life throughout the study period.

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I would like to thank Professor Catherine Exley and Dr Robert Wassell for their useful comments and suggestions to the project. Thanks are also extended to Ms Linda Errington for her help in the systematic reviews' studies and to Mrs Sue Wilkinson and Gwen Forster for their time and efforts to facilitate all the necessary arrangements during the study period. I am thankful to my colleagues at Newcastle University, Faaiz, Maythm, Sa'ad, Olushola, Mustafa, and Ahmed for their support during the study years.

I would like to acknowledge the authors who responded to my queries about their randomised trials included in the systematic review study. I would like also to acknowledge all the clinicians who participated in the qualitative study and thank them for providing their insight and experience and making this thesis possible. I hope the outcome of this research project can support them in their practice for the 'optimum' care of their patients. I wish them all the best in their career.

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Last but surely not least, I cannot thank enough my wonderful and beloved wife Mayis, who I married during this research journey, for her dedication, sacrifice, patience, commitment, advice, and reassurance. I hope I could make her dream true.

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List of Abbreviations

2D: Two-Dimensional
3D: Three-Dimensional
A&E: Accident and Emergency
AAOMS: American Association of Oral and Maxillofacial Surgery
AAOP: American Academy of Orofacial Pain
AC: Arthrocentesis
ACL: Acute Closed Lock
ADP: Anchored Disc Phenomenon
aMMO: active Maximum Mouth Opening
APA: American Psychological Association
APS: American Pain Society
ARS: Anterior Repositioning Splint
Arthrogr: Arthrography
AS: Arthroscopy
AsSp: Associate Specialists
ATN: Auriculotemporal Nerve
BCT: Behaviour Change Technique
CBCT: Cone-Beam Computed Tomography
CBT: Cognitive Behavioural Therapy
CCG: Clinical commissioning groups
CCL: Chronic Closed Lock
CDMP: Clinical Decision-Making Process
CDS: Community Dental Service
CDSS: Clinical Decision Support System
CENTRAL: Cochrane Central Register of controlled trials
Ch: Chronic
CI: Confidence Interval
CL: Closed Lock
cm: centimetres
CMI: Craniomandibular Index
cMMO: comfortable Maximum Mouth Opening
CNS: Central Nervous System
COFP: Chronic Orofacial Pain
COM-B: Capability, Opportunity, and Motivation of Behaviour
Comb: Combination therapy of splints + physiotherapy ± medication/education
Cons: consultant
CONSORT: Consolidated Standards of Reporting Trials
CPD: Continuing Professional Development
CPI: Characteristic Pain Index
CRD: Centre for Reviews and Dissemination
CS: Corticosteroids
CT: Computed Tomography
Ctrl: Control
DAL: Daily Activity Limitation
DC/TMD: Diagnostic Criteria for Temporomandibular Disorders
DDwoR: Disc Displacement without Reduction
DDwR: Disc Displacement with Reduction
DDwRwIL: Disc Displacement with Reduction with Intermittent Locking
DEC: Dental Emergency Clinic
DFD: Downward Flexure Deformation
DJD: Degenerative Joint Disease
DLA: Daily Living Activity
DOH: Department Of Health
DR: Disc Recapturing
drp: drop-outs
Dx: Diagnosis
Rx: Treatment
dy: day
EACD: European Academy of Craniomandibular Disorders
EBD: Evidence-Based Dentistry
EBM: Evidence-Based Medicine
EBP: Evidence-Based Practice
Educ: Education
EGDP: Experienced General Dental Practitioner
eHealth: electronic Health platform
EMG: Electromyography
EMGDP: EMergency General Dental Practitioner
ENT: Ear, Nose, and Throat
e-tool: electronic tool
Exr+Sp: Exercises plus Splint
exc: excluded
Exr: Exercises
F: Female
FMS-EC: Faculty of Medical Sciences-Ethics Committee
FOC: Frequency Of Complaints
GA: General Anaesthesia
GC: Glucocorticosteriods
GCPS: Graded Chronic Pain Scale
GDC: General Dental Council
GDP: General Dental Practitioner
GMC: General Medical Council
GMP: General Medical Practitioner
HA: Hyaluronic Acid
HS: Sodium Hyaluronate
IAOMS: International Association of Oral and Maxillofacial Surgery
ID: Internal Derangement
IL: Intermittent Locking
IM: Intra-Muscular
IMF: Inter-Maxillary Fixation
IMMPACT: Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
iontoph: iontophoresis
IQ: Interquartile
ITT: Intention-To-Treat analysis
IV: Intra-Venous
j: joint
JFLS: Jaw Functional Limitation Scale
LA: Local Anaesthesia
LDF: Limitation in Daily Function
LLLT: Low Level Laser Therapy
LM: Lateral Movement
LMO: Limited Mouth Opening
LOCF: Last Observation Carried Forward
LT: Long-Term
M: Male
CID: Clinically Important Difference
MD: Mean Difference
Med: Medication

MFIQ: Mandibular Function Impairment Questionnaire
mHealth: mobile Health platform
min: minute
MM: Mandibular Manipulation
mm: millimetres
MMO: Maximum Mouth Opening
mo: month
MPQ: McGill Pain Questionnaire
MR: Muscle Relaxant
MRC: Medical Research Council
mRCT: multi-centre Randomised Clinical Trial
MRI: Magnetic Resonance Imaging
N: Number
NA: Not Applicable
NGDP: New General Dental Practitioner
NHMRC: National Health and Medical Research Council
NHS: National Health Service
NICE-CKS: National Institute for Health and Care Excellence-Clinical Knowledge Summaries
NICE: National Institute of Clinical Excellence
NIDCR: National Institute of Dental and Craniofacial Research
NR: Not Reported
NRS: Numerical Rating Scale
NS: Non-Significant
NSurg: Non-Surgical
NSAID: Non-Steroidal Anti-Inflammatory Drug
NWCtotal: Total number of words chosen
OA: Osteoarthritis
OAdj: Occlusal Adjustment
OHIP-TMD: Oral Health Impact Profile for Temporomandibular Disorders
OMFS: Oral and Maxillofacial Surgery
OPG: Orthopantomogragh
OPPERA: Orofacial Pain Prospective Evaluation and Risk Assessment
OS: Open Surgery
PA: Power-Analysis
PCT: Primary Care Trust
PEMF: Pulsed Electromagnetic Field
PICOS: Participants, Interventions, Comparators/Control, Outcomes, and Studies
P/LMO: Painful/Limited Mouth Opening
PM: Pumping Manipulation
pMMO: passive Maximum Mouth Opening
PRI: Pain Rating Index
PRISMA: Preferred Reporting Items for Systematic reviews and Meta-Analyses
PrM: Protrusive Movement
PROSPERO: International Prospective Register of Systematic Reviews database
PS: Pivot Splint
P-HS: Pumping Sodium Hyaluronate
PT: Physiotherapy
QoL: Quality of Life
qRCT: quasi-Randomised Clinical Trial
R&D: Research and Development
RCT: Randomised Controlled Trial
RDC/TMD: Research Diagnostic Criteria for Temporomandibular Disorders
RDLA: Restriction of Daily Life Activities
Reh: Rehabilitation
ROWS: Rule Out Worst-case Scenario
RR: Risk Ratio
S&S: Signs and Symptoms
SD: Standard Deviation
self-ex: self-exercise
self-MM: self- Mandibular Manipulation
SG: Successful Group
SHO: Senior House Officer
SLPM: Superior head of Lateral Pterygoid Muscle
SM: Self-Management
SMD: Standardised Mean Difference
SpR: Specialist Registrar doctor
SPSS: Statistical Package for the Social Sciences
SR: Systematic Review
SS: Stabilization Splint
SSI: Symptoms Severity Index
ST: Short-Term
StG: Staff Grade specialty
Sub-ac: Sub-acute
TDF: Theoretical Domains Framework
TDI: Theoretical Domains Interview
TENS: Transcutaneous Electric Nerve Stimulation
TIDieR: Template for Intervention Description and Replication
TMD: Temporomandibular Disorders
TMJ: Temporomandibular Joint
Tx: Tenoxicam
UDAs: Units of Dental Activity
UFD: Upward Flexure Deformation
UG: Unsuccessful Group
UM: Unlock Manipulation
US: Ultrasonography
USOT: UK Specialist interest group in Orofacial pain and TMD
VAS: Visual Analogue Scale
VGIR: Visually Guided Irrigation
W: Wilkes staging of internal derangement
wk: week
WTD: Wooden Tongue Depressor
yr: year

Chapter 1. Introduction and Outline of Thesis

1.1 Introduction

The management protocols for temporomandibular disorders are vast and confusing but there is increasing evidence that these disorders are best managed initially with conservative reversible treatment (List and Axelsson, 2010), a standpoint which is supported and advised by a number of authorities from within the field (De Boever *et al.*, 2008; Greene, 2010a). Temporomandibular disorders (TMD), however, are a collection of heterogeneous disorders rather than being a singular "catch-all" entity and grouping the patients and managing them under the generic 'TMD' term[1] may rather cause further confusion in the field (Laskin, 2008; Benoliel, 2010). In a specific subtype of TMD such as disc displacement without reduction (DDwoR), which may intuitively be considered as a predominantly biomechanical disorder, a conservative approach may be considered somewhat counter-intuitive.

In its acute stage, DDwoR can be associated with sudden-onset painful/limited mouth opening (closed lock) symptom. There is, however, a lack of understanding on the duration of closed lock symptoms and their effects on DDwoR management. It is reasonable to hypothesise that there should be a difference if the clinicians intervene early as opposed to intervening late in terms of both the possibility of recapturing the displaced disc and reducing symptom-related disability. This is addressed in the first systematic review of this thesis which examines locking duration effects on clinical outcome of DDwoR management. However, understanding whether to intervene early is not enough because there are contradictory opinions about the most appropriate therapeutic intervention that should be employed.

For acute and chronic DDwoR management, where therapeutic interventions vary considerably in invasiveness, opinions are contradictory in the literature. In terms of the clinical decision-making process, the contradictory opinions around DDwoR management may lead management to become based more on subjective experience than evidence (Durham *et al.*, 2007). Subjective decision-making, however, may decrease the probability of making optimal therapeutic risk-benefit and cost-benefit

[1] For the purpose of discussing these disorders and readability, however, the singular term 'TMD' will be used throughout this thesis.

decisions. As a consequence, patients may not receive the most appropriate treatment and some may receive unnecessary investigations, which delay their active treatment and waste resources. It is also possible that some may experience, unnecessary, or even more importantly, harmful treatment. Management should, therefore, be examined based on the best and most up-to-date available evidence in order to optimise patients' healthcare. This is addressed in the second systematic review of this thesis which examines the therapeutic effects of interventions on DDwoR.

In clinical practice, however, research evidence alone is not sufficient to make a decision. Clinical decision-making is a complex adaptive process in which various clinical and non-clinical factors can influence clinicians' decisions (Kay and Nuttall, 1995c). For evidence-based clinical decisions, clinicians relate the evidence to some extent to their practical experience, clinical circumstances, and patient wishes and values prior to making a decision on whether or not to apply the research evidence (Haynes *et al.*, 2002a). Knowledge of the most appropriate intervention, therefore, is insufficient without an understanding of how clinicians behave if they are confronted with a patient having DDwoR and what might influence the decisions they make. The factors influencing clinicians' decision-making processes around DDwoR management are examined in the third and final part of this thesis.

In summary, this research project is the initial step in the development process of a future intervention aiding clinicians when managing DDwoR at the first point of contact. It involves two systematic reviews and one qualitative study. The systematic review studies provided the best available evidence to-date for timing and therapeutic effects of interventions for DDwoR management whilst the qualitative study provides insights into clinicians' decision-making processes in DDwoR management and the influences on the processes. The findings from the data in this thesis will help to provide evidence and layout the components for the proposed intervention to be implemented in the future.

1.2 Thesis layout

The layout of this thesis involves eight main chapters. Following this introductory first chapter, a second chapter reviews the current available literature around TMD and DDwoR, clinical decision-making processes, and outlines the development process of complex behavioural interventions. The third chapter describes the project aim and objectives. The following three chapters report both systematic reviews and the qualitative study examining clinical decision-making in DDwoR management. The penultimate chapter summarises the conclusions of the three studies whilst the final chapter outlines the recommendations for clinical practice and implications for future intervention design and future research.

Chapter 2. Literature Review

2.1 Introduction

The literature review's chapter is divided into three main sections:

- Section 2.2 contains a generic description of the temporomandibular disorders but focuses specifically on the pathophysiology, differential diagnosis, and management of the disc displacement without reduction disorder.
- Section 2.3 covers the clinical decision-making process and the factors influencing this process.
- Section 2.4 reviews briefly the implementation of research evidence in clinical practice and the development of behaviour change interventions for professionals.

Each of these sections will be presented separately with its own distinct conclusion but the sections will complement each other to reach the final conclusion.

2.2 Temporomandibular disorders

2.2.1 Introduction

Temporomandibular disorders are a collection of heterogeneous disorders (Peck *et al.*, 2014). It is, therefore, more appropriate to refer to these disorders according to the 'exact' diagnosis of each disorder or at least according to subgroups of these disorders (e.g., muscular, degenerative, or derangement joint disorders) rather than referring to them using the 'catch-all' plural 'TMDs' or singular 'TMD' terms (Laskin, 2007; Benoliel, 2010). For the purposes of discussing these disorders and readability of the text, however, the singular term 'TMD' will be used throughout the thesis.

This section will cover broadly the whole temporomandibular disorders (TMD) in general, but throughout this section the focus will be on disc displacement disorders, specifically on the main topic of this thesis: disc displacement without reduction (DDwoR) disorder.

Before reviewing the disorders involving the temporomandibular joint and its associated masticatory structures, it is important to have an idea about the basic anatomy and unique characteristics of the temporomandibular joint.

2.2.2 Anatomy of the temporomandibular joint and associated masticatory structures

The temporomandibular joint (TMJ) is a complex synovial joint consisting of temporal bone, mandibular bone, articular disc, synovial membrane, and associated ligaments and muscles. Anatomically, the TMJ is a 'diarthrodial' joint articulating two bones: the mandibular condyle and the squamous portion of the temporal bone (Figure 2.1). Functionally, the TMJ is a 'ginglymoarthrodial' joint permitting two motions: a hinge or rotatory motion (ginglymoid) and a gliding or translatory motion (arthrodial) (Figure 2.2) (Fletcher *et al.*, 2004; Alomar *et al.*, 2007; Molinari *et al.*, 2007).

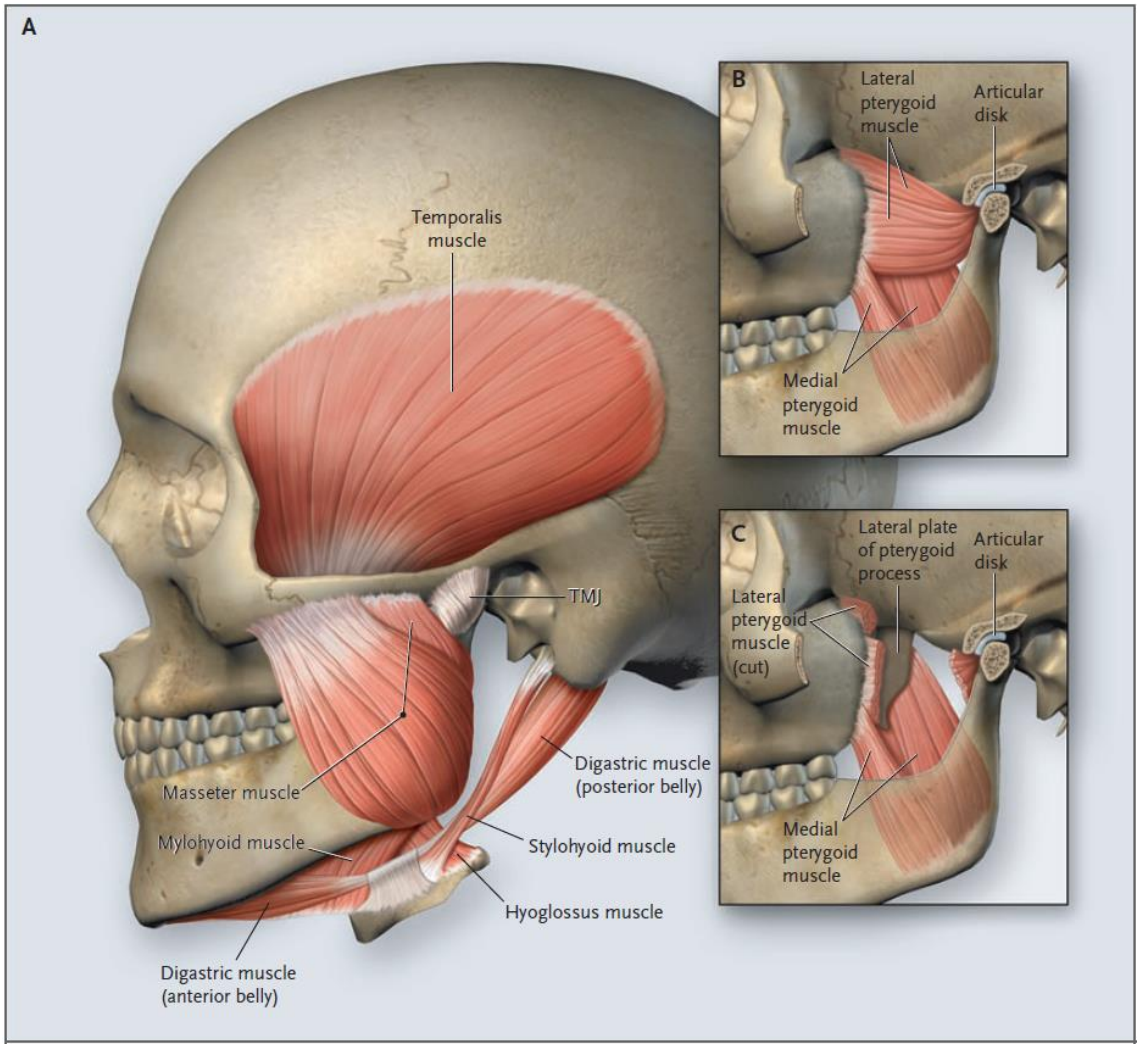


Figure 2.1: Normal anatomy of the TMJ and masticatory muscles. (A) Lateral view of the skull showing the normal position of the mandible in relation to the maxilla, the TMJ capsule, and the muscles associated with mandibular function (temporalis, masseter, mylohyoid, anterior and posterior digastric, hyoglossus, and stylohyoid). (B and C) showing the deep muscles associated with mandibular function (lateral and medial pterygoid) and the articular disc. Reproduced from Scrivani *et al.* (2008) with permission from Massachusetts Medical Society.

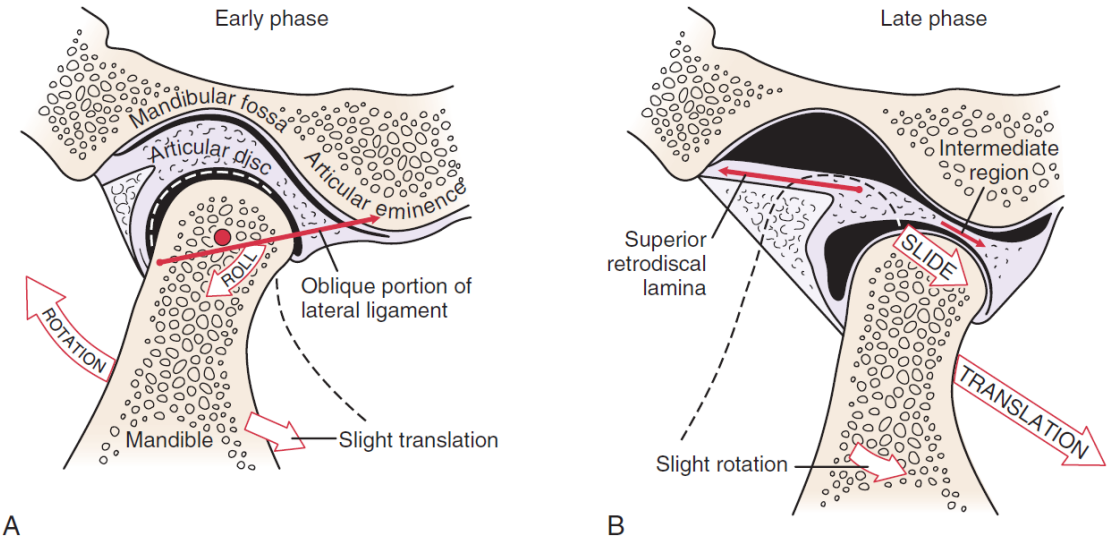


Figure 2.2: Opening movement of the TMJ. (A) Early opening rotatory movement. (B) Late opening translatory movement. Note the normal disc position and function during mouth opening. Reproduced from Neumann (2010) and Magee (2014) with permissions from Elsevier.

The TMJ is a unique joint. It has several distinctive features which differentiate it from other joints in the human body (Alomar *et al.*, 2007; Fanghanel and Gedrange, 2007):

- TMJ articular surfaces are covered by fibrocartilage instead of hyaline cartilage.
- TMJ movements have additional guidance through the occlusion of the teeth.
- TMJ has two principle motions: rotation and translation.
- Two joints function together and cannot move independently of each other.
- TMJ is 'two joints in one' with upper and lower joint compartments, acting synchronously.
- TMJ is a load-bearing joint (heavily loaded joint: 5-15 kg biting force).
- TMJ condylar cartilage represents a chondrogenic growth centre in children.

These peculiar characteristics of the TMJ may have several clinical implications when diagnosing and treating temporomandibular disorders.

2.2.3 Defining TMD and DDwoR

Temporomandibular disorders (TMD) are a collective group of musculoskeletal disorders that include painful and/or functional problems relating to the TMJ and/or its related musculoskeletal structures (McNeill *et al.*, 1990; Laskin, 2008). The disorders are many but encompass broadly three main subgroups, those primarily involving the

muscles (muscle disorders), those primarily involving the TMJ (joint disorders), and those associated with headache attributed to these disorders (Peck *et al.*, 2014). The TMJ disorders include different subtypes, mainly joint pain and intra-articular degenerative and derangement disorders as well as other hypo/hyper-mobility disorders (de Leeuw and Klasser, 2013).

In the healthy TMJ, the disc is normally positioned between the condylar head and the articular eminence during mandibular movements resulting in normal jaw function (Figure 2.2). The disc, however, may sometimes displace from its normal position resulting in disc derangement disorders.

Disc derangement disorders of the TMJ are a group of intra-articular biomechanical disorders in which there is an abnormal relationship in the functional 'articular cartilaginous' condyle-disc complex (Okeson, 2007). In comparison with the other joints in the human body, a clear classification of disc derangement disorders seems to be only identified for TMJ. In the orthopaedic literature, the 'disc displacement' term is rarely used; for example, the displacement of intervertebral disc between adjacent vertebral bodies in mobile tri-joint complex of spine is often referred to using other terminologies such as disc herniation, prolapse, protrusion, or bulging (Santilli *et al.*, 2006; Manchikanti *et al.*, 2010). In contrast, the TMJ disc derangement disorders are recently classified functionally into three main types of disc displacements in the Axis 1 of newly recommended diagnostic criteria (DC/TMD) (Table 2.1) (Schiffman *et al.*, 2014a), as follows:

1. Disc displacement with reduction (DDwR)

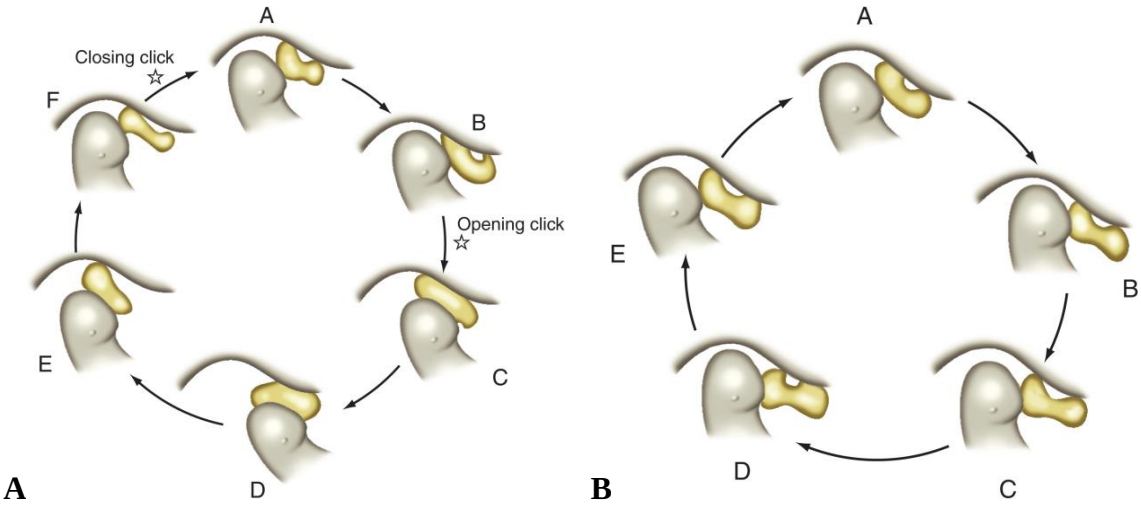
DDwR is a disorder involving the condyle-disc complex in which the disc is displaced in an anterior position relative to the condylar head when the mouth is closed but the disc reduces upon mouth opening resulting 'clinically' in clicking, popping, or snapping sounds (Schiffman *et al.*, 2014a) (Figure 2.3-A).

2. Disc displacement with reduction with intermittent locking (DDwRwIL)

DDwRwIL is a disorder involving the condyle-disc complex in which the disc is displaced in an anterior position relative to the condylar head when the mouth is closed but the disc intermittently reduces upon mouth opening resulting 'clinically' in intermittent locking (Schiffman *et al.*, 2014a).

3. Disc displacement without reduction (DDwoR)

DDwoR is a disorder involving the condyle-disc complex in which the disc is displaced in an anterior position relative to the condylar head when the mouth is closed and the disc does not reduce upon mouth opening resulting 'clinically' in permanent locking (Schiffman *et al.*, 2014a) (Figure 2.3-B). This disorder has two subtypes related to presence or absence of mouth opening limitation symptom: DDwoR with limited opening disorder also referred to as 'closed lock' and DDwoR without limited opening disorder and both subtypes of DDwoR (with/without limited opening) can be associated with or without TMJ pain.



A **B**

Figure 2.3: Anatomical disc displacement and its clinical implications. (A) DDwR on mouth opening resulting 'clinically' in reciprocal 'opening and closing' clicking sounds. (B) DDwoR on attempted mouth opening resulting 'clinically' in limited mouth opening 'closed lock' because the displaced disc blocks complete translation of the condyle. Reproduced from McCarty (1980) and Firestein and Kelley (2008) with permissions from Quintessence Publishing Company Inc. and Elsevier respectively.

In DDwoR, the disc is most frequently permanently displaced anteriorly to the condyle resulting in a 'closed lock' condition (i.e., inability to open mouth fully due to anterior DDwoR) (Santos *et al.*, 2013), but it may rarely displace posteriorly to the condyle resulting in an 'open lock' condition (i.e., inability to close mouth fully due to posterior DDwoR) (Huddleston Slater *et al.*, 2005; Chiba *et al.*, 2007). The latter, however, will not be considered further in this thesis due to its rarity and different symptomatology (Westesson *et al.*, 1998; Nitzan *et al.*, 2008). Further description about disc displacements classification is detailed in Section 2.2.7.

<table>
<tr><td colspan="3">Axis 1 Diagnostic Criteria for TMD (DC/TMD)</td></tr>
<tr><td colspan="3">▪ Most common pain-related TMD</td></tr>
<tr><td colspan="3">• Myalgia
- Local myalgia
- Myofacial pain
- Myofacial pain with referral
• Arthralgia
• Headache attributed to TMD</td></tr>
<tr><td colspan="3">▪ Most common intra-articular TMD</td></tr>
<tr><td colspan="3">• Disc derangement disorders</td></tr>
<tr><td colspan="3">- Disc displacement with reduction</td></tr>
<tr><td rowspan="2">Clinical</td><td>History</td><td>Positive for at least one of the following:
1. In the last 30 days*, any TMJ noise(s) present with jaw movement or function; OR
2. Patient report of any noise present during the exam.</td></tr>
<tr><td>Exam</td><td>Positive for at least one of the following:
1. Clicking, popping, and/or snapping noise during both opening and closing movements, detected with palpation during at least one of three repetitions of jaw opening and closing movements; OR
2a. Clicking, popping, and/or snapping noise detected with palpation during at least one of three repetitions of opening or closing movement(s); AND
2b. Clicking, popping, and/or snapping noise detected with palpation during at least one of three repetitions of right or left lateral, or protrusive movement(s).</td></tr>
<tr><td colspan="2">Validity</td><td>Without imaging: sensitivity 0.34; specificity 0.92.
Imaging is the reference standard for this diagnosis.</td></tr>
<tr><td colspan="2">Imaging</td><td>When this diagnosis needs to be confirmed, TMJ MRI criteria are positive for both of the following:
1. In the maximum intercuspal position, the posterior band of the disc is located anterior to the 11:30 position and the intermediate zone of the disc is anterior to the condylar head; AND
2. On full opening, the intermediate zone of the disc is located between the condylar head and the articular eminence.</td></tr>
<tr><td colspan="3">- Disc displacement with reduction with intermittent locking</td></tr>
<tr><td rowspan="2">Clinical</td><td>History</td><td>Positive for both of the following:
1a. In the last 30 days*, any TMJ noise(s) present with jaw movement or function; OR
1b. Patient report of any noise present during the exam; AND
2. In the last 30 days*, jaw locks with limited mouth opening, even for a moment, and then unlocks.</td></tr>
<tr><td>Exam</td><td>Positive for at least one of the following:
1. Clicking, popping, and/or snapping noise detected during both opening and closing movements, detected with palpation during at least one of three repetitions of jaw opening and closing movements; OR
2a. Clicking, popping, and/or snapping noise detected with palpation during at least one of three repetitions of opening or closing movement(s); AND
2b. Clicking, popping, and/or snapping noise detected with palpation during at least one of three repetitions of right or left lateral, or protrusive movement(s).</td></tr>
<tr><td colspan="2">Validity</td><td>Without imaging: sensitivity 0.38; specificity 0.98.
Imaging is the reference standard for this diagnosis.</td></tr>
</table>

Axis 1 Diagnostic Criteria for TMD (DC/TMD)		
Imaging		When this diagnosis needs to be confirmed, the imaging criteria are the same as for DDwR if intermittent locking is not present at the time of imaging. If locking occurs during imaging, an imaging-based diagnosis of DDwoR will be rendered and clinical confirmation of reversion to intermittent locking is needed.
Note: Although not required, when this disorder is present clinically, examination is positive for inability to open to a normal amount, even momentarily, without the clinician or patient performing a maneuver to reduce the lock.		
- **Disc displacement without reduction with limited opening****		
Clinical	**History**	Positive for both of the following: 1. Jaw locked so that the mouth would not open all the way; AND 2. Limitation in jaw opening severe enough to limit jaw opening and interfere with ability to eat.
	Exam	Positive for the following: 1. Maximum assisted opening (passive stretch) movement including vertical incisal overlap < 40 mm.
Validity		Without imaging: sensitivity 80%; specificity 97%. Imaging is the reference standard for this diagnosis.
Imaging		When this diagnosis needs to be confirmed, TMJ MRI criteria are positive for both of the following: 1. In the maximum intercuspal position, the posterior band of the disc is located anterior to the 11:30 position and the intermediate zone of the disc is anterior to the condylar head, AND 2. On full opening, the intermediate zone of the disc is located anterior to the condylar head.
Note: Maximum assisted opening of < 40 mm is determined clinically. Note: Presence of TMJ noise (e.g., click during opening) does not exclude this diagnosis.		
- **Disc displacement without reduction without limited opening****		
Clinical	**History**	Positive for both of the following in the past: 1. Jaw locked so that the mouth would not open all the way; AND 2. Limitation in jaw opening severe enough to limit jaw opening and interfere with ability to eat.
	Exam	Positive for the following: 1. Maximum assisted opening (passive stretch) movement including vertical incisal overlap ≥ 40 mm.
Validity		Without imaging: sensitivity 54%; specificity 79%. Imaging is the reference standard for this diagnosis.
Imaging		When this diagnosis needs to be confirmed, TMJ MRI criteria are the same as for disc displacement without reduction with limited opening.
Note: Maximum assisted opening of ≥ 40 mm is determined clinically. Note: Presence of TMJ noise (e.g., click during opening) does not exclude this diagnosis.		
• Degenerative joint disease • Dislocation - Luxation - Subluxation		

* The time frame for assessing selected biomechanical intra-articular disorders is in "the last 30 days" since the stated sensitivity and specificity of these criteria were established using this time frame. Although the specific time frame can be dependent on the context in which the noise or biomechanical complaints are being assessed, the validity of this diagnosis based on different time frames has not been established.

** Both types of DDwoR (with/without limited opening) can be associated with or without TMJ pain.

Table 2.1: Axis 1 diagnostic criteria for TMD (DC/TMD). Adapted from Schiffman *et al.* (2014a).

2.2.4 Prevalence and incidence

TMD has been identified as the most common cause of non-odontogenic pain in the oral and maxillofacial region and it is the commonest condition among other chronic orofacial pain (COFP) conditions such as trigeminal neuralgia, burning mouth syndrome, and atypical facial pain or persistent dentoalveolar pain (Yazdi *et al.*, 2012).

Epidemiologic studies about TMD prevalence report variable rates (5%-50%) of TMD signs and symptoms at any particular time amongst the general population (de Oliveira *et al.*, 2006; NIDCR, 2008; Visscher *et al.*, 2015). A meta-analysis of TMD prevalence studies shows a rate of 30% perceived dysfunction among participants of 23 studies and a rate of 44% clinically assessed dysfunction among participants of 22 studies (de Kanter *et al.*, 1993). This difference between people's perceptions and professionals' clinical assessment may reflect the difference in treatment need/demand by people; that is, only individuals with moderate to severe clinically assessed pain/dysfunction perceived some need or demand for treatment. The authors, therefore, concluded that the TMD prevalence studies are appropriate only for quantification of TMD signs and symptoms and cannot reflect the TMD patients' need and demand for treatment (de Kanter *et al.*, 1993). Several studies, therefore, showed that only 5% to 17% of the general population have severe TMD symptoms that need treatment (Solberg *et al.*, 1979; Schiffman *et al.*, 1990; Nassif *et al.*, 2003).

Many studies found that TMD is most prevalent in young females (LeResche, 1997; Kohler *et al.*, 2012). However, in a cohort of 2737 initially TMD-free participants (aged 18-44 years), 260 developed first-onset TMD during a follow-up average of 2.8 years, yielding an average annual incidence rate of 3.5% (Greenspan *et al.*, 2013; Slade *et al.*, 2013a). This incidence of first-onset TMD was more common among older age adults with only slightly greater incidence in females than males (Slade *et al.*, 2013a). The differences in reported prevalence and incidence rates among the studies, however, are probably attributed to studies' methodological differences; one of these is the difference in inclusion/exclusion criteria of the targeted population. For example, in Slade *et al.* (2013a), the participants were volunteers of a specific age cohort (18-44 years) with no significant history of TMD whereas the defined populations in many other studies were randomly sampled of a wider age range (Yekkalam and Wanman, 2014; Visscher *et al.*, 2015).

The prevalence of different subgroups of TMD is also quite variable and difficult to determine. A systematic review on the prevalence of different TMD subgroups according to research diagnostic criteria for TMD (RDC/TMD) axis I diagnoses reported an overall prevalence of up to: 13% for muscle disorders, 16% for disc derangement disorders, and 9% for joint pain and degenerative disorders among general population and found an overall prevalence of: 45% for muscle disorders, 41% for disc derangement disorders, and 30% for joint pain and degenerative disorders among TMD patients (Manfredini *et al.*, 2011).

The exact rate of occurrence of symptomatic DDwoR is not fully determined but its incidence amongst TMD patients is estimated to occur in about 2-8% (List and Dworkin, 1996; Lee *et al.*, 2008; Manfredini *et al.*, 2012; Poveda-Roda *et al.*, 2012) whist its prevalence amongst young population is estimated to occur in about 4% (Wieckiewicz *et al.*, 2014). DDwoR, however, is also diagnosed radiographically by magnetic resonance imaging (MRI) in people without any clinical signs and symptoms with a reported prevalence of 3% amongst the asymptomatic general population (Katzberg *et al.*, 1996; Kecik *et al.*, 2005; Naeije *et al.*, 2013).

The prevalence and incidence of TMJ dislocation is undetermined but seems to be comparable to that of DDwoR. In a meta-analysis of TMD prevalence studies, the prevalence of TMJ dislocation and jaw 'locking' conditions was found to be less than 1% of all participants in included studies' samples (de Kanter *et al.*, 1993). In one study, the incidence of acute and chronic TMJ dislocation (luxation and subluxation) was found to be about 22% as opposed to 71% TMD patients attending emergency service during 6 months period (Luz and Oliveira, 1994). In another study, however, among 1500 COFP patients referred over 4 years and a half to specialist service, 94 patients have 'closed lock' (i.e., DDwoR) (6%) whilst only 13 patients have acute or recurrent TMJ dislocation (1%) (Dahlstrom, 1998).

2.2.5 Aetiology and pathophysiology

This subsection will be presented in two parts. Firstly, a brief summary of the aetiology of TMD in general and secondly a more detailed part of the pathophysiology of disc derangement disorders in particular.

TMD aetiology

TMD aetiology is undetermined but considered to be multifactorial. In the literature, various aetiological factors have been proposed as risk factors for TMD development. These include: traumatic (macrotrauma and microtrauma), anatomical (skeletal and occlusal), pathophysiological (systemic, local, and genetic), and psychosocial (psychological and social) factors (de Leeuw and Klasser, 2013). However, direct causation of any of these factors has not been confirmed and generally there is only weak/modest evidence to support any of the systematically reviewed risk factors for TMD development (Oakley and Vieira, 2008; Lindenmeyer *et al.*, 2010; Luther *et al.*, 2010; Manfredini and Lobbezoo, 2010; Iodice *et al.*, 2013; Rocha *et al.*, 2013; Haggman-Henrikson *et al.*, 2014; Visscher and Lobbezoo, 2014).

In the last decade, the aetiology of TMD has been the subject of a multimillion dollar National Institute of Dental and Craniofacial Research (NIDCR) program called "Orofacial Pain: Prospective Evaluation and Risk Assessment" (OPPERA) (NIDCR, 2006). In this prospective clinical series of studies, multiple phenotypic domains which may have a role in TMD aetiology have been investigated including: sociodemographic profiles (Slade *et al.*, 2013a), clinical findings and pain symptoms (Ohrbach *et al.*, 2013), psychosocial factors (Fillingim *et al.*, 2013), pain sensitivity (Greenspan *et al.*, 2013), autonomic profiles (Maixner *et al.*, 2011), and genetic factors (Smith *et al.*, 2013). The project's initial findings are that a broad range of phenotypic variables contributed to the first-onset development of TMD. The greatest contribution was from the health status domain followed by psychological and clinical orofacial domains, the modest contribution was from pain sensitivity and cardiac autonomic responses domains, whilst there were several genetic associations with intermediate phenotypes 'risk factors' contributing to TMD incidence (Slade *et al.*, 2013b). This broad range of phenotypic risk factors influencing TMD incidence and distinguishing TMD patients from controls (non-TMD) reflects the complex and multidimensional nature of TMD aetiology which is consistent with the biopsychosocial model of illness often applied to TMD (Suvinen *et al.*, 2005). These findings show promise for advancing our understanding of the aetiology of TMD and may have future clinical implications for TMD diagnosis and treatment. However, despite these advances, a singular 'direct' causative factor for developing TMD has yet to be identified. At present, TMD aetiology remains controversial with its multifactorial aetiology being best represented

by a biopsychosocial framework of initiating, predisposing, and perpetuating factors (Greene, 1995).

Pathophysiology of disc derangement disorders

The pathophysiology of TMJ disorders is a multifaceted complex process involving numerous intra-articular biomechanical and biochemical events and several extra-articular factors resulting in joint derangement and/or degenerative disorders. These events and factors are discussed in-detail in Nitzan *et al.* (2008). This part will focus on the aetiology and the clinical course progression (pathogenesis) of disc derangement disorders in general and DDwoR in particular.

Pathogenesis of disc displacement

Aetiology of disc displacement

The aetiology of TMD in general is controversial and the aetiology of disc displacement is no exception. Controversies have been reported in determination the causes of disc displacement and various aetiological factors have been suggested to play a role in the genesis of disc displacement including: trauma (direct or indirect 'whiplash' trauma) (Yun and Kim, 2005; Sale *et al.*, 2014), functional overloading (parafunctional habits and parafunctional masticatory activity) (Israel *et al.*, 1999; Michelotti *et al.*, 2010), ligaments laxity and joint hypermobility (Ogren *et al.*, 2012), joint effusion (Manfredini *et al.*, 2009), degenerative joint disease (osteoarthritis) (Stegenga, 2001), increased friction between the moving TMJ parts (Nitzan, 2001; del Pozo *et al.*, 2003; Tanaka *et al.*, 2008b), lateral pterygoid muscle spasm (Taskaya-Yilmaz *et al.*, 2005), as well as skeletal discrepancy and occlusal factors (Nebbe and Major, 2000; Kwon *et al.*, 2013; Matsumoto *et al.*, 2013; Chang *et al.*, 2015a).

Most of these factors, however, are not well established and still debatable. For example the cause-and-effect relationship between disc displacement and osteoarthritis is undetermined because osteoarthritis can be regarded as an initiating cause in the development of disc displacement (Stegenga *et al.*, 1991; de Bont and Stegenga, 1993) but it can be also a consequence of disc displacement (Eriksson and Westesson, 1983; Kalladka *et al.*, 2014). In addition, the osteoarthritis initiating role does not explain the displacement of the disc in joints without degenerative changes (Stegenga, 2001).

Another example is the possible aetiological role of the attached muscle to the TMJ disc. Anterior displacement of the disc has been attributed to spasm of the superior head of the lateral pterygoid muscle (SLPM) attached to the disc (Fujita *et al.*, 2001; Taskaya-Yilmaz *et al.*, 2005). Different hypotheses have been proposed for the aetiological role of the dysfunction of the lateral pterygoid muscle in displacement of TMJ disc such as: muscle hyperactivity (resulting from myofascial pain) or hypoactivity (muscle pathologic changes: hypertrophy or atrophy), lack of coordination between the superior and inferior heads of the muscle, and/or a disturbance in the normal function of the muscle in stabilising and controlling the movements of the disc (Mahan *et al.*, 1983; Juniper, 1984; Liu *et al.*, 1989; Hiraba *et al.*, 2000). Most of these hypotheses, however, are not supported currently by sufficient evidence (Murray *et al.*, 2004). This is in addition to the fact that the SLPM has a variable attachment to the disc (Carpentier *et al.*, 1988; Naidoo, 1996; Antonopoulou *et al.*, 2013). In a review about the percentage of SLPM insertion into the disc, highly variable insertion percentages were found ranging from 2% to 70% (Contreras *et al.*, 2011). Although Taskaya-Yilmaz *et al.* (2005) found that the SLPM attached solely to the disc in 86% of all the joints with DDwoR suggesting that the contraction of this muscle may easily displace the disc anteriorly, a recent study invalidated this finding and found no difference between DDwoR, DDwR, and normal disc position in patients having a SLPM attached only to the disc (Park *et al.*, 2012). Furthermore, other studies found no difference between the type of muscle attachment and the presence or absence of disc displacement (Dergin *et al.*, 2012; Imanimoghaddam *et al.*, 2013). All these findings suggest that the explanation of anterior disc displacement based on anatomic SLPM attachment, muscle spastic activity, and/or dysfunction is not probable.

Joint hypermobility, whether generalised or localised, has also been reported to have a role in the aetiology of disc displacement of the TMJ (Kavuncu *et al.*, 2006; Ogren *et al.*, 2012). Generalised Joint hypermobility (GJH) is a systemic disorder characterized by the increase in range of motion of multiple joints in the human body (Conti *et al.*, 2000; Winocur *et al.*, 2000) and it can be associated with a variety of complaints of the locomotor system such as joints dislocation and soft tissue lesions (Kirk *et al.*, 1967). GJH is mostly attributed to hereditary disorders of the connective tissue (collagen defect) (Child, 1986; Westling *et al.*, 1992), but it can occur without collagen defect (Beighton *et al.*, 2012). The sequence of events resulting in disc displacement in TMJ involved in GJH is hypothesised as follows: biochemical changes to the structure of

collagen and elastin; causing a loss of resistance to traction and laxity of capsular or ligamentous structure of the TMJ; resulting in increase in joint mobility; increasing propensity to mechanical overloading due to joint hypermobility; the joint overloading associated with parafunctions and/or trauma resulting in degenerative changes, joint inflammation, and disc derangements (Dijkstra *et al.*, 1992; Kavuncu *et al.*, 2006; Pasinato *et al.*, 2011). However, a systematic review of the studies analysing the association between TMJ disorders and GJH performed up to 2001 found conflicting evidence of this association (Dijkstra *et al.*, 2002). Several studies have been conducted after this systematic review and have reported conflicting results. Some studies found there is an association between GJH and disc displacement (Hirsch *et al.*, 2008; Ogren *et al.*, 2012), whilst others found there is no such association (Saez-Yuguero Mdel *et al.*, 2009; Wang *et al.*, 2012). In fact, the observations of absence of joint hypermobility in many patients with disc displacement supports the multifactorial aetiology of disc displacement (Khan and Pedlar, 1996). Currently, GJH is regarded as one of the important predisposing factors for developing disc displacement and, therefore, individuals with GJH involving the TMJ should be carefully evaluated and monitored for the potential increased risk of disc displacement (Chang *et al.*, 2015b).

Overall, most of the studies investigating the aetiology of disc displacement had the shortcoming of not controlling the other 'risk' factors that can play a potential role in disc displacement initiation. In fact, the aetiology of disc displacement, as the whole TMD, is multifactorial and many aetiological factors can contribute not only to the genesis of disc displacement but also to the type and direction of disc displacement.

Progression of disc displacement

The classical clinical progression sequence in disc derangement of TMJ has been described to progress from reciprocal clicking (DDwR) to intermittent locking 'catching' (DDwRwIL) to permanent locking 'closed lock' (DDwoR) culminating in an end stage of degenerative joint disease (osteoarthritis) (Rasmussen, 1981; Wilkes, 1989; Kalladka *et al.*, 2014). Although these progressive changes may happen in some patients with disc displacement, the findings from several studies suggest that this is far from a *fait accompli* in disc derangement disorders (Greene and Laskin, 1988; de Leeuw *et al.*, 1994), and even if this progression sequence occurs, it may not be clinically relevant to patients' symptoms in terms of jaw pain, function, and disability (Chantaracherd *et al.*, 2015).

Numerous observational studies on patients with DDwR reported different progression rates from DDwR to DDwoR ranging from 0% to 69% over varying periods of observation ranging from 3 months to 15 years (Lundh *et al.*, 1987; Westesson and Lundh, 1989; Kononen *et al.*, 1996; Sato *et al.*, 2003; Kalaykova *et al.*, 2010; Cai *et al.*, 2011; Manfredini *et al.*, 2013; Sale *et al.*, 2014). A systematic review about disc displacement disorders found that the progression to permanent locking (closed lock) occurred in only (12–30%) of patients who had lost reciprocal clicking sounds over the observation period (Naeije *et al.*, 2013). In a recent study, significant osseous organisational differences were found between most clicking and locking joints suggesting that DDwR and DDwoR can be two distinct disorders and not necessarily a single disease continuum (i.e., a sequence progression from one to another) and there were only a subset of clicking joints contain characteristics of locking joints that may contribute to symptom progression (Pullinger, 2013). All these findings indicate that the 'clicking' is not always a reliable predictor for 'locking' and there could be a lot of predisposing factors leading to initiation of symptomatic DDwoR and the closed lock condition.

Pathogenesis of DDwoR

Aetiology of DDwoR

In addition to various aetiological factors suggested earlier for disc displacement genesis, several factors have been also discussed in the literature that can be involved specifically in initiation or predisposition of jaw locking (DDwoR or closed lock) such as: frequent intermittent locking (Friedman, 1993; Yoda *et al.*, 2006; Kalaykova *et al.*, 2010; Takahara *et al.*, 2014), bruxism (Katzberg *et al.*, 1996; Ghanem, 2011), genetic (Huang *et al.*, 2011), skeletal (Ooi *et al.*, 2013; Ooi *et al.*, 2014), and traumatic (Knibbe *et al.*, 1989; Gould and Banes, 1995) factors. These 'risk' factors may be regarded as important predictors for progressing clicking into locking.

Progression of DDwoR

The progression of DDwoR has been studied in several observational studies and shown to be 'favourable'. In studies on the long-term natural course of 'chronic' DDwoR, about two thirds of patients have resolution or spontaneous improvement in their clinical signs and symptoms without any therapeutic intervention over an observation period of 1 to 2.5 years, whilst the other one third did not improve or became worse

during the observation period (Lundh *et al.*, 1992; Sato *et al.*, 1997a; Kurita *et al.*, 1998b). In a recent study on the short-term natural course of 'acute' DDwoR, 95% of patients have resolution in their signs and symptoms over 3 months period of observation (Yura, 2012). These findings suggest that any treatment offered for patients with symptomatic DDwoR must be easier and more effective than waiting for symptoms resolution during the natural course of the disorder.

The improvement in some patients with DDwoR over time is often attributed to retrodiscal tissues' stretching, remodelling, and 'pseudo' disc adaptation (Isberg and Isacsson, 1986; Pereira Junior *et al.*, 1996). Several studies, however, have proved that the deformity of the condyle-disc complex and the displacement of the disc increases despite the improved symptoms (Sato *et al.*, 1999a; Kurita *et al.*, 2006; Cai *et al.*, 2011). Some studies have also pointed out that the permanently displaced disc can result in changes in maxillofacial skeletal morphology over the long-term (Gidarakou *et al.*, 2004; Bertram *et al.*, 2011; Xie *et al.*, 2015).

Adaptation versus degeneration

The TMJ is a load-bearing joint (Smith *et al.*, 1986). Its articular tissues have an impressive adaptive capacity to mechanical loading (Milam and Schmitz, 1995). This capacity, however, is not infinite because continued overloading may raise the susceptibility to degenerative joint disease (Kai *et al.*, 1998; Milam, 2005). In addition, several 'risk' factors may adversely influence the joint adaptive capacity such as: age, systemic illness, nutritional, hormonal, mechanical, traumatic, and genetic factors (Milam and Schmitz, 1995; Nitzan *et al.*, 2008; Tanaka *et al.*, 2008a). Hence, a degenerative state may ensue if functional demands surpass the joint adaptive capacity or if the affected individual is susceptible to maladaptive responses (Milam, 2005).

Milam (2003) proposed three models that may be involved in the pathogenesis of degenerative TMJ disorders: direct mechanical trauma model, hypoxia reperfusion model, and neurogenic inflammation model. In these models, the molecular events and cascades in response to mechanical overloading may result in an imbalance between catabolic and anabolic events leading ultimately to catabolism (i.e., degeneration) of the articular tissues in the susceptible joints (Milam and Schmitz, 1995; Milam, 2003; Milam, 2005). In one study, the risk of degenerative changes has been shown to be four times greater in joints with DDwoR than in joints with normal disc position and

suggestions have been made to the susceptibility for degenerative disease initiation by an imbalance in the patient's adaptive capacity and functional loading of the TMJ (Roh *et al.*, 2012). Many studies have also provided biochemical evidence of increasing susceptibility to osteoarthritic degenerative changes in 'chronic' DDwoR patients (Kubota *et al.*, 1997; Paegle *et al.*, 2003; Sicurezza *et al.*, 2013).

All these findings suggest the need for a thorough individualised assessment of each patient with DDwoR in order to evaluate the various potential 'risk' factors that may play a role in DDwoR prognosis and contribute towards the progression to degenerative disorder. At present, however, the borderline separating 'healthy' remodelling adaptive responses from 'pathological' degenerative responses is ill-defined which means it is difficult to predict the DDwoR prognosis in an individual patient.

In fact, DDwoR is a disorder with two possible scenarios: it is either a benign self-limiting disorder in which most patients' symptoms improve with time and not necessarily progress to degenerative joint disease (de Leeuw *et al.*, 1994; Murakami *et al.*, 2002; Imirzalioglu *et al.*, 2005), or it can be also a debilitating disorder resulting in significant pain and dysfunction leading to patients' disability and disturbing their quality of life with the potential for persistence of symptoms and progression to degenerative disease in susceptible patients over the long-term (Chiba and Echigo, 2005; Paegle *et al.*, 2005; Holmlund, 2007; Ishimaru *et al.*, 2015; Millon-Cruz *et al.*, 2015). Both scenarios are possible in patients with DDwoR and it is still yet unclear which patients have, or which bio-mechanical/chemical factors predict, the greatest risk for progressing to the more advanced stages. This is in addition to the fact that there are other risk factors that can be involved in developing chronic pain in some individuals such as: increasing age at presentation, gender (females with concurrent myogenous TMD), higher pain intensity and disability (graded chronic pain scale (GCPS) score of 3 or 4), non-specific widespread symptoms, genetics, phenotype, and psychosocial (concurrent psychiatric diagnosis or mood disturbance such as depression, anxiety, anger) factors (Denk *et al.*, 2014; Durham *et al.*, 2015). Therefore, it is important to treat all DDwoR patients early in order to prevent degenerative disease progress in susceptible patients and to mitigate progression from an acute to a chronic condition and hopefully avoid the development of chronic pain/disability and its psychosocial consequences (Gatchel *et al.*, 2006). Nevertheless, any early intervention must be simple and non-invasive to allow for potential healing (adaptation) and symptomatic

resolution during the ‘favourable’ natural course of the DDwoR disorder (Yura, 2012; Tajima *et al.*, 2013).

In recent years, numerous synovial fluid analyses and investigations have been conducted to further comprehend the pathogenesis of disc derangement and degenerative joint disorders (Bouloux, 2009; Wei *et al.*, 2010; Li *et al.*, 2014). Despite these investigative advances, at present, the events that underlie TMJ adaptation versus degeneration are still not fully understood (Wang *et al.*, 2015) and the molecular and cellular basis of DDwoR pathophysiology is still unclear.

In summary, the aetiology and pathophysiology of the TMD is yet to be completely revealed and their clinical implications on TMD management are still undefined. Nevertheless, this brief review provides some evidence from a pathophysiological perspective of the need for early intervention in the DDwoR management pathway.

2.2.6 Presenting signs and symptoms

TMD may present with a multitude of overlapping signs and symptoms including pain in the masticatory musculature and/or joint, limitation of mandibular movements (e.g., locking), TMJ sounds (e.g., clicking, snapping, popping, grating or crepitus), and occasionally headaches (Wassell *et al.*, 2004; de Leeuw and Klasser, 2013). The natural course of TMD is not yet well understood but most TMD symptoms are often remitting and self-limiting but can recur or fluctuate over time (de Bont *et al.*, 1997; Manfredini *et al.*, 2013).

Patients with DDwoR are usually characterised by distinct combinations of signs and symptoms: history of clicking followed by sudden-onset TMJ pain and limited mouth opening (locking without clicking), impaired mandibular lateral movement towards the opposite ‘unaffected’ side, and deflection towards the same ‘affected’ side during mouth opening (Farrar, 1972; Okeson, 2007). These characteristic symptoms are usually present in ‘acute’ rather than ‘chronic’ DDwoR (Naeije *et al.*, 2013).

In its acute stage, DDwoR is often associated with severe symptoms that have considerable negative impact on patient’s quality of life (Reissmann *et al.*, 2007). The two biomedical complaints which are often predominant in ‘acute’ DDwoR (i.e., closed lock) are: TMJ pain and limited mouth opening (Farrar, 1978; Eriksson and Westesson,

1983; Okeson, 2007). The causes of these symptoms in DDwoR, however, are unclear and controversial with various putative theories suggested.

The first biomedical complaint predominant in DDwoR is the sudden-onset TMJ pain. The exact cause of pain is still not fully understood (Fujiwara *et al.*, 2013). The displaced disc has been thought to play an important role in the pain process due to overstretching and pulling the highly vascularized and innervated retrodiscal tissues and joint capsule in addition to condylar impingement on the capsule and/or compression to the retrodiscal tissue (Isberg *et al.*, 1986; Lin *et al.*, 2012). This, however, is unlikely to be the sole reason of pain because disc displacement is not always associated with pain and several studies have shown that DDwoR can be asymptomatic and some considered it as an anatomic variant rather than a pathologic abnormality (Katzberg *et al.*, 1996; Peroz *et al.*, 2011). In addition to alteration in disc position, other factors have been suggested in the development of pain in patients with DDwoR such as joint effusion and inflammatory reactions including synovitis, capsulitis, or retrodiscitis (Murakami *et al.*, 1991; Westesson and Brooks, 1992; Segami *et al.*, 2001), as well as accompanied muscular spasm and pain (Murakami *et al.*, 1992; Manfredini, 2009).

The other biomedical complaint predominant in DDwoR is the abrupt restriction in mouth opening (Mariz *et al.*, 2005; Campos *et al.*, 2008). It is widely accepted that the restriction in mouth opening in DDwoR is mostly attributed to mechanical obstruction by the displaced disc to the translating condylar movement (Farrar, 1972; Rammelsberg *et al.*, 1997). This limitation in mouth opening is often termed, almost colloquially, since early 1980s as ‘closed lock’ (CL) (Katzberg *et al.*, 1980; Weisberg and Friedman, 1981). This term, however, describes a clinical symptom not an anatomic diagnosis and the CL condition is not always exclusively refer to DDwoR. Several studies by Nitzan and co-authors suggested various putative biomechanical and biochemical processes within the joint resulting in a phenomenon of anchoring the articular disc to the glenoid fossa termed ‘anchored disc phenomenon’ (ADP) as potentially responsible for mouth opening limitation in some of the cases of CL (Nitzan and Dolwick, 1991; Nitzan and Marmary, 1997). The putative pathogenic sequential processes underpinning ADP involve the following: joint overloading resulting in direct mechanical injury, hypoxia-reperfusion injury, resulting in free radicals release into the synovial fluid, causing hyaluronic acid degradation, resulting ultimately in a vacuum effect (suction cup effect). The culmination of these proposed sequential pathological processes collectively leads

to tight disc adherence to the roof of the glenoid fossa, thereby preventing the condylar sliding movement and producing more pronounced jaw locking but that responds better to arthrocentesis than DDwoR (Nitzan and Dolwick, 1991; Nitzan *et al.*, 1992; Nitzan and Marmary, 1997; Nitzan and Etsion, 2002; Nitzan *et al.*, 2002; Nitzan, 2003). According to Nitzan, ADP has been mistakenly included with DDwoR. Nitzan's claim is that ADP differs from DDwoR disorder in its origin, clinical presentation, and treatment required (Table 2.2) and, therefore, she suggests that there is a need to identify ADP as a distinct entity within the group of TMJ disorders (Nitzan *et al.*, 1997).

Characteristics	ADP	DDwoR
History:		
Occurrence (Onset of limitation)	Sudden	Gradual
Nature of limitation	Persistent	Pliable
Past clicks (History of clicking)	No (30%)	Yes
Clinical signs and symptoms:		
Main complaint	Severe LMO	Pain + LMO
Pain (self-assessment)	-	+
Dysfunction (self-assessment)	+	-
Maximum mouth opening (mm)	15-25 mm	30-45 mm
Contralateral movement	Limited	Limited
Ipsilateral movement	Normal	Normal
Occlusal changes	-	-
Imaging:		
Bony changes on radiographs, computed tomography (CT)	No	No
Magnetic resonance imaging (MRI) (open mouth position)	Stuck disc, located above and behind the condyle	Displaced-deformed disc, located in front of the condyle
Treatment:		
Efficacy of conservative treatments	Poor 10%	Excellent 90%
Effect of arthrocentesis	Excellent 90%	Moderate 40%

Table 2.2: Summary of comparison of history, clinical signs and symptoms, imaging, and treatment required between ADP and DDwoR. Adapted from (Nitzan and Marmary, 1997; Nitzan, 2002; Nitzan *et al.*, 2008).

Despite these attempts to differentiate ADP from DDwoR, it is still unclear if ADP is a distinct entity from DDwoR or a differing stage of the same clinical entity due to considerable similarity in signs and symptoms between the two conditions. This similarity makes it virtually impossible to differentiate the two conditions on the basis of clinical diagnosis alone. Although there is still a possibility to differentiate the adhered fixed or 'stuck' disc from displaced disc on the basis of MRI (Rao *et al.*, 1993)

(Figure 2.4), it is doubtful and questionable as apart from very few ADP studies involving exclusively patients with normally positioned discs (Kaneyama *et al.*, 2007b), most ADP studies involve patients with displaced discs as well as normally positioned discs (Nitzan *et al.*, 1997; Casares *et al.*, 1999; Sanroman, 2004). Further studies with MRI evidence of normally positioned discs in CL patients are needed to gain a better understanding whether ADP is a separate entity within the 'closed lock' category (Hoffman, 1997; Kaneyama *et al.*, 2007b).

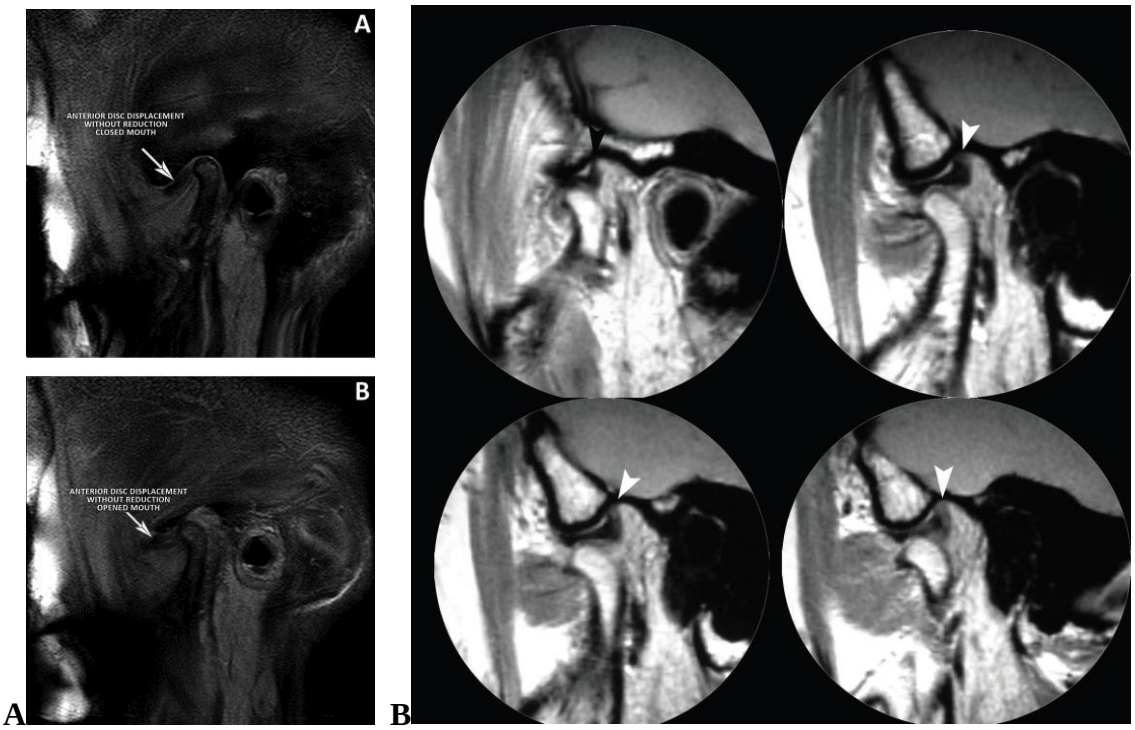


Figure 2.4: MRI sagittal views of anteriorly displaced disc and normally positioned adhered disc. (A) Anterior DDwoR on closed and opened mouth positions. (B) ADP during mouth opening movement. The images show: condylar hypomobility, normally positioned disc with limited mobility, and apparent fibrous adhesion band between the posterior band of the disc and the glenoid fossa (arrows). Reproduced from Galhardo *et al.* (2013) and de Melo *et al.* (2014) with permissions from Elsevier and Revista Gaúcha de Odontologia (RGO) respectively.

Overall, the role of disc displacement in the development of clinical signs and symptoms in DDwoR is yet to be determined; whether disc displacement is the result, the cause, or an accompanying factor of TMJ-related pain and dysfunction is unclear (Dolwick, 1995; Hall, 1995). Many studies emphasised the importance of disc position as an underlying causative factor of TMJ-related pain and dysfunction suggesting that the disc requires repositioning in order to improve DDwoR signs and symptoms (Okeson, 1988; McCain *et al.*, 1992a; Jiang *et al.*, 2013; He *et al.*, 2015). This is, however, proven to be unnecessary as high success rates have been reported by

conservative and surgical interventions without influencing the disc position and repositioning (recapturing) the displaced disc (Montgomery *et al.*, 1989; Choi *et al.*, 1994; Nitzan, 2001). Currently, it is generally agreed that the disc mobility rather than disc position is more important to improve patients' signs and symptoms when managing DDwoR (Takatsuka *et al.*, 2005; Ohnuki *et al.*, 2006).

2.2.7 Diagnosis

Diagnostic classification systems of TMD

Several diagnostic and screening systems have been suggested for TMD such as: Bell's classification (Bell, 1970), Helkimo's anamnestic and dysfunction indices (Helkimo, 1974), American Academy of Orofacial Pain (AAOP) guidelines (de Leeuw, 2008), and Research Diagnostic Criteria for TMD (RDC/TMD) (Dworkin and LeResche, 1992). Ideally, any diagnostic classification system should be based on the aetiology of the disease. For TMD, however, all the diagnostic classifications are generally based solely on signs and symptoms of the disorders rather than their 'actual' aetiological factors due to limited knowledge about TMD aetiology (Section 2.2.5).

Amongst all diagnostic classification systems suggested for TMD, the most widely accepted is the RDC/TMD (Dworkin and LeResche, 1992) because it uses a biopsychosocial approach including biological, psychological, and social factors for TMD diagnosis (Zakrzewska, 2004; Suvinen *et al.*, 2005). The RDC/TMD applies a dual-axis system to diagnose and classify patients with TMD. The physical axis 1 distinguishes between groups of TMD patients with (I) myofascial pain, (II) disc displacement with/without reduction, and (III) arthralgia, osteoarthritis, and osteoarthrosis. The psychosocial axis 2 includes a 31-item questionnaire that assesses TMD-related pain and psychosocial factors (Dworkin and LeResche, 1992). This multi-axial approach allows better characterization of the patient from several standpoints (Zakrzewska, 2004).

Satisfactory reliability and validity (specificity and sensitivity) are the prerequisites for the use of any diagnostic measures (Turp and Minagi, 2001). The validation project examined the reliability and validity of RDC/TMD (Anderson *et al.*, 2010). The main finding of this project was that the RDC/TMD axis 1 has the reliability but not the 'target' validity (i.e., sensitivity < 70% and specificity < 95%) (Look *et al.*, 2010; Schiffman *et al.*, 2010; Truelove *et al.*, 2010), and that the axis 2 had both reliability

and validity (Ohrbach *et al.*, 2010). The RDC/TMD is also criticised for being too complex and takes a lot of time to be used in routine clinical practice and is more suitable for research purposes (Zakrzewska, 2004; Hasanain *et al.*, 2009). For all these shortcomings, the RDC/TMD has been recently revised to the diagnostic criteria for TMD (DC/TMD) (Schiffman *et al.*, 2014a).

The newly recommended DC/TMD also include two axes. The new axis 1 (Table 2.1) includes reliable and valid criteria for differentiating 'clinically' the common pain-related TMD as well as one intra-articular disorder (DDwoR with limited opening) but still lacks adequate validity to clinically diagnose other intra-articular disorders without using TMJ imaging. The new axis 2 is expanded by adding further instruments to assess pain, jaw function, behavioural and psychological status, and psychosocial functioning. It involves two self-report instrument sets: a simple screening set of different psychometric instruments, to be used initially, includes a 41-item questions that assesses TMD-related pain intensity, disability, and location as well as jaw functional limitations, psychosocial distress, and parafunctional behaviour; a more comprehensive set of psychometric instruments, to be used when indicated, includes an 81-item questions that assesses in further detail jaw functional limitations and psychosocial distress as well as anxiety and presence of comorbid pain conditions. The new DC/TMD has been suggested to have more clinical utility than the 'original' RDC/TMD and are more appropriate for use in clinical and research settings (Schiffman *et al.*, 2014a).

Diagnostic classification of disc displacement

The classification of disc displacement in relation to disc position and function and its clinical relevance has been studied and documented by clinical, anatomic, radiographic, and surgical observations (Wilkes, 1989).

Precise localisation of disc position on TMJ imaging is crucial for disc displacement diagnosis (Drace and Enzmann, 1990). Normal disc position has been defined according to the radiological location of either the posterior band of the disc (i.e., the junction of the posterior band of the disc and the bilaminar zone) or the intermediate zone of the disc using different reference criteria. Many studies used the traditional 12 o'clock criterion to define the normal position of the posterior band of the disc on MRI (Rao *et al.*, 1993; Tasaki *et al.*, 1996; Katzberg and Tallents, 2005) (Figure 2.5-A). However,

the normal position of the junction of the posterior band of the disc and the bilaminar zone was identified by Drace and Enzmann (1990) to be anywhere up to 10° from the 12 o'clock position (Figure 2.5-B).

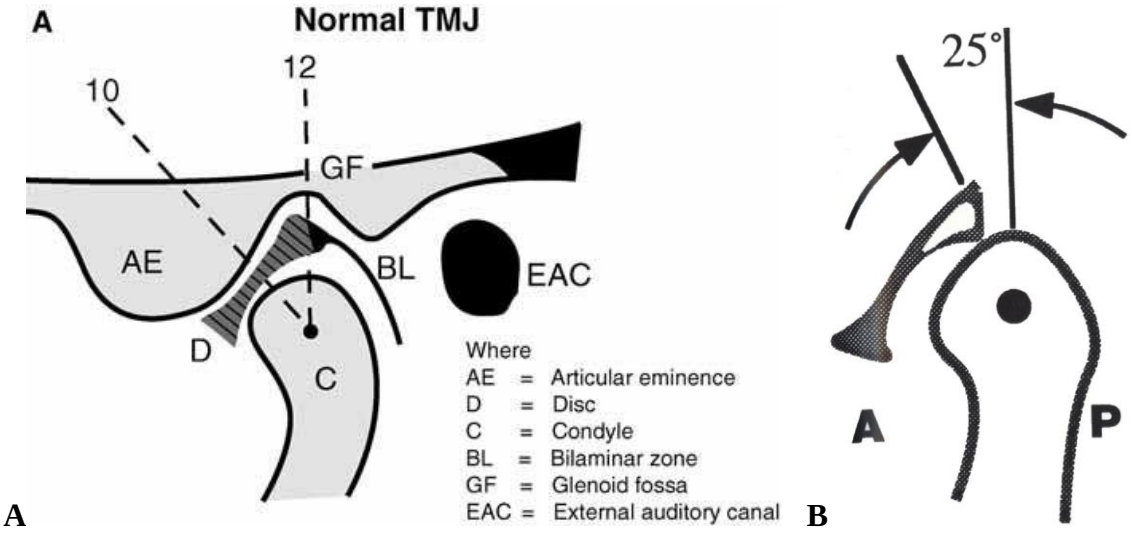


Figure 2.5: Disc position according to 12 o'clock criterion. (A) Diagram illustrating the normal disc position defined according to 12 o'clock criterion at the junction of the posterior band of the disc and the bilaminar zone. (B) Diagram illustrating the quantification of degree of disc displacement. The angle from the 12 O'clock criterion represents the amount of displacement, specified in degrees: A=anterior, P=posterior. Reproduced from Styles and Whyte (2002) and Drace and Enzmann (1990) with permissions from Elsevier and Radiological Society of North America (RSNA) respectively.

Orsini and colleagues evaluated four different criteria for normal disc position on MRI: three clock positions of the posterior band (12, 11, and 10 o'clock) and one intermediate zone criterion (Figure 2.6) in order to identify the best reference criterion for disc position on MRI that reflects the clinical findings of the joint (i.e., signs and symptoms) (Orsini *et al.*, 1998; Orsini *et al.*, 1999). The study found that the intermediate zone criterion is the most rigorous criterion having fewest false positives and false negatives (Orsini *et al.*, 1998; Orsini *et al.*, 1999). Therefore, the intermediate zone criterion is preferred over the other suggested criteria and used currently by the new DC/TMD because it avoids the possibility of over-diagnosis/over-treatment and under-diagnosis/under-treatment (Orsini *et al.*, 1999; Provenzano Mde *et al.*, 2012).

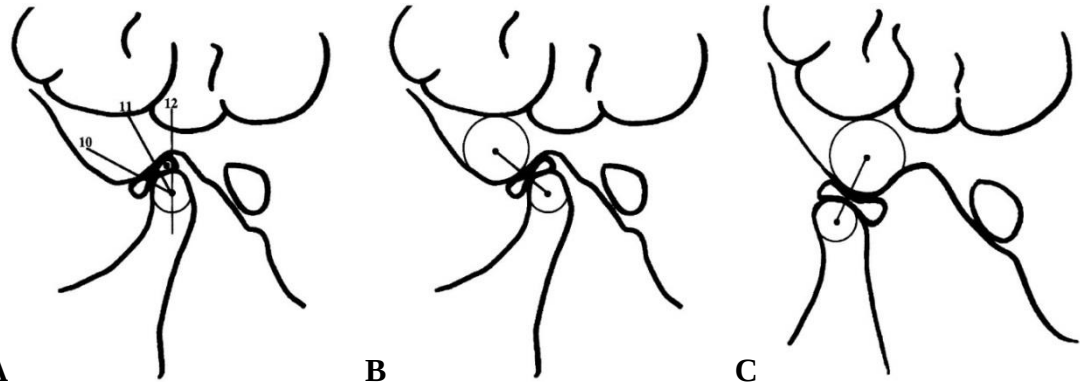


Figure 2.6: Normal disc position according to four different criteria. (A) 12, 11, and 10 o'clock posterior band criteria in the closed-mouth position (if the posterior band of the disc touched the line of the criterion zone, the disc position considered normal for that criterion). (B) Intermediate zone criterion in the closed-mouth position (if the intermediate zone of the disc located between the anterosuperior aspect of the condyle and the posteroinferior aspect of the articular eminence in the middle of the line, the disc position considered normal). (C) Intermediate zone criterion in the opened-mouth position (if the intermediate zone of the disc located between the condyle and the articular eminence when the mouth is wide open in the middle of the line, the disc position considered normal). Reproduced from Orsini *et al.* (1998) with permission from Elsevier.

On the basis of the MRI sagittal and coronal images analysis, Tasaki *et al.* (1996) propose a classification system for TMJ disc displacement involving ten different categories of disc position into which normal and abnormal joints can be classified. The ten disc positions are summarised in Table 2.3 and illustrated in Figure 2.7.

Disc position category	Criteria for classification of disc positions
Superior disc position (normal anatomical disc position)	Posterior band of disc superior to condyle or central thin zone (intermediate zone) of disc located between anterior prominence of condyle and posterior aspect of articular eminence (Figure 2.3-1).
Anterior disc displacement	Posterior band of disc anterior to anterior prominence of condyle throughout mediolateral dimension of joint (Figure 2.3-2).
Partial anterior disc displacement in lateral part of joint	Disc anteriorly displaced in lateral part of joint and disc in superior position in medial part of joint with no sideways component to displacement (Figure 2.3-3).
Partial anterior disc displacement in medial part of joint	Disc anteriorly displaced in medial part of joint and in superior position in lateral part of joint with no sideways component to displacement (Figure 2.3-4).
Rotational anterolateral disc displacement	Disc anteriorly and laterally displaced (Figure 2.3-5).
Rotational anteromedial disc displacement	Disc anteriorly and medially displaced (Figure 2.3-6).
Lateral disc displacement	Disc displaced lateral to lateral pole of condyle (Figure 2.3-7).
Medial disc displacement	Disc displaced medial to medial pole of condyle (Figure 2.3-8).
Posterior disc displacement	Disc displaced posterior to 12 o'clock position on top of condyle (Figure 2.3-9).
Indeterminate	This category was used when a large perforation, prior surgical therapy or no clear image of the disc prevented classification into any of the above categories.

Table 2.3: Criteria for classification of disc positions. Adapted from Tasaki *et al.* (1996).

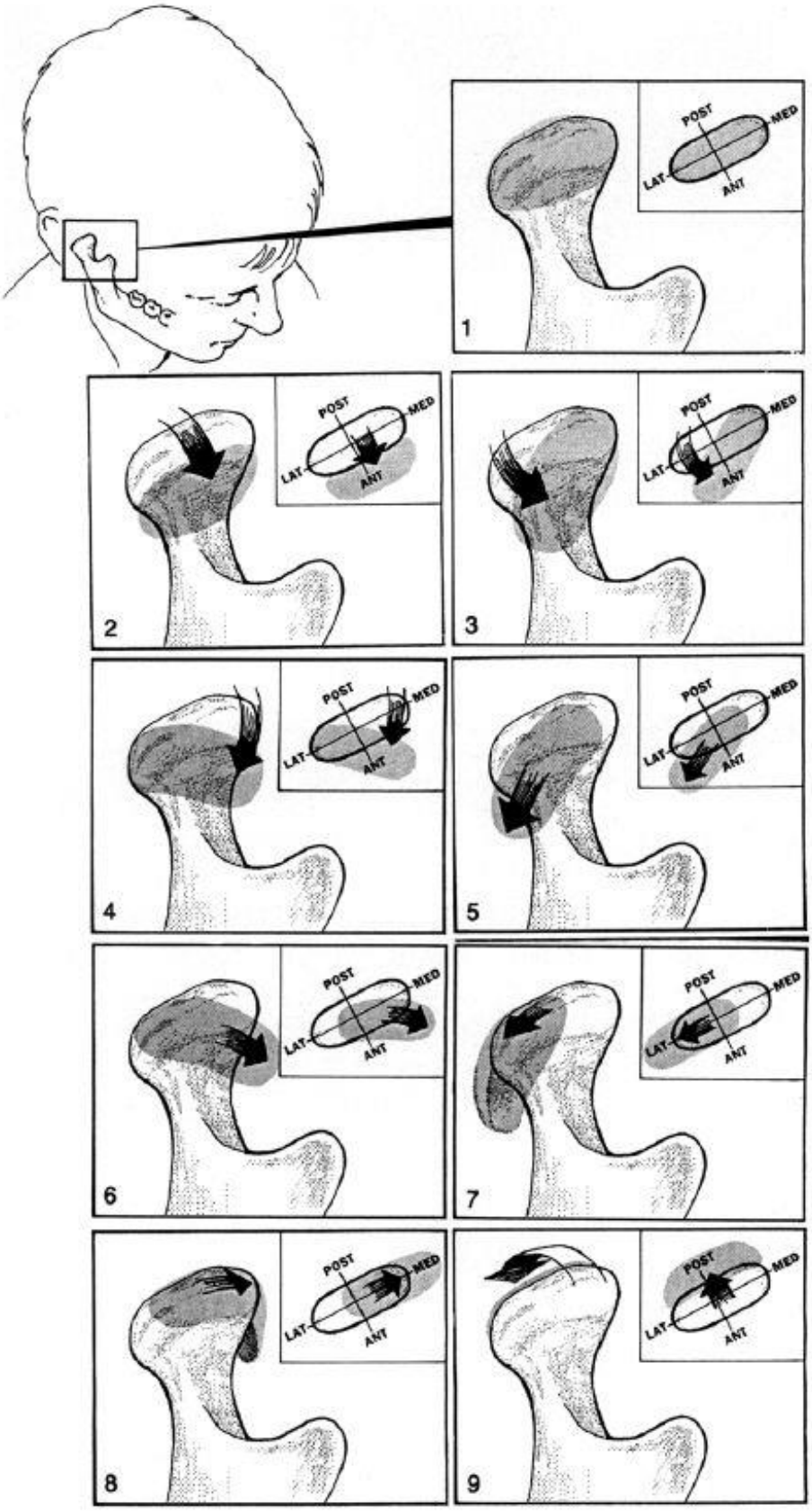


Figure 2.7: Schematic figures illustrate nine categories of disk position described in Table 2.3. Reproduced from Tasaki *et al.* (1996) with permission from Elsevier.

Among the different directions of disc displacement, 'pure' anterior disc displacement has been consistently reported as the most common type of disc displacement (Tasaki *et al.*, 1996; Foucart *et al.*, 1998; Whyte *et al.*, 2006). The second commonest type of disc displacement, however, is not generally agreed. Many studies found it is anteromedial (Nebbe and Major, 2000; Ogutcen-Toller *et al.*, 2002; Schmitter *et al.*, 2005a), whilst others found it is anterolateral disc displacement (Katzberg *et al.*, 1996; Tasaki *et al.*, 1996; Emshoff *et al.*, 2002b). Other types of disc displacement such as posterior or 'pure' lateral or medial disc displacements are generally uncommon (Katzberg *et al.*, 1988; Westesson *et al.*, 1998).

Despite the importance of classifying and identifying the different disc positions, in clinical practice increasing the diagnostic options may result in reducing the diagnostic reliability (Ahmad *et al.*, 2009). In practice, the most important is the disc function rather than its position. In this regard, Ahmad *et al.* (2009) develop comprehensive criteria for image analysis using panoramic, computed tomography (CT), and MRI imaging techniques as a part of axis 1 RDC/TMD diagnostic system. The RDC/TMD image analysis recommended criteria for disc position were based on Orsini *et al.* (1999) and classify the disc position in relation to the osseous joint components simply into 5 (Table 2.4) instead of 10 types (Table 2.3). The RDC/TMD image analysis criteria have good reliability and it can be used in both clinical as well as research settings (Ahmad *et al.*, 2009). Recently, on the basis of MRI images evaluation and classification according to Ahmad *et al.* (2009), a strong correlation was found between severe stage of disc displacement (i.e., bilateral DDwoR) and both osseous abnormalities and pain in symptomatic young patients (de Melo *et al.*, 2015).

Disc diagnosis	MRI findings
A. Normal	Disc location is normal on closed- and open-mouth images.
B. Disc displacement with reduction	Disc location is displaced on closed-mouth images but normal in open-mouth images.
C. Disc displacement without reduction	Disc location is displaced on closed-mouth and open-mouth images.
D. Indeterminate	Disc location is not clearly normal or displaced in the closed-mouth position.
E. Disc not visible	Neither signal intensity nor outlines make it possible to define a structure as the disc in the closed-mouth and open-mouth views. If the images are of adequate quality in visualizing other structures in the TMJ, then this finding is interpreted to indicate a deterioration of the disc, which is associated with advanced disc pathology.

Table 2.4: Disc diagnosis for TMJ using MRI. Adapted from Ahmad *et al.* (2009).

This image analysis means that the clinician in clinical practice can simply categorise the disc displacement positions according to disc function into three distinct categories: normal, abnormal (displaced with or without reduction), or indeterminate. According to Tasaki *et al.* (1996), these disc functions are defined as follows:

- Normal disc function: "when a disc in the superior position in the closed mouth position maintained a position interposed between the condyle and the articular eminence in the open mouth position".
- Reduction: "when a displaced disc in the closed mouth position assumed a position interposed between the condyle and the articular eminence in the open mouth position".
- No reduction: "when a displaced disc in the closed mouth position did not achieve a position between the condyle and the articular eminence in the open mouth position".
- Indeterminate disc function: "when the disc cannot be identified by imaging because of surgical removal, metallic artifacts, or postsurgical scarring".

Currently, three main types of disc displacements are classified clinically in the newly recommended DC/TMD: disc displacement with reduction (DDwR), disc displacement with reduction with intermittent locking (DDwRwIL), and disc displacement without reduction (DDwoR) (Schiffman *et al.*, 2014a).

To-date, the most widely used criteria for DDwoR diagnosis in clinical trials are: RDC/TMD (Dworkin and LeResche, 1992), AAOP diagnostic guidelines (de Leeuw, 2008), and Wilkes staging for TMJ internal derangement (Wilkes, 1989; Wilkes, 1991). All the three diagnostic classifications have some general agreement about the presence of pain and limited mouth opening as common complaints in DDwoR patients (Table 2.5).

AAOP Criteria (de Leeuw, 2008)	
Criteria for acute DDwoR:	
Clinical	*All the following must be present:* 1. Persistent markedly limited mouth opening ≤ 35mm with history of sudden onset. 2. Deflection to the affected side on mouth opening. 3. Markedly limited laterotrusion to the contralateral side (if unilateral disorder). *Any of the following may accompany the preceding items:* - Pain precipitated by forced mouth opening. - History of clicking that ceases with locking. - Pain with palpation of the affected joint. - Ipsilateral hyper occlusion
Imaging	Optional soft tissue imaging reveals DDwoR. *Can be accompanied with:* No or mild osteoarthritic changes with hard tissue imaging.
Criteria for chronic DDwoR:	
Clinical	1. History of sudden onset of limited mouth opening. *Any of the following may accompany the preceding item:* - Pain, when present, is markedly reduced from the acute stage. - History of clicking that resolved with sudden onset of the locking. - Crepitation on mandibular movement. - Gradual resolution of limited mouth opening.
Imaging	Soft tissue imaging reveals DDwoR. *Can be accompanied with:* Mild to moderate osteoarthritic changes with imaging of hard tissues.
RDC/TMD (Dworkin and LeResche, 1992)	
Criteria for DDwoR with limited mouth opening:	
Clinical	*All the following must be present:* • History of locking or catching that interfered with eating. • Absence of TMJ clicking or presence of TMJ sounds not meeting criteria for DDwR. • Maximum unassisted opening ≤ 35mm. • Passive stretch < 5mm (from unassisted opening to assisted opening < 40mm). • Contralateral excursion < 7mm and/or uncorrected ipsilateral deviation on opening.
Imaging	No need for TMJ imaging investigation.
Criteria for DDwoR without limited mouth opening:	
Clinical	*All the following must be present:* • History of locking or catching that interfered with eating (history of previously limited opening). • Presence of TMJ sounds not meeting criteria for DDwR 'clicking'. • Maximum unassisted opening > 35mm. • Passive stretch ≥ 5mm (from unassisted opening to assisted opening > 40mm). • Contralateral excursion ≥ 7mm.
Imaging	Optional TMJ imaging (arthrography or MRI) to confirm disc displacement in closed and opened mouth positions.
Wilkes staging (Wilkes, 1989)	
Stage III criteria: Intermediate stage of internal derangement	
Clinical	Multiple frequent episodes of pain, joint tenderness, headaches; Major mechanical symptoms consisting of locking (closed lock): restriction of motion; Functional difficulties (pain with function: painful chewing).
Imaging	Anterior disc displacement (non-reducing disc when the mouth is open) with significant anatomic deformity or prolapse of disc, moderate to marked thickening of posterior band of disc, no hard tissue changes and normal osseous contours.
Stage IV criteria: Late intermediate stage of internal derangement	
Clinical	Chronicity with variable and episodic pain, headaches, and variable restriction of motion (increase in severity over intermediate stage).
Imaging	Anterior disc displacement (non-reducing), marked disc thickening, early to moderate degenerative changes of articulating surfaces (e.g., flattening of eminence, deformation of condylar head, osteophytes, erosions, sclerosis) and abnormal hard tissue changes and abnormal osseous contours (increase in severity over intermediate stage).

Table 2.5: Clinical and imaging diagnostic criteria of different systems for DDwoR diagnosis. Adapted from (Wilkes, 1989; Dworkin and LeResche, 1992; de Leeuw, 2008).

The newly developed diagnostic criteria for DDwoR (Table 2.1) have been recommended for use in clinical practice and research instead of RDC/TMD and AAOP criteria (Table 2.5) (Schiffman *et al.*, 2014a). The main changes to the 'original' RDC/TMD in the 'new' DC/TMD for DDwoR are summarised in Table 2.6.

Changes from RDC/TMD to DC/TMD for DDwoR with or without limited opening		
History	**RDC**	**DC**
"Ever have jaw lock or catch so that it would not open all the way" and "interfered with eating" applicable to disc displacement without reduction with and without limited opening	✓	✓
Examination		
Disc displacement without reduction with limited opening:		
Unassisted opening* ≤ 35 mm and assisted opening ≤ 5 mm more than unassisted opening.	✓	
Assisted opening* < 40 mm.		✓
Contralateral movements < 7 mm and/or uncorrected deviation to the ipsilateral side on opening.	✓	
Absence of noise, or noise not meeting criteria for disc displacement with reduction	✓	
Disc displacement without reduction without limited opening:		
Unassisted opening* > 35 mm and assisted opening > 5 mm more than unassisted opening.	✓	
Assisted opening* ≥ 40 mm.		✓
Contralateral and protrusive movements ≥ 7 mm.	✓	
Noise not meeting criteria for disc displacement with reduction	✓	

* Measurement of opening includes interincisal opening plus vertical incisal overlap.

Table 2.6: Changes from RDC/TMD to DC/TMD for DDwoR with or without limited opening. Adapted from Schiffman *et al.* (2014a).

Diagnostic process

History and clinical examination

The diagnosis of TMD is based primarily on the presenting signs and symptoms depending largely on thorough history and careful intra-oral hard/soft tissue and occlusal examination and extra-oral clinical examination (Baba *et al.*, 2001). However, multiple diagnostic devices have been used in many studies for TMD diagnosis such as pressure algometers, surface electromyography (EMG), sound/vibration detection, and jaw tracking devices (Sato *et al.*, 1998; Yilmaz *et al.*, 2008; Santana-Mora *et al.*, 2014). The studies claimed that such investigative devices serve as a diagnostic aid to the clinical diagnosis of TMD. However, systematic reviews about their diagnostic efficacy demonstrate little benefit of these devices over the traditional TMD diagnosis by history and clinical examination in terms of both overall validity (reproducibility and accuracy)

and practical use (ease of use and cost versus benefit) (Baba *et al.*, 2001; Klasser and Okeson, 2006; Armijo-Olivo *et al.*, 2007; Suvinen and Kemppainen, 2007; Al-Saleh *et al.*, 2012; Sharma *et al.*, 2013).

The clinical diagnosis for patients with DDwoR focuses mainly on common symptoms of pain and limited opening. These painful-limited opening symptoms, however, are usually present in 'acute' DDwoR (i.e. closed lock) as opposed to decreased pain-improved opening in 'chronic' DDwoR (see DDwoR pathogenesis). This makes the clinical diagnosis of the former more readily achievable in clinical practice without the need for imaging the joint (Dworkin and LeResche, 1992). The latter, however, may be difficult to diagnose clinically without TMJ imaging investigation (Suarez and Ourique, 2000; Naeije *et al.*, 2013).

Imaging investigations

Several imaging modalities have been used for imaging the hard and soft tissues of TMJ with the aim of adding information to the clinical findings, including: plain radiography, panoramic radiography, arthrography, ultrasonography (US), MRI, conventional CT and cone-beam CT (CBCT) scan (Tvrdy, 2007; Petersson, 2010; Bakke *et al.*, 2014). Among these, three main imaging techniques have been considered to visualise the TMJ intra-articular soft tissue changes and to identify the position of the displaced disc: arthrography, US, and MRI (Anderson *et al.*, 1989; Habashi *et al.*, 2015).

Arthrography has been used in the past to determine disc position, disc perforation, and intra-articular adhesions (Donlon and Moon, 1987; Zhang *et al.*, 2007), but its invasive nature, potential for complications, and the emergence of less invasive advanced soft tissue imaging techniques such as US and MRI limits its use as a routine soft tissue TMJ imaging technique (Trumpy *et al.*, 1997).

Another suggested TMJ soft tissue imaging technique is ultrasonography (US). This technique has several advantages and disadvantages (Sharma *et al.*, 2014). It is usually regarded a non-invasive, low cost, easy, simple, quick, and dynamic technique to identify disc position (Emshoff *et al.*, 2002a; Tognini *et al.*, 2003; Manfredini and Guarda-Nardini, 2009). US main advantage over MRI is that it is a dynamic investigation allowing the possibility of direct observation of TMJ disc mobility during mouth opening and closing movements which may help the clinician to determine the

disc position more clearly than in a singular static investigation (Bas *et al.*, 2011; Barchetti *et al.*, 2014). The disc observation 'visualisation' can also be repeated if the disc is unclear by asking the patient to move his jaw again and can be performed by the dentist or surgeon himself to confirm his/her provisional clinical diagnosis (Jank *et al.*, 2005) or to guide needle positioning during intra-articular injection (Levorova *et al.*, 2015).

Many studies examined the sensitivity, specificity, and accuracy of US in determining disc position in relation to MRI findings and/or clinical diagnosis (Tognini *et al.*, 2005; Cakir-Ozkan *et al.*, 2010; Kaya *et al.*, 2010; Bas *et al.*, 2011; Habashi *et al.*, 2015). Most studies found that US is an acceptable tool in detecting disc displacement but not as effective as MRI in differentiating DDwR from DDwoR (Tognini *et al.*, 2005; Kaya *et al.*, 2010). US has also some limitations such as its operators' dependant accuracy and its insufficiency in detecting all disc displacement positions (Jank *et al.*, 2001; Jank *et al.*, 2005; Manfredini and Guarda-Nardini, 2009; Bas *et al.*, 2011). These shortcomings make it difficult for US to replace MRI as a routine soft tissue TMJ imaging method at the moment. However, rather than being an alternative to MRI, US has several advantages and acceptable diagnostic efficacy permits its use as a quick preliminary diagnostic investigation to exclude any clinical suspicion which can be confirmed afterwards by MRI (Li *et al.*, 2012; Kundu *et al.*, 2013; Dong *et al.*, 2015).

MRI is widely accepted as a TMJ soft tissue imaging technique for disc displacement diagnosis. MRI technique allows the analysis of joint imaging using both sagittal and coronal planes (Whyte *et al.*, 2006). This two plane analysis allows more accurate evaluation of disc position. MRI has widely replaced arthrography as a main adjunct to DDwoR clinical diagnosis due to its several advantages: non-invasiveness, no ionizing radiation, excellent soft tissue visualization and differentiation of tissue types, and can be performed simply with little technical expertise (Tasaki and Westesson, 1993; Okochi *et al.*, 2008; Butzke *et al.*, 2010). MRI, however, is not without its disadvantages: false positives, potentially low therapeutic benefit, high cost, limited clinical availability in every practice setting, and may be contraindicated in some patients such as those with pacemakers or metal particles in the vital structures, claustrophobia, small children or those unable to remain motionless during the imaging investigation which may take several minutes (about 20-40 min) to complete (Emshoff

et al., 2003a; Jank *et al.*, 2005; Manfredini and Guarda-Nardini, 2009; Park *et al.*, 2012).

The sensitivity, specificity, and accuracy of MRI have been demonstrated to be good to excellent in the assessment of disc position of the TMJ (Santler *et al.*, 1993; Tasaki and Westesson, 1993) but it should be performed with closed mouth to diagnose disc displacement and with closed and opened mouth to differentiate type of disc displacement (with or without reduction) on sagittal view (Figure 2.4-A) (Drace and Enzmann, 1990; Benbelaid and Fleiter, 2006). MRI has been shown to be as accurate as arthrography or diagnostic arthroscopy in confirming disc displacement whilst its diagnostic accuracy for intra-articular adhesions and disc perforation has been reported to be poor and less than that of arthrography or arthroscopy (Schellhas *et al.*, 1988; Rao *et al.*, 1990; Nitzan *et al.*, 1991a). However with recent advances, fat-saturated T2-weighted MRI has been shown to be as accurate as arthrography or arthroscopy in detection intra-articular adhesions and disc perforation (Zhang *et al.*, 2009b; Yura *et al.*, 2012b; Yura *et al.*, 2012a).

Another advanced technique reported, is the three-dimensional reconstruction of two-dimensional MRI or CT scan. The 3D reconstruction technique from 2D imaging is indicated for understanding TMJ anatomical structures and as a useful and accurate prediction of disc displacement (Chirani *et al.*, 2004; Kitai *et al.*, 2004). It can also be used as a complementary tool to assist the TMJ surgeons in clinical decision-making and surgical planning (Costa *et al.*, 2008).

Limchaichana *et al.* (2006) specified three goals for TMJ imaging: evaluation of the suspected structures' integrity, confirmation of the extent and stage of the disorders' progression, and evaluation of the effects of treatment. Many of the advanced imaging techniques of TMJ can achieve these goals and can confirm the clinical diagnosis of derangement and degenerative joint disorders. Any requested TMJ image, however, must have diagnostic and therapeutic efficacy, that is: "the value of imaging methods for supporting clinicians in their diagnoses and treatment decisions" (Fryback and Thornbury, 1991). Efficacy is also defined as "the probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use" (Ribeiro-Rotta *et al.*, 2011). In comparison with the other imaging techniques, MRI of the TMJ is currently regarded as the gold standard for disc position determination (Liedberg *et al.*, 1996; Park *et al.*, 2012). The diagnostic and

therapeutic efficacy of MRI for DDwoR, however, remains unclear (Limchaichana *et al.*, 2006). Systematic reviews about diagnostic and therapeutic efficacy of TMJ imaging techniques demonstrated insufficient evidence to support their use for TMJ disorders diagnosis (Limchaichana *et al.*, 2006; Koh *et al.*, 2009; Ribeiro-Rotta *et al.*, 2011; Li *et al.*, 2012).

Although guidelines for requesting imaging for TMJ disorders' diagnosis, treatment plan, and follow-up have been reported to aid clinician's decision (Brooks *et al.*, 1997; White *et al.*, 2001), to-date, the decision for when to request a TMJ imaging for DDwoR diagnosis is still controversial due to lack of evidence to base decision on. Some authors suggested it has an important role in the diagnosis of DDwoR (Benbelaid and Fleiter, 2006; Dias *et al.*, 2012) especially for patients without limited opening (Park *et al.*, 2012). Others, however, pointed out that DDwoR can be usually diagnosed in clinical practice through a thorough history and clinical examination and the TMJ imaging findings do not necessarily correlate with the clinical signs and symptoms (Emshoff *et al.*, 2002b; Usumez *et al.*, 2004; Muhtarogullari *et al.*, 2013; de Melo *et al.*, 2015). Soft tissue imaging is only, therefore, an optional tool to confirm the clinical diagnosis of DDwoR and is unnecessary in most cases.

Overall, the decision to request a TMJ imaging for patients with DDwoR should depend on a number of factors and should only be made after careful consideration of patient's history, clinical findings and differential diagnosis, imaging cost, radiation exposure, previous examination results, response to previous conservative treatment, treatment plan, and expected treatment outcomes (prognosis) (Ribeiro-Rotta *et al.*, 2011; Bakke *et al.*, 2014).

Differential diagnosis of DDwoR

Patients with DDwoR are often present to clinicians in clinical practice complaining of pain and limited mouth opening. These symptoms, however, are not specific because numerous pathological conditions can present clinically with a chief complain of painful limited opening (Kouyoumdjian *et al.*, 1988; Luyk and Steinberg, 1990; Eanes, 1991; Marien, 1997). Table 2.7 summarises the aetiology and differential diagnosis of mouth opening limitation. The conditions in the table are roughly divided according to aetiology into nine main themes: TMD-related, infective, traumatic, treatment-related or reactive, neoplastic, congenital, psychogenic, systemic, and neurologic causes. Clearly,

most of the causes can fall into more than one theme, but each is listed in the most common category. Although the list can help clinicians to make a differential diagnosis of DDwoR, it is not exhaustive.

Conditions causing the symptom of limited mouth opening
1. Temporomandibular Disorders (TMD) - Joint disorders including: disc derangement disorders (DDwoR with limited opening and ADP), degenerative disorders (arthralgia and osteoarthritis 'OA'), intra-articular adhesions, fibrous and bony ankylosis, and other rare conditions such as synovial chondromatosis, pigmented villonodular synovitis, gout and pseudogout. - Muscular disorders including: myofascial pain with limited opening, myospasm (muscle spasm), and tendonitis and myositis (of non-infective or infective origin) and polymyositis.
2. Infections - Odontogenic including: pulpal, periodontal, and pericoronal (pericoronitis: mostly related to mandibular third molars causing submasseteric space abscess). - Non-odontogenic including: tonsillitis and peritonsillar abscess, tetanus, meningitis, encephalitis, brain abscess, parotitis (parotid abscess), mumps, Cancrum oris (gangrenous stomatitis), osteomyelitis of the mandible and temporal bone, and abscesses of the submasseteric, lateral pharyngeal, pterygomandibular, submandibular, and temporal spaces.
3. Trauma - Bony trauma: fractures of mandible (particularly: condyle, coronoid, or ramus), zygoma (especially zygomatic arch) (depressed fracture cause coronoid interference/impingement or bony union), or temporal bones. - Muscular trauma: myositis ossificans traumatica (i.e., injury to the masticatory muscles or ligaments causing myositis ossificans due to scarring and calcification). - Mucosal trauma: due to buccally placed upper molar teeth (particularly third molars) - Others: foreign bodies (penetrating injuries), paradoxical muscle spasm following head injury, scar contracture post-thermal injury (burn), general anaesthesia and birth trauma.
4. Treatment related - Local anaesthetic dental injection-treatment related: post-local anaesthetic dental block injection. - Oral and maxillofacial surgical-treatment related: post-dental/oral/maxillofacial/neuro-surgical treatment. - Radiotherapy and chemotherapy: post-chemo/radiotherapy fibrosis. - Drug-related (pharmacologic) (drug toxicity): drug induced (extrapyramidal reaction or facial dyskinesia) such as Phenothiazine, Succinyl choline, Tricyclic antidepressant, Metaclopramide, Halothane, Strychnine poisoning, Statins.
5. Neoplastic lesions - Benign or malignant primary or metastatic head and neck tumours: nasopharyngeal and oropharyngeal regions, infra-temporal fossa, base of skull, parotid region, jaws joint, masticatory muscles, mandibular condyle or coronoid process, brain stem. - Pre-cancerous submucous fibrosis (oral submucous fibrosis)

Conditions causing the symptom of limited mouth opening
6. Congenital/Developmental - Hypertrophy of: coronoid process (coronoid hyperplasia) or Jacob's disease (exostoses at posterior aspect of zygoma) or condylar process (condylar hyperplasia). - Atrophy with degenerative changes within the temporalis muscle connected to the coronoid process of unknown cause (idiopathic) - Elongated styloid process (Eagles' syndrome) - Trismus-pseudo-camptodactyly syndrome - Birth injury/trauma - Other congenital diseases: Hecht, Beals, and Wilson syndrome, arthrogryposis multiplex congenital, craniocarpotarsal dysplasia, hemifacial microsomia, fibrodysplasia ossificans progressive, popliteal pterygium syndrome.
7. Psychogenic - Hysteria (hysterical trismus).
8. Systemic diseases - Neuromuscular disorders such as Parkinson's disease. - Autoimmune connective tissue diseases such as lupus erythematosus, scleroderma, systemic sclerosis. - Inflammatory diseases such as rheumatoid arthritis, Still's disease, ankylosing spondylitis, Marie-Strümpell disease, psoriatic arthritis, infectious arthritis or septic arthritis. - Neurologic diseases such as Epilepsy, Guillain-Barre syndrome and CNS lesions such as cerebral lesions - Centrally mediated myalgia, fibromyalgia, and multifocal idiopathic fibrosis
9. Neurologic - Hyperventilation syndrome: Tetany related to reduced calcium concentration (hypocalcemia) - Extrapyramidal reactions (drug-related)

Table 2.7: Aetiology and differential diagnosis of limited mouth opening. The causes of trismus are summarised by reviewing the relevant literature but adapted primarily from (Poulsen, 1984; Kouyoumdjian *et al.*, 1988; Luyk and Steinberg, 1990; Eanes, 1991; Marien, 1997; Leonard, 1999; Dhanrajani and Jonaidel, 2002; Garnett *et al.*, 2008).

Most conditions shown in Table 2.7 can be readily diagnosed from careful patient history and examination such as trauma and treatment-related trismus (Luyk and Steinberg, 1990). Others, however, can be difficult to diagnose and may cause a diagnostic dilemma, diagnostic delay, improper initial treatment, and multiple referrals causing prolongation of disease state with possible fatal results (Cohen and Quinn, 1988; Gobetti and Turp, 1998; Tahery *et al.*, 2004). Unfortunately, those conditions that usually have delayed diagnosis, delayed treatment, and delayed referral are the most potentially life-threatening conditions such as tetanus and malignant tumours. Patients with shrouded neoplasia presenting as TMD patients are, however, unusual and rare (Luyk *et al.*, 1991). In one study, over 10 years only 16 out of 2000 patients present with facial pain (0.8%) were found to harbour intracranial tumours (Bullitt *et al.*, 1986).

Similarly, in a more recent study, the rate of incidentally found malignant tumours by TMJ MRI was very low (0.07%) because only two malignant tumours were discovered in 2776 MRIs examined for suspicion of TMJ arthrosis over 6 years and a half (Yanagi *et al.*, 2003). Although neoplasia very rarely presents mimicking TMD/DDwoR signs and symptoms, it is often the thing that clinicians and patients are most concerned about. In the literature, several case reports have been published about different underlying pathologies, including malignancy, misdiagnosed initially as 'DDwoR or ADP'; some of these are detailed in Table 2.8.

Author (year)	Age yrs	Gender	Chief complaint	Initial diagnosis	Key signs necessitating further examination & investigation	Definitive diagnosis
Trumpy and Lyberg (1993) [3 cases]	29	Female	TMJ pain, LMO	DDwoR by tomography and arthrography	No improvement of symptoms after discectomy	Benign meningioma involving infra-temporal fossa by CT
	45	Male	Intermittent hearing loss, TMJ pain, LMO	DDwoR by arthrography	No improvement of symptoms after discectomy, facial swelling	Nasopharyngeal carcinoma by CT
	39	Male	TMJ pain, LMO	DDwoR by arthrography	No improvement of symptoms after discectomy, facial swelling	Adenoid cystic carcinoma of parotid gland by needle biopsy
Heo *et al.* (2003)	45	Male	TMJ pain, swelling, LMO	Chronic DDwoR by plain radiographs	No improvement of symptoms after conservative therapy	Pigmented villonodular synovitis by MRI
Honda *et al.* (2006)	62	Female	TMJ and muscle pain, LMO	ADP by MRI	No improvement of symptoms after conservative therapy and arthrocentesis, swelling of temporal region, paraesthesia extending from lower eyelid to upper lip	Mucinous adenocarcinoma of the temporal region by MRI, bone scintigraphy, and biopsy
Hasegawa *et al.* (2008)	62	Female	TMJ pain, LMO	Bilateral DDwoR by MRI	Increased severity of symptoms	Submasseteric space abscess by MRI
Kruse *et al.* (2010)	75	Female	TMJ pain, LMO	DDwoR clinically	No improvement of symptoms after conservative therapy	Metastatic adenocarcinoma of parotid gland by MRI
Beddis *et al.* (2014) [2 cases]	NR	NR	Pain in muscles, ear, and neck, no clicking, LMO	DDwoR by arthrography	No improvement of symptoms after conservative therapy and arthrocentesis	Adenoid cystic carcinoma of maxillary sinus by MRI
	NR	NR	Pain in muscles and ear, LMO	DDwoR	No improvement of symptoms after conservative therapy	Oral squamous cell carcinoma of mandible by OPG

Author (year)	Age yrs	Gender	Chief complaint	Initial diagnosis	Key signs necessitating further examination & investigation	Definitive diagnosis
Kim *et al.* (2014) [2 cases]	43	Male	LMO, stiffness of the bilateral masseter muscles	DDwoR clinically	No DDwoR on MRI	Coronoid hyperplasia by OPG and CT
	21	Male	TMJ pain, LMO	DDwoR clinically	No DDwoR on MRI No improvement of symptoms after conservative therapy and arthroplasty	Coronoid hyperplasia by CT
Kang *et al.* (2015) [4 cases]	80	Female	TMJ and muscle pain, LMO	DDwoR clinically and then by MRI	No improvement of symptoms after conservative therapy	Non-infectious myositis of the lateral pterygoid muscle by CT
	25	Female	TMJ and muscle pain, LMO, limited lateral movement, crepitus	DDwoR clinically	No improvement of symptoms after conservative therapy and arthrocentesis	Non-infectious myositis of the lateral pterygoid muscle by MRI
	49	Female	LMO, limited bilateral movements	DDwoR clinically	NR	Non-infectious myositis of the lateral pterygoid muscle by MRI
	19	Male	Bilateral TMJ and muscle pain, limited lateral and protrusive movements, headache, tinnitus	DDwoR clinically	NR	Non-infectious myositis of the lateral pterygoid muscle by MRI

Table 2.8: Summary data of misdiagnosed cases as DDwoR or ADP reported in the literature.

This brief review about some misdiagnosed malignant tumours shown in Table 2.8, emphasises that the clinicians should maintain a high index of suspicion for the presence of malignancy whenever there is a mouth opening limitation. In fact, limited opening can be sometimes the only presenting symptom of malignancy that induces the patient to seek care (Kristensen and Tveteras, 1984; Ozyar *et al.*, 2005; Patrocinio *et al.*, 2008). The medical and dental practitioners, therefore, should be familiar with establishing a differential diagnosis of mouth opening limitation symptom (Eanes, 1991; Azaz *et al.*, 1994; Marien, 1997). Failure to establish an adequate differential diagnosis may cause considerable delay in proper treatment which can be life threatening for patients with neoplastic diseases (Gomez *et al.*, 2009; Cleveland and Thornton-Evans, 2012; Seoane *et al.*, 2012). This is because "the most important prognostic factor in oral cancer is the stage of the tumour at the time of diagnosis" (Dave, 2013). Therefore, early diagnosis of head and neck malignancy without referral delay is especially crucial for patient's survival (Seoane *et al.*, 2012). Important risk factors in the development of malignancy such as age, gender, history of cancer, tobacco, alcohol, betel quid, candida and the human papilloma virus infections are all needed to be routinely assessed from the patient's medical history (Scully and Bagan, 2009; Brocklehurst *et al.*, 2010). Besides these, the presence of red flags' signs and symptoms should alert the clinician to a serious pathology other than TMD/DDwoR. The red flags summarised in Table 2.9 can help the clinician to differentiate TMD/DDwoR from serious pathological conditions to rule out their possibility in patients initially presenting with TMD pain and/or limited mouth opening symptoms.

Red flags	Possible neoplasia
Neurologic signs	Unexplained sensory changes (in the distribution of the 'V' trigeminal nerve) such as numbness, altered sensation, lack of feeling, or reduced sensation. This may suggest an enlarged tumour mass pressing on, or affecting, the peripheral nerve branches or other intracranial pathology causing nerve injury. Auditory complaints (related to sensory changes in the distribution of the vestibulocochlear 'VIII' nerve) such as decreased hearing or progressive hearing loss, ringing, dizziness, and plugging sensation. This may suggest a nasopharyngeal tumour or acoustic neuroma or other ear diseases. Motor facial function changes (related to motor changes in the distribution of the facial 'VII' nerve). This may suggest a tumour or intracranial pathology or infection.
Otologic (ear, nose, and throat) signs and symptoms	ENT signs and symptoms such as nosebleed (recurrent epistaxis), nasal stuffiness (nasal blockage/obstruction), hemoptysis, altered olfactory function (persistent loss of smell 'anosmia'), runny nose (purulent nasal discharge), ear drainage, otalgia, cough, and dysphagia. This may suggest a nasopharyngeal tumour or chronic sinusitis.
Pain that is sudden-onset, severe, interrupts sleep, or precipitated by exertion, coughing, or sneezing	This may indicate intracranial pathology or cardiac ischaemia.
Progressive decrease in mouth opening	In DDwoR diagnosis, the limitation in mouth opening (about 20 to 30 mm) is of sudden-onset that gradually improves over time. In contrast, most other conditions such as tumours, infections, sub-mucous fibrosis, coronoid hyperplasia, intra-articular adhesion or fibrous ankylosis cause progressive 'gradual' decrease in mouth opening.
Persistent or worsening symptoms despite initial management (pain and/or limited opening symptoms remaining unchanged or increasing in severity)	No relief or progressively worsening symptoms over time despite management may suggest a misdiagnosis of tumour and, therefore, reassessment the presumptive diagnosis is essential.
Patient's age and gender	TMD is more common in the second to fourth decades female patients whilst neoplastic diseases are more common in elderly people (> 50 years).
History of malignancy	This may suggest recurrence or metastasis.
Facial asymmetry	This is uncommon in TMD unless there is masseteric hypertrophy and may indicate a tumour, infection, or inflammation.

Red flags	**Possible neoplasia**
Neck masses or swelling including lymphadenopathy	This may suggest tumour, infection, inflammation, or autoimmune condition.
Systemic symptoms of unexplained pyrexia, anorexia, weight loss, malaise, myalgia, chills, or sweating	This may suggest malignant tumours, immunosuppression, or an infection in the maxillofacial region such as septic arthritis, osteomyelitis, intracranial abscess, tooth abscess, or mastoiditis.
Occlusal changes (change in bite)	This can be seen in TMD but it may also suggest a tumour, bone growth disturbance of condyle, inflammatory or rheumatoid arthritis, or facial bones fractures.
Red flags	**Other serious pathologies**
History of head and neck trauma (apart from recent trauma)	This may suggest a fracture of one of the facial bones. Recent trauma may cause limitation in mouth opening as well as physical functional changes due to muscular spasm and/or fractures of the oral and maxillofacial skeleton.
Paroxysmal unilateral lancinating pain with or without autonomic features	This is more likely associated with trigeminal neuralgia or one of the trigeminal autonomic cephalagias.
First episode in patient over 50 years of age with unilateral headache or scalp tenderness accompanied by jaw claudication, visual symptoms, and general malaise	This may suggest giant cell arteritis (temporal arteritis).

Table 2.9: Red flags that may mimic TMD/DDwoR signs and symptoms. These are concluded from the reviewed case reports misdiagnosed initially as TMD/DDwoR and adapted further from (Epstein and Jones, 1993; Huntley and Wiesenfeld, 1994; Gobetti and Turp, 1998; Heo *et al.*, 2003; Wassell and Durham, 2010; Durham, 2012; Renton *et al.*, 2012; Durham *et al.*, 2015).

Recently a ‘trismus’ checklist has been proposed as an ‘aide-memoire’ to alert the clinicians to red flags for an alternative underlying pathology possibility to DDwoR including malignancy (Table 2.10) (Beddis *et al.*, 2014).

Trismus checklist: for completion in patients with limited opening*	Yes	No
• Opening less than 15 mm		
• Progressively worsening trismus		
• Absence of history of clicking		
• Pain of non-myofascial origin (neuralgia etc.)		
• Swollen lymph glands		
• Suspicious intra-oral soft tissue lesion		

* If any of the answers are yes, consider radiograph and/or arrange review/referral to a senior clinician.

Table 2.10: Trismus checklist for patients with limited mouth opening. Adapted from Beddis *et al.* (2014).

Beddis *et al.* (2014) stated that the annual audits of the checklist use within their departments show successful results in terms of both: increase use and completion of the checklist for patients attended with mouth opening limitation symptom and early identification of malignancy in a patient presenting initially with trismus. The authors advocated the use of the checklist within general practice by general practitioners to help them avoid risk of delayed- or mis-diagnosis and determine the need for referral urgency (Beddis *et al.*, 2014). This trismus checklist, however, is incomplete and needs further refinement to be more comprehensive in order to help the clinicians address and identify all the potential red flags (Table 2.9).

In summary, the professionals must have a thorough knowledge about the differential diagnosis of the multiple conditions causing limited mouth opening (Table 2.7) and must apply a systematic diagnostic approach in order to achieve an accurate diagnosis for a patient presented with a chief complain of painful/limited opening. The professionals' diagnosis process should involve the following: obtaining a complete history; performing a full careful head and neck clinical examination; giving particular attention to the presence of red flags (alarming signs or symptoms) (Table 2.9); ordering the appropriate investigations as deemed necessary. Consequently, the patient will more likely receive an appropriate treatment and a better prognosis.

2.2.8 Management

The literature about the management of TMD and DDwoR is vast and confusing with various treatment protocols and divergent opinions. One of the reasons for the controversy is attributed to that fact that all the treatment approaches claim success and the majority of patients are reported to improve (Okeson, 1997b). This makes the rationale behind the selection of different treatment options constitute one of the most controversial areas in the field of TMD (Forssell and Kalso, 2004).

Evidence-based management means the use of best available evidence from research findings to improve patient care (Haynes and Haines, 1998). The most reliable sources of research evidence are high-quality systematic reviews and meta-analyses based on methodologically-robust randomised controlled trials (RCTs) (Levels of Evidence, 2009). In TMD field, where controversial and conflicting ideas about management are common, an evidence-based approach could be particularly useful (Forssell and Kalso, 2004).

There are three basic treatment goals for patients with TMD or DDwoR: reducing pain, restoring function, and optimising patients' quality of life (QoL) (de Leeuw and Klasser, 2013). In the literature, however, the treatment approaches used to achieve these goals are highly variable in invasiveness ranging from non-invasive reversible interventions to minimally-invasive and invasive irreversible interventions. Given that the effects of the therapeutic interventions used for DDwoR are systematically reviewed in Chapters 4 and 5, this subsection will briefly review the available evidence for the various treatment modalities used in TMD management and discusses the technique and rationale of each treatment modality used for DDwoR.

Reversible treatment modalities

The non-invasive conservative treatment is often the first choice in TMD management. In the literature, different conservative treatment options have been suggested, most commonly: patient education and self-management, psychosocial therapy, pharmacotherapy, splint therapy, and physiotherapy.

Patient education and self-management

Patient education is the simplest treatment approach and involve an explanation to the patient about: the clinical condition; its signs and symptoms; its potential causative biopsychosocial factors; the normal TMJ and masticatory muscles functions in simple understandable terms. The clinician should seek to reassure the patient that the symptoms of TMD are not an indication of serious or sinister pathology and it is benign and self-limiting in the majority of cases with a generally favourable prognosis, but it is not always curable and can therefore recur or fluctuate in symptomatology (Dimitroulis *et al.*, 1995b; Michelotti *et al.*, 2012). For DDwoR, patient education should also involve clear explanation of the mechanism of the articular disc in TMJ with reassurance about the 'favourable' natural course of the disorder which may improve with time alone without any active therapeutic intervention or with simple self-care (Minakuchi *et al.*, 2004; Imirzalioglu *et al.*, 2005; Craane *et al.*, 2012a).

Self-management programme involves activities required by patient for personal care. Different self-care strategies are described in the literature but all generally involve instructing and advising the patients for: rest (jaw and muscle relaxation); 'pain-free' soft diet and balanced chewing; parafunctional habits awareness and modification; diaphragmatic breath training, sleep improving, and posture training. They occasionally include also the following therapies: home physiotherapy programme such as self-exercises, self-massages, and hot or cold packs application; pharmacotherapy such as oral and/or topical analgesics and anti-inflammatories; psychosocial therapy such as optimistic counselling and biofeedback with an explanation of the advantages of each (Wright and Schiffman, 1995; Mulet *et al.*, 2007; Wright, 2010; DeVocht *et al.*, 2013). Each component of self-management has a different mechanism of action but in general the main aim of a self-care programme is to prevent further injury to the musculoskeletal structures thereby allowing for healing to occur (Dimitroulis *et al.*, 1995b).

The success of self-management depends largely on patients themselves, particularly patients' motivation, cooperation, compliance, adherence, and active participation. The outcome of self-management also depends on clinicians' communication skills, appropriate choice of treatment, self-support, being empathetic, as well as their ability to explore patients' beliefs, expectations, and own goals before initiating long-term

management strategies in order to clarify that TMD/DDwoR cannot always be 'totally' cured (Zakrzewska, 2002; Wig *et al.*, 2004; de Leeuw and Klasser, 2013).

A number of RCTs investigated the effect of this treatment modality in patients with TMD/DDwoR and all found that patient education and/or self-management is as effective or slightly more effective in comparison with other active treatment modalities (Dworkin *et al.*, 2002; Michelotti *et al.*, 2004; Minakuchi *et al.*, 2004; Truelove *et al.*, 2006; Craane *et al.*, 2012a; Michelotti *et al.*, 2012). A recent systematic review of self-management shows that self-care strategies were as effective as other active treatments and found promising evidence to support using this non-invasive low-cost treatment modality to manage TMD patients (de Freitas *et al.*, 2013).

Psychosocial therapy

The biopsychosocial model of TMD mandates the psychosocial therapy to be one of the therapeutic interventions used for TMD management (Dworkin, 1996). A variety of psychological and behavioural interventions have been reported to effectively manage patients with chronic pain related-TMD such as biofeedback and cognitive behavioural therapy (Sherman and Turk, 2001; Turner *et al.*, 2006; Calderon *et al.*, 2011).

Cognitive behavioural therapy (CBT) is a multi-component treatment that involves different cognitive-behavioural techniques such as relaxation training, problem-solving training, behavioural activation and modification, behavioural goals setting and targeting, activity pacing, and cognitive restructuring. CBT aims to reduce pain, anxiety, and distress and improve function by helping TMD patients to increase their self-efficacy, adapt and cope with their pain, identify and correct their negative thoughts and beliefs, and modify their behaviours (i.e., decreasing maladaptive behaviours and increasing adaptive behaviours) (Ehde *et al.*, 2014). Behavioural modification, however, can be done easily for simple habits but changing persistent habits may be more difficult and require a tailored individualised program with different structured strategies such as: lifestyle counselling, progressive relaxation, hypnosis, and habit reversal strategies (Rugh, 1987; Liu *et al.*, 2012a; de Leeuw and Klasser, 2013). For patients with DDwoR, CBT was also used as an adjunctive to other conservative therapies (Schiffman *et al.*, 2007)

Systematic reviews performed in this area suggest that there is some evidence for the effectiveness of the psychosocial therapy in TMD management (Crider *et al.*, 2005; Turp *et al.*, 2007a; Kroner-Herwig, 2009; Aggarwal *et al.*, 2011; Liu *et al.*, 2012a; Kotiranta *et al.*, 2014; Roldan-Barraza *et al.*, 2014; Zhang *et al.*, 2015).

Pharmacological therapy

A wide range of pharmacological medications are available for treating TMD/DDwoR patients. The main aim of pharmacotherapy is to aid TMD/DDwoR patients to manage their pain and/or jaw dysfunction rather than to 'cure' the pain (Dionne, 1997). Each of the medications suggested in the literature has a specific indication for use in TMD management (Kopp *et al.*, 1985; Mejersjo and Wenneberg, 2008; Cascos-Romero *et al.*, 2009; Majid, 2010; de Leeuw and Klasser, 2013) but, in summary, the most common uses of these medications are as follows:

- For acute TMD pain: analgesics, corticosteroids, and benzodiazepines;
- For both acute and chronic TMD: anti-inflammatories and muscle relaxants;
- For chronic TMD pain: tricyclic antidepressants, particularly amitriptyline, due to their analgesic properties aside from their antidepressant effect;
- For muscular pain: intra-muscular Botulinum toxin type A (Botox);
- For joint pain and/or dysfunction: intra-articular glucocorticoids and sodium hyaluronate. The use of these intra-articular medications for DDwoR will be covered in further detail later on in this subsection.

In spite of the fact that these medications are currently used in common for the management of pain in patients with TMD, limited numbers of high-quality RCTs were performed to investigate their effectiveness. Therefore, systematic reviews about the effectiveness of the pharmacological interventions found insufficient and limited evidence to support the efficacy of many medications used for TMD management (List *et al.*, 2003; Shi *et al.*, 2003; Ihde and Konstantinovic, 2007; Cascos-Romero *et al.*, 2009; Manfredini *et al.*, 2010; Mujakperuo *et al.*, 2010; Linde *et al.*, 2011; de Souza *et al.*, 2012; Senye *et al.*, 2012; Machado *et al.*, 2013; Stoustrup *et al.*, 2013; Chen *et al.*, 2015b; Vidya and Felicita, 2015). In the absence of sufficient evidence, the clinicians must fully understand the medications' side effects in order to avoid unnecessary harmful adverse effects to TMD/DDwoR patients with little beneficial outcome.

Physical therapy

A wide variety of physiotherapeutic techniques have been used either alone or as adjunct to other treatments for TMD and DDwoR management, most commonly: active and passive jaw exercises and manual therapy, posture training, and other physiotherapeutic modalities including iontophoresis, electrotherapy, ultrasound therapy, and laser therapy (Gray *et al.*, 1994b; Nicolakis *et al.*, 2001; Kato *et al.*, 2006; Ahrari *et al.*, 2014; Ucar *et al.*, 2014). Although acupuncture and trigger point injections is not a physical therapy per se, it is considered a specialty field within the scope of practice for many physiotherapists working in the United Kingdom (Medlicott and Harris, 2006; Rashid *et al.*, 2013).

The aforementioned physiotherapeutic techniques have different mechanisms of actions (Rashid *et al.*, 2013) but all aimed mainly to restore normal jaw function by improving the range of mandibular movements and relieving joint/muscular pain. Physiotherapy is usually regarded as an effective treatment modality to achieve these goals and there is, currently, some evidence supporting its use (Chortis *et al.*, 2006; McNeely *et al.*, 2006; Medlicott and Harris, 2006; Brantingham *et al.*, 2013; Moraes Ada *et al.*, 2013; Chipaila *et al.*, 2014; Calixtre *et al.*, 2015; Martins *et al.*, 2015). There is also good evidence supporting the use of acupuncture and laser therapy for treating TMD (Rosted, 1998; Ernst and White, 1999; Fink *et al.*, 2006; Cho and Whang, 2010; La Touche *et al.*, 2010; Jung *et al.*, 2011; Petrucci *et al.*, 2011; Maia *et al.*, 2012; Melis *et al.*, 2012; Tengrungsun *et al.*, 2012; Herranz-Aparicio *et al.*, 2013; Chen *et al.*, 2015a; Doeuk *et al.*, 2015; Herpich *et al.*, 2015).

Among wide variety of physiotherapeutic interventions used, mandibular manipulation (MM) has been suggested specifically to ‘unlock’ the ‘locked’ jaws in patients with ‘acute’ DDwoR (Wright, 2010; Okeson, 2013). The first manual manipulation technique was reported in 1971 by Farrar (Farrar, 1971). This technique is described and depicted in Figure 2.8.

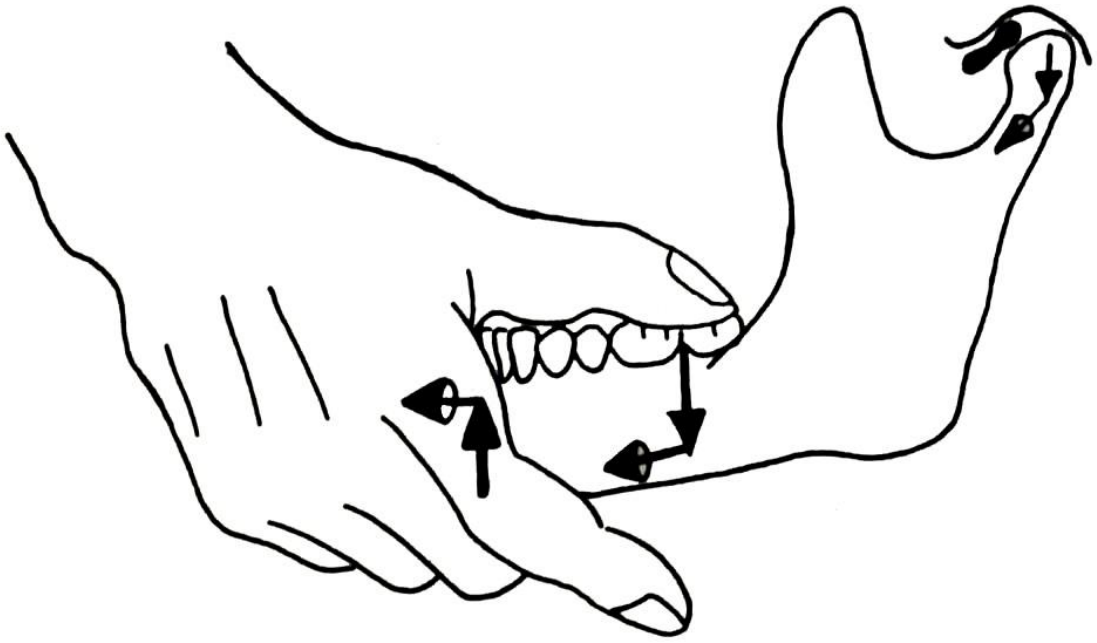


Figure 2.8: Farrar's manipulation technique to 'unlock' the jaw. Farrar's method involves instructing the patient to move the jaw as far as possible toward the opposite 'unaffected' side; grasping the mandible firmly with the clinician's thumb placed intra-orally over the occlusal surfaces of the mandibular molar teeth at the affected side and the fingers grasp the inferior border of the mandible extra-orally; stabilizing the cranium with the other hand; and applying gentle but firm force downward on the molar teeth at the affected side by the thumb and upward on the chin with the fingers; and then pulling the mandible downward and forward and to the opposite 'unaffected' side, to enable the condyle to move under the 'thick' posterior band of the displaced disc, and the disc returns back to its normal position above the condyle (Farrar, 1971; Farrar, 1972; Farrar, 1978). Reproduced from Farrar (1978) with permission from Elsevier.

Farrar's technique, however, may not be practicable in patients with severe mouth opening limitation. A more practical technique is depicted in Figure 2.9 and can be more appropriately applied in such cases.

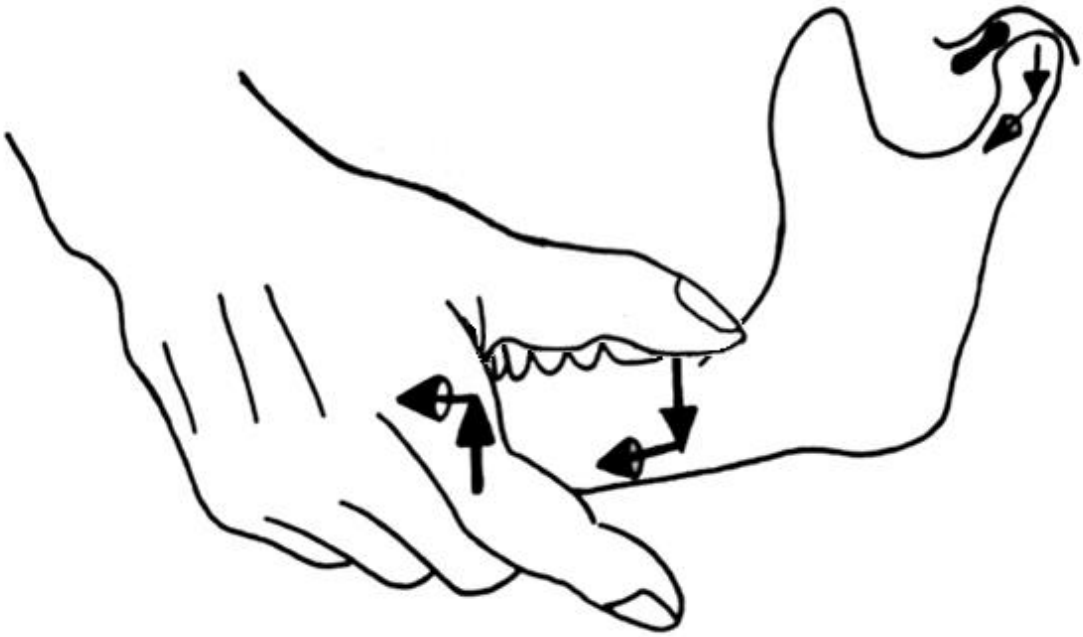


Figure 2.9: Modified manipulation technique to ‘unlock’ the jaw. A modified technique to ‘unlock’ the jaw in which the clinician’s thumb is placed intra-orally at the affected side over the external oblique ridge rather than on the occlusal surfaces of the mandibular molar teeth in order to enable manual manipulation in severely limited mouth opening cases. Modified from Farrar (1978) with permission from Elsevier.

Since the manipulation technique was first reported by Farrar, various other techniques have been described in the literature (Harkins *et al.*, 1987; Van Dyke and Goldman, 1990; Jagger, 1991; Minagi *et al.*, 1991; Mongini, 1995; Martini *et al.*, 1996; Suarez and Ourique, 2000; Sugisaki *et al.*, 2005; Yoshida *et al.*, 2011). Nevertheless, Farrar’s manipulation remains the most widely used technique in many clinical trials for DDwoR management. It was either performed without anaesthesia (Segami *et al.*, 1990; Friedman, 1993; Chiba and Echigo, 2005), or under different anaesthetic approaches such as: local anaesthesia (Correa *et al.*, 2009), sedation (Helkimo and Hugoson, 1988), or general anaesthesia (Foster *et al.*, 2000), or with different adjunctive techniques such as hydraulic pumping (Murakami *et al.*, 1987; Totsuka *et al.*, 1989; Ozawa *et al.*, 1996; Ohnuki *et al.*, 2006), or lavage (Ross, 1989; Sembronio *et al.*, 2008a).

In general, all the manual manipulation techniques and procedures used share similar aim to help restore the displaced disc into its normal anatomical position. Several studies, however, investigated the efficacy of manipulation techniques in recapturing the displaced disc and most found that complete anatomic reduction (recapturing) of the disc by manipulation is difficult to achieve and even if achieved (unlocking) many patients may experience recurrence of disc displacement (relocking) (Totsuka *et al.*,

1989; Segami *et al.*, 1990; Kurita *et al.*, 1999). In one study using Farrar's technique, MM has been found to be successful in recapturing only about 9% of permanently anteriorly displaced discs 'DDwoR' (Kurita *et al.*, 1999). Different factors have been attributed to influence the possibility of recapturing the displaced disc by manipulation such as duration of locking (Segami *et al.*, 1990; Sembronio *et al.*, 2008a), and stage of intra-articular derangement of the TMJ and articular and skeletal morphological variations (Kurita *et al.*, 1999). Okeson (2007) identified three factors that could influence the success of manipulation in reducing the displaced disc in 'acute' DDwoR: level of superior lateral pterygoid muscle (SLPM) activity, intra-articular joint space size, and condylar position. The author claimed that disc 'recapturing' can be achieved when the SLPM is relaxed, the joint space is increased, and the condyle is in the maximum forward protrusive position (Okeson, 2007). In fact, the success of MM in recapturing the displaced disc may depend primarily on determining the exact direction of the displaced disc to manipulate the jaw. Unfortunately, most manipulation techniques reported in the literature are often described to recapture a disc displaced anteromedially because the disc is assumed to be displaced commonly in an anteromedial direction. This, however, is not always correct as the disc can be displaced in any direction (see diagnostic classification of disc displacement).

Overall, the necessity to recapture the displaced disc for successful treatment of DDwoR remains questionable and may be unnecessary because improvement in clinical symptoms of DDwoR have been shown to be unrelated to disc position (disc recapturing) (Segami *et al.*, 1990; Nicolakis *et al.*, 2001; Sembronio *et al.*, 2008b) and may be related more to disc mobilisation and/or ligaments stretching.

Splint therapy

Splint therapy is one of the most widely used treatment modalities for managing patients with TMD and DDwoR (Pierce *et al.*, 1995; Tegelberg *et al.*, 2001). Various types of occlusal splints have been described in the literature but in terms of their hypothesised function, the full-coverage splints are classified into three main groups: relaxation/stabilization soft or hard splints, distraction/pivot splints, and repositioning splints, in addition to partial-coverage splints (Klasser and Greene, 2009; Muhtarogullari *et al.*, 2014). Although the mechanism of action of these splints is still controversial and yet to be fully determined (Lickteig *et al.*, 2012; Lickteig *et al.*, 2013), their beneficial effects are usually attributed to a combination of behavioural and

mechanical interventions increasing the joint space and reducing TMJ overload, articular disc strain, and forces to the retrodiscal tissues (Kreiner *et al.*, 2001; Ettlin *et al.*, 2008; Klasser and Greene, 2009; Ok *et al.*, 2014). Each splint has different indications and proposed functions and a summary of their aims would include: protections from tooth surface loss; reducing patients' bruxism and parafunctional habits; redistributing occlusal forces and providing ideal occlusion; reducing pain and abnormal muscle activity; alter structural relationships in the TMJ; in addition to distraction and mobilisation of the joint (Glaros *et al.*, 2007; Ettlin *et al.*, 2008; Klasser and Greene, 2009; Muhtarogullari *et al.*, 2014). Furthermore, occlusal splints, mostly anterior repositioning splints, are often used for acute DDwoR management with a proposed aim to help retain the condyle-disc relationship after disc 'recapturing' by mandibular manipulation (Okeson, 2007).

Occlusal splints are generally regarded as non-invasive treatment approach. Despite their non-invasive nature, these appliances may be costly and may cause potential complications such as teeth decay, periodontal disease, mouth odours, speech difficulties, psychological dependence on the appliance, and more importantly irreversible occlusal changes which may arise from their excessive use or incorrect design (Abbott and Bush, 1991; Lundh *et al.*, 1992; Brown *et al.*, 1994; de Leeuw and Klasser, 2013).

Many trials reported the effectiveness of occlusal splints in improving symptoms (Stiesch-Scholz *et al.*, 2005; Al Quran and Kamal, 2006; Wassell *et al.*, 2006) whilst others showed no additional benefit of such appliances (Lundh *et al.*, 1992; Truelove *et al.*, 2006; Michelotti *et al.*, 2012). To-date, controversy about TMD/DDwoR management by occlusal splints still exists as well as about what is the most effective splint design for treatment. Currently, the evidence supporting the splints therapy for TMD is promising but is still weak and limited and needs to be confirmed in future research (Santacatterina *et al.*, 1998; Kreiner *et al.*, 2001; Al-Ani *et al.*, 2004; Forssell and Kalso, 2004; Turp *et al.*, 2004; Stapelmann and Turp, 2008; Fricton *et al.*, 2010; Ebrahim *et al.*, 2012).

Irreversible treatment modalities

Occlusal therapy

TMD management by occlusal therapy such as occlusal adjustment, restorative therapy, orthodontic treatment, or orthognathic surgery is a subject of considerable debate (Kirveskari *et al.,* 1998; Tsukiyama *et al.*, 2001; Huang, 2004). This debate is because it is difficult to establish a cause-and-effect relationship between the occlusion and the TMD; that is, malocclusion can be the result of TMD rather than being its cause (Michelotti and Iodice, 2010; Turp and Schindler, 2012).

In general, there is a lack of evidence that irreversible occlusal therapy providing an 'ideal' occlusion is necessary for management of TMD (Koh and Robinson, 2003; Forssell and Kalso, 2004; Fricton, 2006; Abrahamsson *et al.*, 2007; Al-Riyami *et al.*, 2009; Lindenmeyer *et al.*, 2010; Luther *et al.*, 2010; Machado *et al.*, 2012). Therefore, based on current lack of evidence and because definitive occlusal therapy is an irreversible treatment modality, treatment by occlusal adjustment, restorative dental rehabilitation, orthodontics, or orthognathic surgery should never be the primary treatment option for TMD management. Nevertheless, occlusal therapy may be considered only for a specific minority of cases that have a severe unstable occlusal relationship or are of recent onset following a restorative dentistry procedure (de Leeuw and Klasser, 2013).

TMJ surgery

TMJ surgical treatment encompasses generally one of two main approaches: closed joint surgical approach by needles or an arthroscope and open joint surgical approach by a skin incision (Dimitroulis, 2005a). There is no role for this treatment modality in managing patients with muscular disorders, but for patients with a biomechanical joint disorder such as DDwoR, a variety of minimally-invasive and invasive surgical interventions are suggested and used.

Minimally-invasive interventions

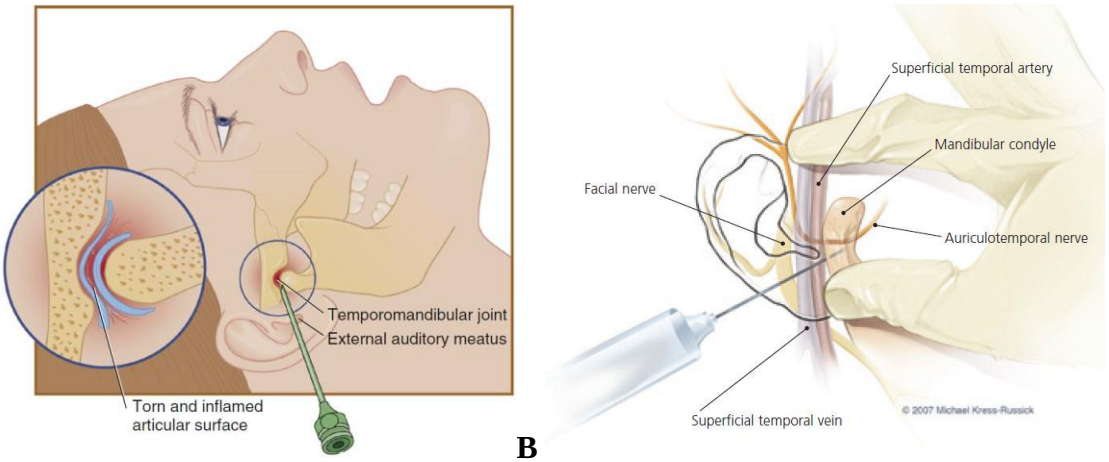
A minimally-invasive treatment option suggested widely for DDwoR management is the intervention inside the joint by needles for intra-articular medication injection and/or lavage. Although intra-articular intervention by needles is not a surgical therapy per se,

it is considered in this part of the review due to its more invasive nature than the conservative interventions and to compare it with the surgical interventions.

Therapeutic injections

Intra-articular injection of medications is one of the least invasive interventions into the joint interior. Numerous medications have been injected into the joint for disc displacement management (Daif, 2012; Hanci *et al.*, 2015; Sipahi *et al.*, 2015), but the most widely used are local anaesthetics, glucocorticoids, and sodium hyaluronate (Long *et al.*, 2009; Samiee *et al.*, 2011; Nascimento *et al.*, 2013).

Local anaesthetics (LA) are generally used as a diagnostic approach for differential diagnosis of joint pain or as an adjunct prior to manipulation or arthrocentesis treatments but are sometimes used as a sole therapeutic modality (Nascimento *et al.*, 2013; Sahlstrom *et al.*, 2013). Two main approaches are generally used to achieve analgesia of TMJ pain by LA: local analgesia by intra-articular infiltration into the superior joint space to anaesthetise the terminal branches of auriculotemporal and masseteric nerves, and regional analgesia by extra-articular auriculotemporal nerve (ATN) trunk block (Figure 2.10) (Donlon *et al.*, 1984; DuPont, 2004).



A **B**

Figure 2.10: Therapeutic injections. (A) Intra-articular injection technique for local analgesia of TMJ. (B) Extra-articular injection technique for auriculotemporal nerve block for regional analgesia of TMJ. Reproduced from Waldman (2013) and Buescher (2007) with permissions from Elsevier and both the American Academy of Family Physicians (AAFP) and the figure illustrator respectively.

The rationale for an ATN block therapeutic effect was attributed to short-term anaesthetic blockage of acute TMJ pain thereby leading to reestablishment of 'painless' joint function which enables its lubrication, nutrition, and waste products removal

(Nascimento *et al.*, 2011). However, the long-term therapeutic effect of this approach is questionable. In a RCT assessing the effects of LA on mechanical and thermal sensitivity in the TMJ area of healthy people, the intra-articular infiltration has been found to have no effect on the sensitivity of the TMJ or surrounding area whilst the ATN block has been found to cause a more pronounced effect on deep mechanical sensitivity than on superficial mechanical sensitivity and thermal sensitivity (Ayesh *et al.*, 2007). The anaesthetic blockage of the ATN is a non-invasive, low-cost technique that can be used in routine clinical practice as a diagnostic and therapeutic tool for acute joint pain (Buescher, 2007), but it may be associated with transient complications such as temporary facial nerve anaesthesia and haematoma (Donlon *et al.*, 1984; Nascimento *et al.*, 2013).

Another option available for managing DDwoR is the intra-articular injection of glucocorticosteriods (GC) such as methylprednisolone, hydrocortisone, or betamethasone (Samiee *et al.*, 2011). These are mainly used to reduce inflammation and relieve acute joint pain as a result of steroids' anti-inflammatory mechanisms of actions (Bjornland *et al.*, 2007). However, the long-term adverse effects of intra-articular injection of GC are questionable. Some studies report good short- and long- term prognosis of intra-articular GC injections with no or minimal radiographically demonstrable side effects of the medication (Wenneberg *et al.*, 1991; Moystad *et al.*, 2008). Others, however, show that intra-articular injections of GC cause destruction to fibrous, cartilaginous, and osseous surfaces of TMJ (Haddad, 2000) which may be aggravated by multiple intra-articular injections of this medication (Toller, 1977).

The other medication widely used for DDwoR management is sodium hyaluronate (HS). Hyaluronic acid (HA) is one of the natural components of synovial fluid in healthy joints. It has three main suggested functions: nutritional, lubrication, and biomechanical stabilising functions of the joint components (Cascone *et al.*, 2002; Shi *et al.*, 2003; Guarda-Nardini *et al.*, 2005). The short- and long- term effects of intra-articular injection of HS are often attributed to these functions plus its anti-inflammatory function (Kopp *et al.*, 1987; Sato *et al.*, 1999b). HS injection has been reported to be safe and effective (Yeung *et al.*, 2006; Basterzi *et al.*, 2009) but it is relatively expensive medication and can be associated with potential complications such as articular surface destruction and localized inflammation (lida *et al.*, 1998; Chen *et al.*, 2002; Gencer *et al.*, 2014).

Arthrocentesis

Arthrocentesis is a joint washing and lavage procedure suggested widely in the literature for DDwoR management (Carvajal and Laskin, 2000). The technique involves using needles rather than arthroscope and it was originally emerged from the observation that arthroscopic lysis and lavage of the superior joint compartment without complex arthroscopic surgeries such as disc repositioning or condylar recontouring is sufficient to produce a 'desirable' outcome of reducing the pain and improving the mandibular movements (Nitzan *et al.*, 1990). Hence, it is also named as 'non-arthroscopic lysis and lavage' (Geist, 2001).

Murakami and colleagues was the first to describe the joint washing technique via a single needle used for frequent injection and aspiration of about 4 ml saline fluid inside the superior joint compartment (Murakami *et al.*, 1987). This technique was used to inflate and distend the joint space by hydraulic pressure in order to aid jaw manipulation in recapturing the displaced disc, a procedure called 'hydraulic pumping' (Figure 2.11) (Murakami *et al.*, 1987; Totsuka *et al.*, 1989). The procedure was then further developed by Ross (1989) and popularised by Nitzan *et al.* (1991b) to involve also washing the superior joint compartment with larger volume (30-200 ml) of saline fluid via two 'inflow and outflow' needles (Figure 2.12). Since then, various techniques of arthrocentesis have been described in the literature (Tozoglu *et al.*, 2011; Senturk and Cambazoglu, 2015) and different lavage fluid volumes (50-500 ml), instruments (needles or catheters), needle gauges (sizes and types), and adjunct medications were used (Al-Belasy and Dolwick, 2007; Monje-Gil *et al.*, 2012).

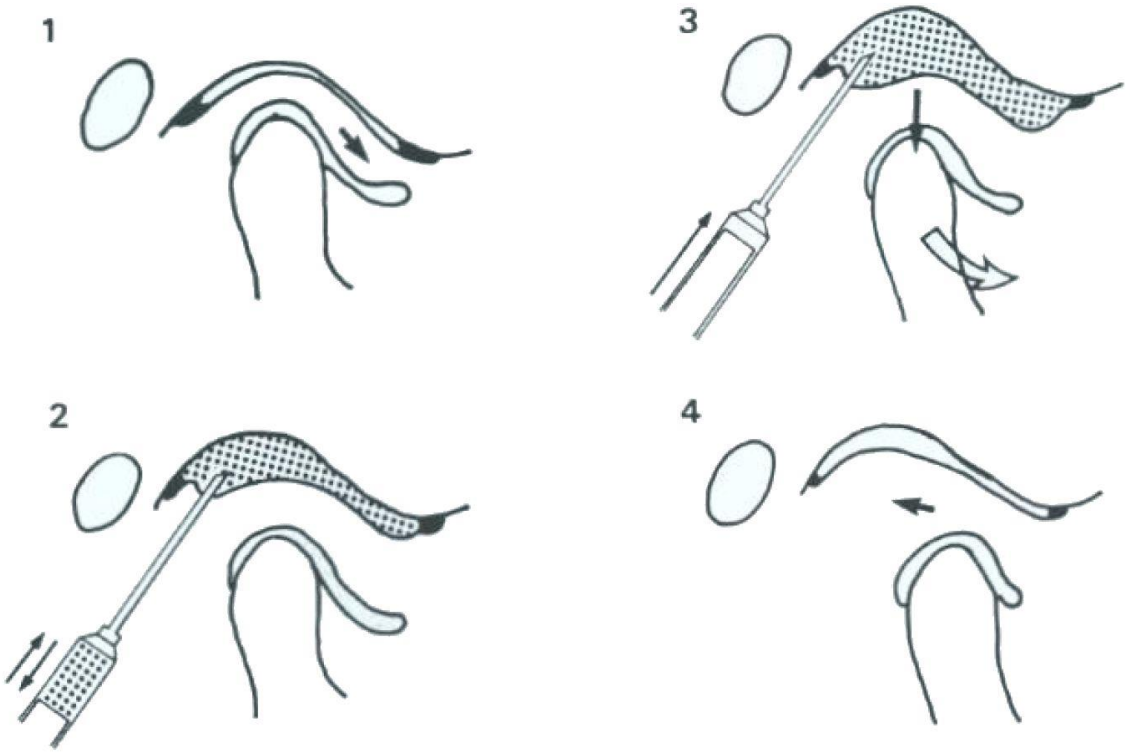


Figure 2.11: Pumping technique with mandibular manipulation for ‘unlocking’ the jaw. Reproduced from Totsuka *et al.* (1989) with permission from Elsevier.

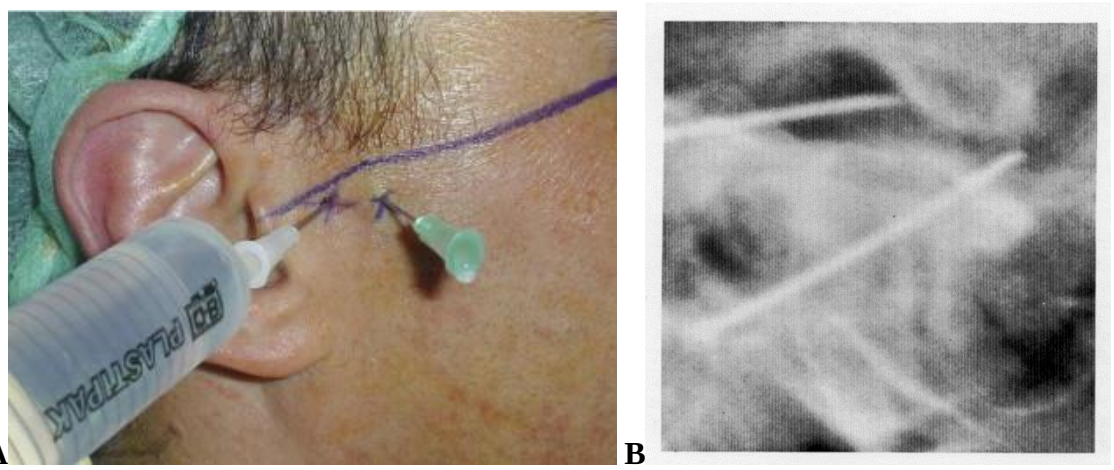


Figure 2.12: Positioning of two needles in arthrocentesis. (A) Placement of two needles for TMJ lavage. (B) Two needles’ entry into the superior joint space for joint lavage visualised fluoroscopically (one needle in the posterosuperior sulcus and the other in the anterosuperior sulcus). Reproduced from Guarda-Nardini *et al.* (2008) and Ross (1989) with permissions from Elsevier and Quintessence Publishing Company Ltd. respectively.

The mechanisms by which arthrocentesis achieves its therapeutic effect are still not fully interpreted but its main effect on reducing pain and improving mouth opening is often attributed to washing-out inflammatory mediators in the joint’s synovial fluid (lavage) and breaking down intra-articular adhesions (lysis) respectively (Yura *et al.*,

2003; Gulen *et al.*, 2009; Tvrdy *et al.*, 2014). Its therapeutic lavage volume has been studied and determined to be within an ideal lavage volume range of 100 ml to 400 ml necessary to wash-out proteins and inflammatory mediators (Zardeneta *et al.*, 1997; Kaneyama *et al.*, 2004); although this may also cause lavage to beneficial components of synovial fluid such as hyaluronic acid and lubricin (Laskin, 2009). In addition this treatment modality has been also claimed to help increase disc mobility, reduce synovial fluid viscosity and surface friction, and naturalise and release the negative intra-articular pressure inside the superior compartment of the 'locked' joints (Nitzan and Etsion, 2002). There is still, however, limited evidence to support many of the proposed mechanisms of action of arthrocentesis (Frost and Kendell, 1999; Ethunandan and Wilson, 2006; Al-Belasy and Dolwick, 2007).

Currently, arthrocentesis is recognized by many as first-line surgical intervention in TMD/DDwoR patients who do not respond to conservative management (Emes *et al.*, 2013; Murakami, 2013). Several advantages were reported to the use of this minimally-invasive procedure as an intermediate treatment modality between non-invasive conservative and more invasive surgical interventions (Nitzan, 2006; Grossmann, 2012; Tvrdy *et al.*, 2013). Arthrocentesis, however, is a 'blind' procedure not enabling the operator to directly observe intra-articular pathology or to perform sweeping and other arthroscopic actions (Murakami, 2013). Despite its minimally-invasive nature, arthrocentesis may cause potential complications (Carroll *et al.*, 2000; Etoz *et al.*, 2011). Its complication rate is not defined in the literature but considered to be less than that for TMJ arthroscopy (Tozoglu *et al.*, 2011). A comparison of the advantages, disadvantages, and surgical complications of each surgical modality used for DDwoR (arthrocentesis, arthroscopy, and open surgery) is summarised in Table 2.11.

Invasive surgical interventions

Invasive surgical management by arthroscopic or open joint surgery is one of the suggested options for DDwoR management.

Arthroscopy

The first use of arthroscopy to visualise the human TMJ was reported by Ohnishi in 1975 (Ohnishi, 1975). Thereafter, the techniques for diagnostic and therapeutic TMJ arthroscopy were further described in the literature (Sanders, 1986; McCain, 1988a;

Tarro, 1988). Over the years, various arthroscopic techniques have been developed with the advancement in equipment technology (Kim *et al.*, 2009; Weedon *et al.*, 2013).

A variety of arthroscopic surgical procedures have been described in the literature ranging from simple arthroscopic lysis and lavage to more complex operative arthroscopic procedures of disc repair, disc repositioning and suturing, disc removal, capsule release, and muscle release (McCain *et al.*, 1992a; Miyamoto *et al.*, 1999; Machon *et al.*, 2012; Yang *et al.*, 2012). These procedures are often accomplished via using three arthroscopic approaches to access the TMJ: inferolateral, endaural, and anterolateral (Figure 2.13) (Holmlund, 2010). Although the operative arthroscopy may have some additional advantages over simple lysis and lavage (McCain and de la Rua, 1989), the lysis and lavage arthroscopy seemed to be the preferred technique to many surgeons due to comparable results (Gonzalez-Garcia and Rodriguez-Campo, 2011) and difficulty to master the triangulation method (McCain, 1988a) mandatory for performing operative arthroscopy (Indresano, 2001; White, 2001).

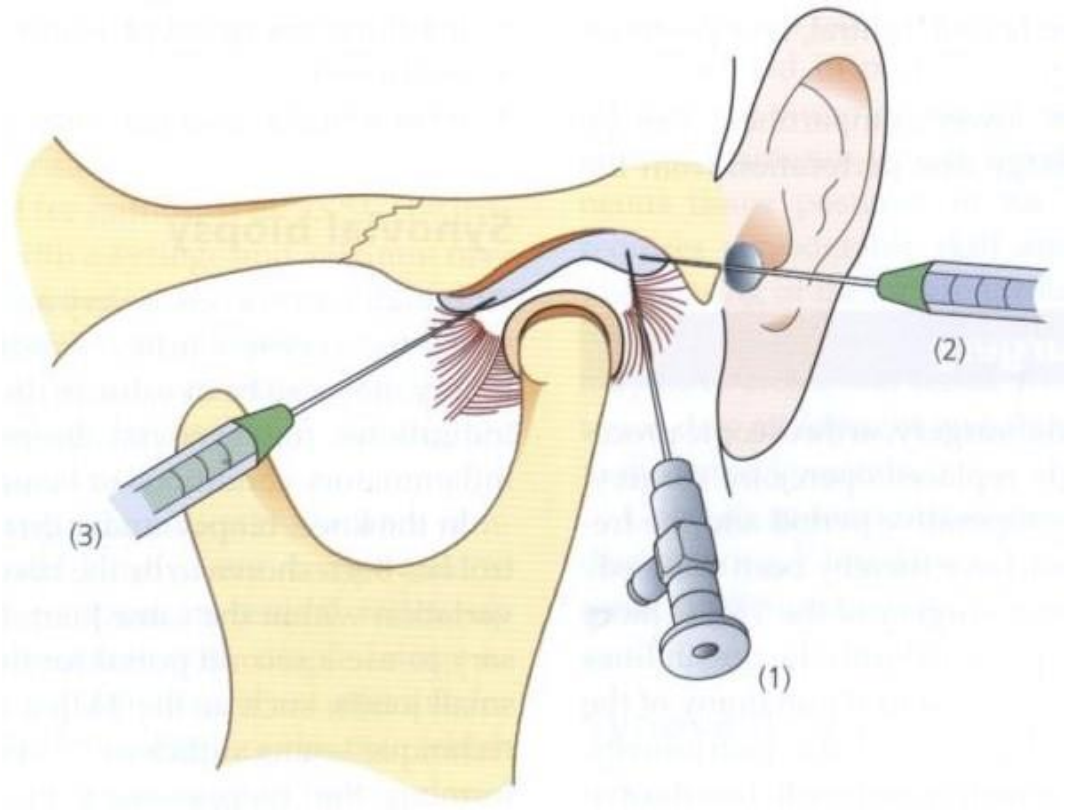


Figure 2.13: Arthroscopic puncture directions for the TMJ. (1) Inferolateral. (2) Endaural. (3) Anterolateral. Reproduced from Holmlund (2010) with permission from Wiley-Blackwell.

The arthroscopic lysis and lavage technique is consisted of arthroscopic sweep of adhesions in the superior joint compartment by blunt trocar and lavage of joint space

(Murakami, 1990). Its main therapeutic effects, therefore, attributed to lavage of inflammatory mediators and lysis of adhesions which are equivalent to those achieved with arthrocentesis. However, its main value over arthrocentesis is the direct arthroscopic visualisation of the joint interior and the potential for instrumentation (Hori *et al.*, 1999; Kim *et al.*, 2009). When compared to open surgery, arthroscopic closed surgery has some obvious advantages related mainly to its relatively less invasive nature (Zhu *et al.*, 2012; Murakami, 2013). Arthroscopic surgery, however, can be associated with several potential intra- and post- operative complications (McCain, 1988b). Its reported complication rate is ranged from 1% to 10% (McCain *et al.*, 1992b; Carls *et al.*, 1996; Tsuyama *et al.*, 2000; Indresano, 2001; Gonzalez-Garcia *et al.*, 2006).

Open surgery

Various open joint surgical procedures were described in the literature such as discectomy (with or without replacement), discoplasty, condylotomy, and eminenctomy (Trumpy and Lyberg, 1995). These procedures are accomplished via using different surgical approaches to gain access to the TMJ, most commonly preauricular and endaural and less commonly postauricular, submandibular, and retromandibular (Figure 2.14) (Kreutziger, 1984).

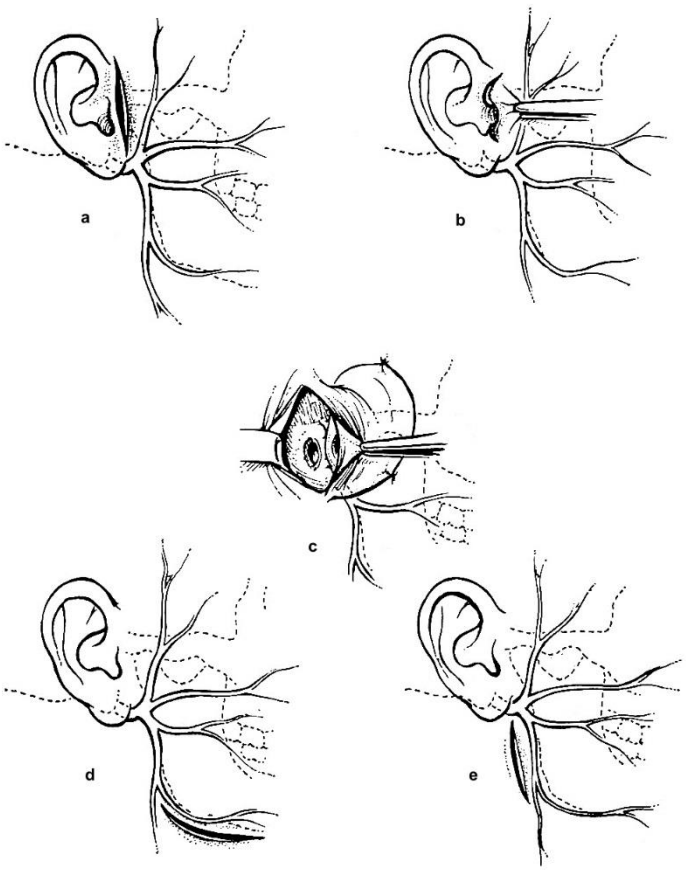


Figure 2.14: Surgical approaches to the TMJ. (a) Standard preauricular approach; (b) endaural approach; (c) postauricular approach; (d) submandibular approach; (e) retromandibular approach. Reproduced from Laskin (2006) with permission from Quintessence Publishing Company Ltd.

Historically, open surgery for managing patients with disc derangement was associated with multiple failures and reoperations leading to catastrophic sequelea (Moody and Clark, 1995; Milam, 1997; Schliephake *et al.*, 1999; Fricton *et al.*, 2002). Although open surgery is still recommended for disc derangement management by many surgeons to-date (Abramowicz and Dolwick, 2010; Miloro and Henriksen, 2010; Dimitroulis, 2013; Holmlund *et al.*, 2013), it is an irreversible invasive treatment modality that can be associated with several potential complications which should be taken in consideration before planning this invasive treatment approach (Keith, 2003; do Egito Vasconcelos *et al.*, 2007).

In fact, there are absolute and relative indications for TMJ disorders' surgical management (Moore, 2006; Dimitroulis, 2013). Before considering irreversible invasive TMJ surgical treatment to patients, the patients must have an adequate, and appropriate, course of reversible non-surgical conservative treatment (Moore, 2006). Elective orthopaedic surgery has also been recommended for refractory cases of other joints in

the human body. To give an example, the available evidence suggests surgical intervention for patients with intervertebral disc herniation causing intolerable pain and persistent neurological deficit after 4-6 weeks of conservative treatment if there is no response to treatment (Atlas and Nardin, 2003; Schoenfeld and Weiner, 2010). For TMJ, a combination of factors have been identified by de Leeuw and Klasser (2013) and can be used as a guide to determine the appropriate duration and complexity of non-surgical treatment prior to proceeding to TMJ surgery including: the actual improvement and expected prognosis, the degree of impairment, and the patient compliance. In general, the decision to perform TMJ surgery and its rationale depends on multiple factors including: the degree of derangement and/or degenerative changes within the joint; the potential for repair of the condition and likely improvement; the outcome of adequate and appropriate non-surgical treatment; the degree of impairment and disability the problem creates for the patient; and the presence or absence of other complicating factors, such as psychosocial factors or previous TMJ surgeries, which may lead to poor surgical prognosis (Moore, 2006; de Leeuw and Klasser, 2013). In addition, the patient should only undergo surgery having given informed consent involving realistic discussion of the disorder prognosis, patient's expectations, and surgical complicating factors. Furthermore, the TMJ surgeon must have full knowledge about the biopsychosocial nature of TMD and the necessity to integrate the preoperative and postoperative conservative treatment into the overall surgical treatment plan and should also have full appreciation of the potential for surgical failure and complications (Razook, 2006; de Leeuw and Klasser, 2013).

Overall, there is high success rate reported in most surgical trials for TMJ disorders management and TMJ surgery may be claimed as an effective approach (Reston and Turkelson, 2003; Monje-Gil *et al.*, 2012). However, the complexity of surgical techniques, potential complications, the biopsychosocial nature of TMD, and the high success rate with the non-surgical conservative approaches suggest that the TMJ surgery should only be used in specific, carefully selected cases not responding to conservative management (AAOMS ParCare TMD, 2012; de Leeuw and Klasser, 2013) with the least invasive surgical procedure should be applied first (Dimitroulis, 2005b). At the moment, there is insufficient evidence to support the use of any of the systematically reviewed surgical interventions for TMJ disorders management (Kropmans *et al.*, 1999; Al-Belasy and Dolwick, 2007; Guo *et al.*, 2009; Rigon *et al.*, 2011; Vos *et al.*, 2013).

Characteristics	Minimally-invasive and invasive surgical interventions		
	Arthrocentesis (AC)	**Arthroscopy (AS)**	**Open surgery (OS)**
Advantages	• Simple • Least invasive • Less financial costs • Not leave scars • Performed on an out-patient basis under local anaesthesia with or without sedation • Less operating time • Early patients' recovery • Less stress for the patient • Not demanding sophisticated instruments and require only common equipment in an out-patient clinic • Sampling of synovial fluid for biochemical synovial fluid analysis • Performed repeatedly and tried before TMJ surgery	**Advantages over AC:** • Visualisation of joint interior thereby enabling the surgeon to: - Examine, resect, and investigate the intra-articular tissue pathology - Release with reliability the fibrous adhesions - Mobilise the disc under direct arthroscopic vision - Perform disc repositioning and suturing and other procedures such as capsular stretching and/or muscular release **Advantages over OS:** • No surgical dissection • Less operating time and shortened general anaesthesia • Possibility to be performed under LA • Early jaw mobilization • Early patient's recovery • Lower financial cost • Less invasive	**Advantages over AS:** • Some open joint procedures can leave the lateral capsule intact or primarily repaired • Can predictably avoid vital structures • No risk of extra-capsular leakage of irrigation solutions or instrument breakage
Disadvantages	• 'Blind' procedure not enabling the operator to directly observe intra-articular pathology or to take a biopsy of pathological tissue • Difficult to treat mature adhesions or perform sweeping and other arthroscopic actions. • Difficult to enter narrow joint spaces in severe degenerative joints • Challenging for inexperienced surgeons to find the exact places for the needles • Difficult to maintain the exact place of the needles during lavage procedure • Repetitive insertions of needles to find the right place can damage capsular tissues, increase the risk of fluid leakage, aggregate TMJ inflammation, and increase the risk of facial nerve injury	• Equipment-dependent procedure depending largely on expensive and unique instruments and complex equipment technology • Needs a skillful arthroscopic surgeon and requires extensive training and can be difficult for many surgeons to develop this expertise **Disadvantages over OS:** • Causes perforation of the lateral capsule • Cannot predictably avoid vital structures • Multiple port procedures cannot predictably circumvent vital structures. • Extra-complications such as fluid leakage or instrument breakage	• Most invasive

Characteristics	Minimally-invasive and invasive surgical interventions		
	Arthrocentesis (AC)	**Arthroscopy (AS)**	**Open surgery (OS)**
Complications	• Neurologic: temporary facial nerve deficit due to local anaesthesia, needle trauma, or swelling of the surrounding tissues; reflex bradycardia (trigeminocardiac reflex) • Vascular: haemorrhage; haematoma (extradural hematoma and periauricular hematoma) • Otologic: otitis; partial or complete hearing impairment; external auditory canal perforation • Leakage of irrigation fluid and extravasation of fluid into surrounding tissues and tissue spaces • Iatrogenic damage to the joint structures • Infection • Instruments breakage • Malocclusion (occlusal bite changes)	• Neurologic: temporary or permanent facial, trigeminal, oculomotor, or trochlear nerves deficit; damage of auriculotemporal or masseteric nerves; reflex bradycardia (trigeminocardiac reflex) • Vascular: traumatic aneurysm; haemorrhage; haematoma; arteriovenous fistula • Otologic: otitis; partial or complete hearing loss; blood clots in external auditory canal; perforation of tympanic membrane; laceration of external auditory canal; ear fullness; vertigo • Ocular: alteration of visual accuracy; Horner syndrome (eye ptosis, miosis, and enophthalmos) • Leakage of irrigation fluid: extravasation of fluid into surrounding tissues and tissue spaces • Upper airway compression due to parapharyngeal swelling requiring prolonged intubation • Iatrogenic damage to the joint structures such as perforation of the disc or rupture; scuffing or laceration of articular fibrocartilage surfaces; perforation of the glenoid fossa • Infection • Instruments breakage • Malocclusion (occlusal bite changes) • Post-operation tissue reactions such as local soft tissue swelling; condylar resorption; marked fibrosis and adhesions	• Neurologic: mostly damage to facial nerve and occasionally to trigeminal and vestibulocochlear nerves; injury to auriculotemporal nerve (Frey's syndrome) • Vascular: haemorrhage • Otologic: middle ear damage • Subcutaneous pneumomediastinum or emphysema • Cranial fossa perforation • Infection • Postoperative fibrous adhesions and ankylosis • Degenerative joint disease (osteoarthritis), • Malocclusion (occlusal bite changes) • Sialocele and parotid gland injury and fistula • Implant failure

Table 2.11: Comparison between invasiveness of closed and open surgical interventions used for DDwoR management. Adapted from reviewing the relevant literature, mainly (McCain, 1988b; McCain *et al.*, 1992b; Carls *et al.*, 1996; Tsuyama *et al.*, 2000; Indresano, 2001; Keith, 2003; Gonzalez-Garcia *et al.*, 2006; Nitzan, 2006; Al-Belasy and Dolwick, 2007; Grossmann, 2012; Monje-Gil *et al.*, 2012; Murakami, 2013).

In summary, the interventions used differ widely in their mechanisms of actions to produce a therapeutic effect on temporomandibular disorders. Nevertheless all the interventions share a generally similar treatment goal to improve patients' symptoms and all appear to be 'successful' in achieving this goal. The current available evidence suggests that the best primary approach for TMD management is 'to not do harm to the patients' via treating them initially by reversible non-invasive conservative treatments (List and Axelsson, 2010; Durham *et al.*, 2015) while irreversible invasive surgical treatments should only be used, if indicated, on specific, selected not-responding cases. The failure of reversible treatments, however, should not be taken as a signal to pursue irreversible treatments. For DDwoR, however, where evidence is lacking, this conservative approach remains controversial with a multitude conflicting and contradictory opinions in clinical research on how and when to manage DDwoR conservatively or surgically (Murakami *et al.*, 1995; de Bont *et al.*, 1997).

2.2.9 Management outcomes

Although TMD is not a life-threatening disease, its chronic pain nature, in addition to dysfunction, can reduce the patients' quality of life (QoL) (Dahlstrom and Carlsson, 2010; Liu *et al.*, 2012a) leading to psychosocial consequences and considerable suffering (Durham *et al.*, 2011). This can be aggravated by delayed diagnosis and inappropriate treatment (Durham *et al.*, 2010). As far as is possible management of patients with TMD/DDwoR, therefore, should be based on evidence rather than subjective experience with its main goal is to reduce patients' suffering and improve patients' QoL (Turp *et al.*, 2007b; Dahlstrom and Carlsson, 2010).

Various valid and reliable tools are available to measure subjective and objective outcomes of TMD/DDwoR management in relation to patients' pain, and mandibular movements and function (Helkimo, 1974; Joyce *et al.*, 1975; Fricton and Schiffman, 1986; Von Korff *et al.*, 1992; Stegenga *et al.*, 1993a; Nixdorf *et al.*, 2010), but there is dearth of valid patient-centred tools to measure multidimensional nature of patients' QoL (Durham *et al.*, 2007; Locker and Allen, 2007). Recently, a validated and reliable patient-based outcome measure (Oral Health Impact Profile for TMD 'OHIP-TMD') is suggested to measure QoL of TMD patients (Yule *et al.*, 2015). The OHIP-TMD, however, is labour and time intensive and may not be used widely in clinical practice. There is still a need to develop a valid reproducible, but simple and practical, patient-

centred outcome measure that can be used in clinical practice in order to base TMD/DDwoR management on.

2.2.10 Management barriers

A range of barriers to patients' care have been identified by different research methods in both the dental and medical fields. The identified barriers of care are broadly related to three general elements of management: clinician factors, patient factors, and practice factors (McColl *et al.*, 1999; Pitt *et al.*, 2008). In the TMD field, these three elements can also provide barriers to TMD care. Nevertheless, there are additional barriers of TMD care related specifically to the biopsychosocial nature of TMD and its controversial aetiology, diagnosis, and treatment.

One of the reasons for the difficulties in providing management for TMD is the difficulty in making a differential diagnosis of painful conditions in the orofacial region and the potential overlap between the signs and symptoms of differing putative diagnoses (Aaron and Buchwald, 2001). The diagnostic process can be even more challenging for the rarer conditions not usually encountered in general clinical practice such as DDwoR (Zakrzewska, 2002; Hegarty and Zakrzewska, 2011).

The considerable controversy surrounding the aetiology and treatment of TMD is another obvious reason for management difficulty. This controversy, coupled with the lack of agreed outcome measures to base management on, undoubtedly leads to increased uncertainty in TMD management (Durham *et al.*, 2007).

Another challenging aspect of TMD management is the biopsychosocial nature of TMD which often means it requires a slightly different approach to more 'standard' biomedical conditions (Dworkin, 2001; Suvinen *et al.*, 2005). This, however, is usually out of the remit of most dental and medical practitioners and it may be that the clinicians try to avoid approaching psychosocial issues because of inadequate training, insufficient incentives, and lack of time and interest (Astin *et al.*, 2005; Astin *et al.*, 2006; Astin, 2007; Turp *et al.*, 2007a; Astin *et al.*, 2008). The nature of clinicians' current clinical environment may favour quick remedies which may be difficult to achieve in some 'chronic' TMD cases that ideally require long-term therapy. Despite this, clinicians' awareness of the psychological ramifications of pain in acute or chronic

TMD patients is important to avoid inadequate focus on dental or surgical 'biomedical' management approaches (Turp *et al.*, 2007a).

2.2.11 Referral

In any healthcare system, there are usually different steps of patients care, mostly: primary, secondary, and tertiary care. In the UK, the National Health Service (NHS) defines these terms as follows:

- Primary care: "the activity of healthcare providers who are the first point of health system contact for patients and who are based in a community, rather than in a hospital" (Makeham *et al.*, 2008).
- Secondary care: a "hospital or specialist care to which a patient is referred to from a primary care provider" (NHS terms, 2013).
- Tertiary care: "the third and highly specialised stage of treatment, usually provided in a specialist hospital centre" (Health encyclopedia, 2013) and indicated mainly to any further point of specialist care within the hospital setting to which a patient is referred from a secondary care provider (Beecroft *et al.*, 2013).

Patients with TMD often seek care first in community-based primary care setting serviced mainly by general dental and medical practitioners (GDPs & GMPs) rather than hospital-based secondary care setting serviced mainly by specialists (Field *et al.*, 2013). The GDPs and GMPs, therefore, have an important role in the diagnosis and treatment of TMD patients at the first point of contact (Okeson and de Kanter, 1996; Dimitroulis, 1998) to avoid potential consequences of delayed diagnosis and treatment (Durham *et al.*, 2010). However, several studies in different parts of the world show that most general practitioners lack adequate education and training in TMD (Le Resche *et al.*, 1993; Glaros *et al.*, 1994; Siritapetawee and Kositbowornchai, 1999; Lee *et al.*, 2000; Baharvand *et al.*, 2010) and, therefore, often prefer to refer TMD patient to specialists. In a recent survey-based study in Germany, the frequency of clinicians' referrals of TMD patients to specialists was about 22.5% (Reissmann *et al.*, 2015). In the UK, one study found that about 75% of referred COFP patients have TMD (Beecroft *et al.*, 2013).

Several studies reported the referral rates of subgroups of TMD. Amongst all the referred TMD patients, referrals of patients with DDwoR were relatively high (11%-22%), specifically 9% to 14% had DDwoR with limited opening and 8% had DDwoR without limited opening (Dahlstrom, 1998; Anastassaki and Magnusson, 2004; Vallon and Nilner, 2009; Kraus, 2014). This proportionally high referral rate of DDwoR is probably linked to severe symptoms and complaints of patients with DDwoR.

Clearly the onward referral of TMD/DDwoR patients from general to specialist service is a problem that requires further attention because a rapid and appropriate diagnosis and treatment at the initial consultation is essential for patients' management to relieve patients' suffering early and achieve optimal outcomes avoiding 'chronic' disability (Gatchel *et al.*, 2006).

2.2.12 Conclusion

The subject of TMD is still one of the most controversial topics in dentistry. The literature about TMD management is enormous and contradictory. Overall, there is increasing evidence from systematic reviews that TMD is best managed initially with non-invasive conservative reversible treatments and currently there is general consensus about this approach and it is advised by many authorities in the TMD field to avoid any harm to TMD patients (De Boever *et al.*, 2008; Greene, 2010b; Yuasa *et al.*, 2013).

As seen in this section, many systematic reviews have been conducted on TMD management. Although this is a good start to improve understanding of this controversial topic, it is also questionable because most of the systematic reviews focused mainly on specific therapeutic intervention applied to generic TMD patients. This may result in different treatment responses and may not depict the real practice which usually involves different treatment combinations (Poggio *et al.*, 2010). In fact, TMD are a collection of disorders rather than being a singular "catch-all" entity and grouping the patients and managing them under this generic 'TMD' term may rather cause further confusion in the field (Laskin, 2008; Benoliel, 2010). In a specific subtype of TMD 'DDwoR', this conservative management remains controversial with a multitude conflicting and contradictory opinions in clinical research. In terms of clinical decision-making in the management of TMD/DDwoR, the competing concepts and diverse opinions may increase the degree of uncertainty in the therapeutic decision-making process among clinicians. This therapeutic decision-making is dependent, to

some extent, on evidence quality (Gordon and Dionne, 2005). At the moment, for TMD/DDwoR management, where opinion is divided, evidence is of poor quality. Professionals' clinical decisions may, as a result, be based on experiential-based knowledge rather than research evidence-based knowledge (Durham *et al.*, 2007). The next section will discuss the clinicians' decision-making process.

2.3 Clinical decision-making

2.3.1 Introduction

Clinical decision-making is a complex process involving many interacting clinical and non-clinical factors leading to variability in clinicians' decisions (Kay and Nuttall, 1995c). The process of decision-making is a critical important area in all disciplines in medicine (Croskerry, 2005a) because clinical decisions are taken several times daily in clinical practice. This section aims to help understanding how the clinicians make decisions in clinical practice, what influences these decisions, and what can be done to improve the clinicians' decisions.

2.3.2 How the clinicians make decisions?

Theoretically, there are two different views on how the clinicians make their decisions in clinical practice: perspective and descriptive. The prescriptive view prescribes how decisions ought to be made and demonstrates how medicine or dentistry should be practiced and offers a way for improving decision-making whilst the descriptive view describes how decisions are made in 'real' clinical practice and demonstrates how medicine or dentistry is 'actually' practiced and offers a way for understanding decision-making (McKinlay *et al.*, 1996; Thompson, 1999).

Prescriptive decision-making

This is a scientific formalised model of decision-making based on mathematical calculations of probabilities and rates of decisions' outcomes (Schwartz *et al.*, 1973; Kassirer, 1976). This model often involves a logical analysis of the pros and cons of each decision by the decision-maker from the various options available in complex decision-making using a branching decision tree (a visual representation map of all possible decisions available in which decisions lead to outcomes) (Luker *et al.*, 1998; Elstein and Schwartz, 2002). In each step of the decision tree, the ratios and probabilities of the outcome of each decision (e.g., benefits-risks) are calculated and assigned a numerical value (Kassirer, 1976).

This formal quantitative decision analysis involves two variables: the probabilities (the probability or likelihood of clinical outcomes that treatments will have the same absolute or relative effects as those measured in clinical trial), and the values or utilities

(a utility is a numerical value representing a patient's preference for one outcome over others) (Schwartz *et al.*, 1973). It uses the Bayesian[2] probabilities (probability calculations of each individual outcome) together with the utilities related to different decision outcomes to determine the best course of action (i.e., best decision) (Lilford *et al.*, 1998). The strength of decision analysis, therefore, is attributed to its ability to combine both medical facts (probabilities) and human values (utilities) together to determine the best available option with maximum expected utility 'optimum decision' (Swales, 1997; Lilford *et al.*, 1998).

This mathematical model can be used to guide the clinical decision-making process and formalise the clinicians' decisions but it has several limitations to be implemented in 'real' clinical practice. First, performing a clinical decision analysis for each patient is time-consuming and less practical in the busy clinical practice (Lilford *et al.*, 1998; Straus, 2002). Second, it depends heavily on availability of objective sources of knowledge such as rationalised research-based knowledge to optimise a decision which is not always available (Luker *et al.*, 1998). Third, it is more 'biomedical' based exclusively on the objective findings of the presenting clinical condition and the probability of that condition and may be less useful in complex conditions where psychological and social factors influence a clinical condition such as biopsychosocial TMD. Fourth, it does not take in consideration other factors (e.g., environmental factors) that may influence decision-making (McKinlay *et al.*, 1996). Despite all these limitations, using sensitivity analysis by knowing how sensitive a decision it is via varying the utilities and outcome probabilities to determine the robustness of a choice made by generic decision analysis may make it possible to provide basis for developing clinical guidelines (Lilford *et al.*, 1998); but again, having a guideline does not simply mean that the clinicians will use it in their decision-making process (van der Sanden *et al.*, 2005). This will be discussed further in Section 2.4.

The sequence of events followed in performing a decision analysis and developing a guideline based on that analysis and then implementing that guideline has been described by Lilford *et al.* (1998) and is presented in Figure 2.15.

[2] Bayesian statistics: is a branch of statistics that utilises prior knowledge from research data to predict future outcomes.

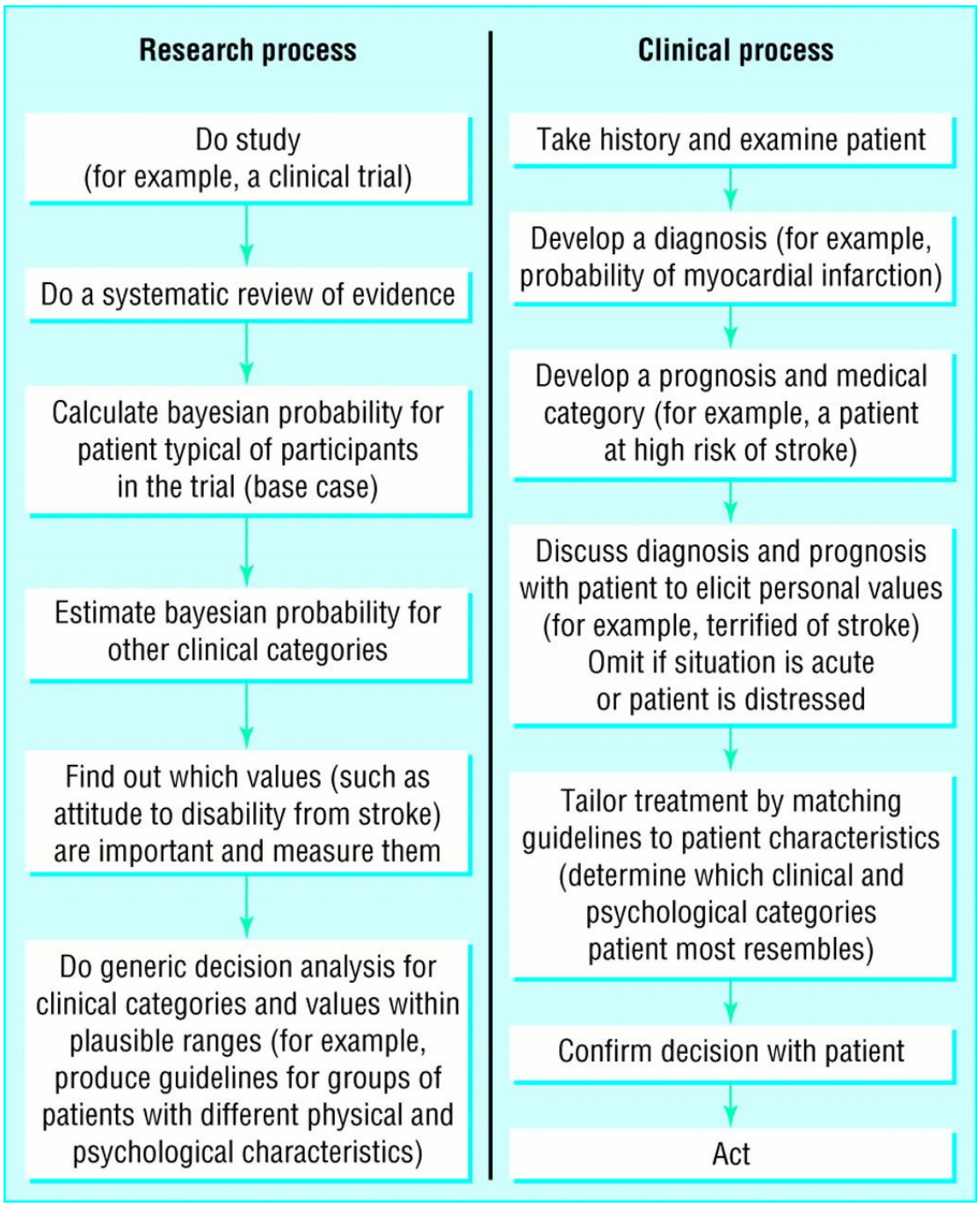


Figure 2.15: The sequence of events followed in performing a decision analysis, developing a clinical guideline based on the analysis, and implementing the guideline. Reproduced from Lilford *et al.* (1998) with permission from BMJ Publishing Group Ltd.

Descriptive decision-making

This is a more subjective model of decision-making than the 'objective' prescriptive one because it depicts how the clinicians use their knowledge and experience in 'real' practice to make a decision. In clinical practice, the clinicians often use two proposed modes of thinking in order to make clinical decisions: analytical and intuitive, each of

which has quite different and distinctive properties and advantages and disadvantages (Dawson, 1993; Croskerry, 2005a; Evans, 2008; Croskerry and Nimmo, 2011). Intuitive decision-making relies upon experiential knowledge and wide range of intuitive thinking which is not 'formally' rationalised (Benner, 1982). This mode of thinking is fast, impulsive, less reproducible, reflexive, multi-channelled, and needs less effort but it is highly context dependent, has low confidence, is less reliable, and is more prone to error (Dawson, 1993; Croskerry and Nimmo, 2011). In contrast, analytical decision-making is based on scientific knowledge and rationalistic thinking that follows rational logic (Hedberg and Satterlund Larsson, 2003; Banning, 2008). This mode of thinking is slow, explicit, reproducible, deliberate, purposeful, single-channelled, and it is relatively independent of context, has high confidence, is more reliable, and has few errors but it requires more effort (Dawson, 1993; Croskerry and Nimmo, 2011). Further description about the characteristics of analytical and intuitive approaches to decision-making are detailed in Croskerry and Nimmo (2011).

In clinical practice, the clinicians may use these cognitive processes (i.e., modes of thinking) to develop different decision-making strategies which they can use singularly or in combination (Charles *et al.*, 1997; Croskerry, 2002). The strategies are:

- Pattern recognition
- Exhaustive method
- Hypothetico-deductive method
- Rule out worst-case scenario (ROWS)
- Heuristics
- Informed and Shared decision-making

Clinical decision-making by pattern recognition method

This strategy involves the recognition of the pattern of a new condition from previously known or encountered conditions with similar pattern (categorisation). Pattern recognition can be done either analytically when the condition is recognised slowly via data collection and analysis or intuitively when the condition is recognised quickly (Offredy, 1998). For example, in intuitive process, the clinician compares the signs and symptoms of a presenting patient with patterns of patients previously seen and held in the clinician's memory from past experience to recognise 'quickly' the category or pattern in which the new patient fits (pattern matching) (Manias *et al.*, 2004; Banning,

2008); while in analytical process, the clinician begins with insufficient information from data-gathering (e.g., history and/or clinical examination) (bottom-up) but further additional data are needed (e.g., imaging investigations) to supplement the process to become more goal-directed (top-down), and thereafter the combination and continuous interplay of data collection and analysis enables the condition to be recognized 'slowly' and the decision to be made (problem solving) (Figure 2.16) (Croskerry, 2002).

The pattern recognition strategy is often developed with the growing experience of the clinician (Cioffi and Markham, 1997) but it has the drawback for the possibility of making incorrect decisions due to possibility of decision-maker overreliance on memory to recognise a pattern that may be inaccurate (Banning, 2008).

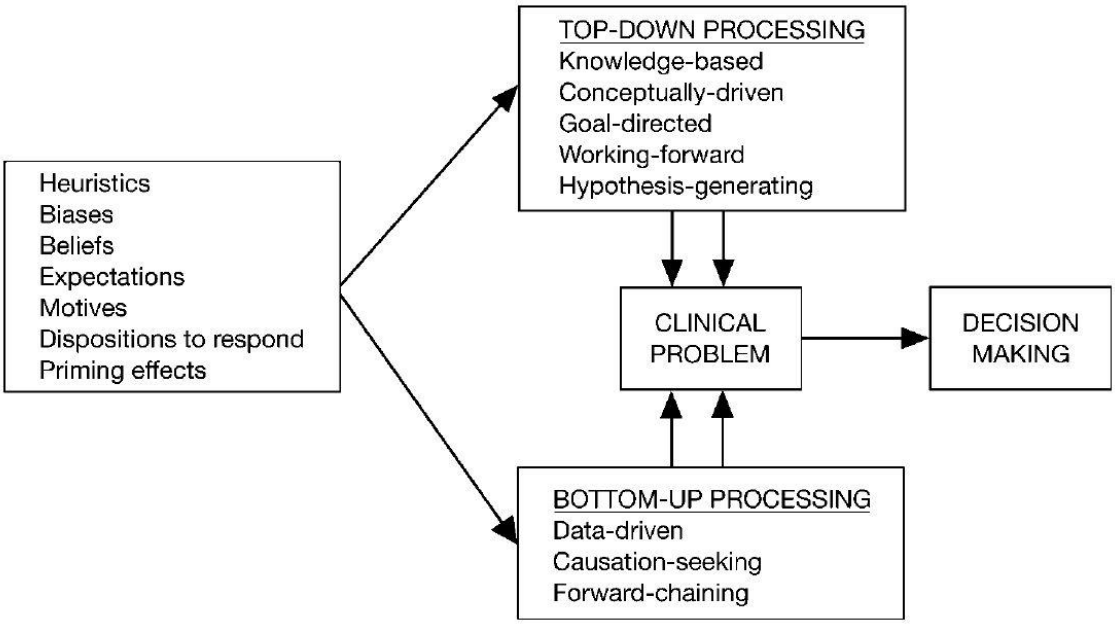


Figure 2.16: Cognitive influences on top-down and bottom-up processing in clinical decision-making. Reproduced from Croskerry (2002) with permission from John Wiley and Sons.

Clinical decision-making by hypothetico-deductive method

This decision-making strategy uses mainly analytical process and depends on the clinician's intellectual ability to make clinical decisions by problem solving using previous knowledge to create new solutions (hypothesis deduction) (Kovacs and Croskerry, 1999; Croskerry, 2000). It involves four basic sequential stages: cue recognition ('initial' hypothesis generation), hypothesis testing, cue interpretation ('final' hypothesis generation), and hypothesis evaluation (Tanner *et al.*, 1987; Offredy, 1998). In practice, the clinicians use this approach to help them transform a seemingly

unmanageable problem into a manageable one by: generating ‘initial’ hypotheses, testing their appropriateness via further data collection and assessment, modifying these hypotheses according to the outcome of the test, generating the ‘final’ hypothesis and making a decision, and evaluating the outcome of their decision (Figure 2.17) (Groen and Patel, 1985; Offredy, 1998).

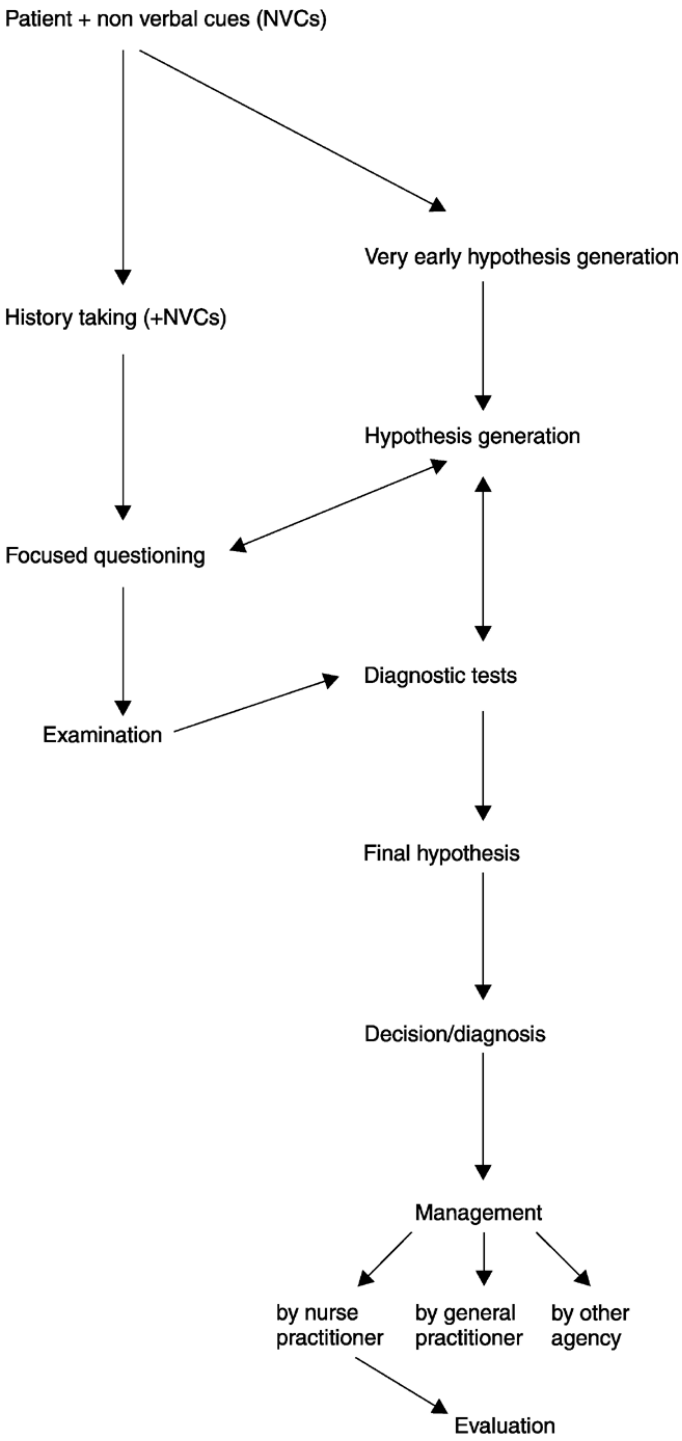


Figure 2.17: Hypothesis testing in clinical decision making. Reproduced from Offredy (1998) with permission from John Wiley and Sons.

The hypothetico-deductive approach may also involve the top-down (goal-directed 'knowledge-based') and bottom-up (data-driven) processes (Figure 2.16). The top-down process predominates when there are little data available (e.g., patient in coma), but when more data become available (e.g., laboratory investigations), bottom-up process predominates (Croskerry, 2002). Elstein and Schwartz (2002) pointed out that the clinicians usually approach and solve the problems flexibly and the method they select depends largely upon the problem's characteristics as well as their experience; that is, easy straightforward cases can be solved by pattern recognition whilst difficult complex cases need testing of hypotheses and it is probable that experienced clinicians use a hypothetico-deductive strategy only with difficult cases (Elstein and Schwartz, 2002).

Clinical decision-making by exhaustive method

This strategy involves seeking all possible data related to the presenting condition, followed by sifting through the data to reach a decision (Croskerry, 2002). It is common amongst novice or inexperienced clinicians who may attempt to make a diagnosis by inappropriate exhaustive data gathering and resources utilisation. This exhaustive approach reflects a high degree of uncertainty due to lack of experience, but with clinical experience, data searching and gathering becomes more focused and directed. Exhaustive approach, however, may also be used by experienced clinicians in their decision-making when there are high levels of uncertainty such as when a particularly rare condition presented and the clinician requires additional thinking time to rule out all possibilities or when the clinician becomes fatigued and stressed which can have a negative impact on cognitive processes of decision-maker (Croskerry, 2002).

Clinical decision-making by rule out worst-case scenario (ROWS)

The ROWS decision-making strategy is important specifically to clinicians encountering emergency or critical acute clinical conditions. The ROWS "is a strategy of safety and errs on the side of caution" (Croskerry, 2002). It requires the emergency clinicians not to miss critical diagnoses and, therefore, they must hold in their working memory a number of worst-case scenarios that they should exclude when presented with an urgent clinical situation (Croskerry, 2002).

Clinical decision-making by heuristic method

Heuristic method is a cognitive process that simplifies the clinicians' decision-making (Gigerenzer *et al.*, 1999). Heuristics are intuitive decisions that the clinicians make without resorting to a logical decision analysis (Croskerry, 2000). They are "rules of thumb, intuitions, abbreviations, simple judgements, and shortcuts" (Croskerry, 2005a). The use of the heuristic method in clinical decision-making requires the clinicians to explore, investigate, discover, and learn things from experience leading to the development of rules learned from clinical practice; that is making personal decision rules based on experiential knowledge (Cioffi, 2001; Croskerry, 2002). This strategy is a quick practical method in decision-making that can provide usually economical, resourceful, effective and successful solutions in clinical problem-solving and decision-making. It is, however, inferential, subjective, and imprecise and can be influenced occasionally by a variety of cognitive biases (errors) leading to failure (Tversky and Kahneman, 1974; Croskerry, 2002).

In clinical practice, the clinicians develop heuristics with growing experience as a part of intuitive decision-making to cope with decision-making complexity. Intuitive decision-making in pattern recognition and heuristics is very similar but the main difference is that the pattern matching occurs at the conscious level of thinking whilst heuristics occurs at the unconscious level of thinking (Offredy, 1998). The clinicians often use these heuristic rules under conditions of uncertainty to make complex decisions simpler but sometimes it may not be the 'best' decision resulting in errors and biases (Cioffi and Markham, 1997; Cioffi, 1998; Hall, 2002). Biases in decision-making process will be discussed further in Section 2.3.3.

Informed and Shared decision-making

The clinicians may sometimes incorporate patients in decision-making process (i.e., shared decision-making) or give them the responsibility to make a decision about their own healthcare (i.e., informed decision-making). Theoretically, there are three types of clinician-patient partnerships in making decisions: paternalistic, informed, and shared (Charles *et al.*, 1999). The key differences between the three approaches are summarised in Table 2.12.

Analytical stages	Paternalistic decision-making	Informed decision-making	Shared decision-making
Information exchange	One way (largely) from clinician to patient	One way (largely) from clinician to patient	Two way between clinician and patient
Deliberation	Clinician alone or with other clinicians	Patient (plus potential others)	Clinician and patient (plus potential others)
Who decides what treatment to implement?	Clinician	Patient	Clinician and patient

Table 2.12: Types of clinician-patient partnerships in making decisions. Modified from Charles *et al.* (1999).

All the previously discussed decision-making strategies have a passive role from the patient in decision-making process representing the traditional paternalistic decision-making. In the last few decades, however, there was an increasing emphasis from healthcare authorities on active involvement of patients in decision-making process about their own healthcare (GMC, 2008; DOH, 2010b). This leads to rapidly growing literature around informed and shared decision-making strategies and models with great intention on implementation of shared decision-making (Elwyn *et al.*, 2010b; Coulter *et al.*, 2011). This is in part due to recognition of appropriateness to 'ethically' involve patients in decisions about their own care (Mulley, 2009) and in part because active patient involvement in decision-making has been shown to be beneficial to patients' healthcare from several aspects: increasing patients' compliance and satisfaction with treatment, reducing patients' anxiety, and improving treatment outcomes (Street *et al.*, 2009; Vicente *et al.*, 2013); however, the evidence for the effects of this involvement on quality of care is still unclear (Crawford *et al.*, 2002).

To promote shared decision-making, two things are required: communication training between clinicians and patients and decision aids to support patient decisions (Adams and Drake, 2006). Decision aid tools and boxes have been developed to support difficult decisions (Elwyn *et al.*, 2010a; Giguere *et al.*, 2012). A recent Cochrane review found that decision aids, compared to usual care, have several advantages: improving patients' knowledge regarding options; reducing patients' decisional conflict; stimulating patients to take a more active role in decision-making; improving accuracy of risk perceptions; improving congruence between the chosen option and the patient's values; achieving more informed, value-based, choices, and improved clinician-patient communication

(Stacey *et al.*, 2014). There are, however, several obstacles limiting the use of the shared decision-making strategies in clinical practice related to both: variability in patients' preferences for participating and taking responsibility in decision-making (Levinson *et al.*, 2005; Say *et al.*, 2006) and the multitude challenges for clinicians to implement these strategies (Say and Thomson, 2003). In a systematic review on the barriers and facilitators to implementing shared decision-making in clinical practice, the most common barriers perceived by healthcare professionals were time constraints and lack of applicability due to patient characteristics or clinical situation. The most common perceived facilitators were: provider motivation and positive impact on the clinical process and patient outcomes (Legare *et al.*, 2008).

In summary, the process of decision-making by clinicians is a highly dynamic, complicated multifaceted process involving different strategies. In the reality of clinical decision-making of everyday practice, a hybrid approach of several strategies based on mixtures of intuitive and analytical cognitive processes can be implemented by the clinician during the decision-making process according to clinical situation. In general, however, experienced clinicians tend to use more intuitive experiential knowledge-based decision-making whilst inexperienced clinicians use more analytical knowledge-based decision-making. At the moment, both prescriptive and descriptive approaches may be used in decision-making, but both have shortcomings. The prescriptive decision-making is more objective and impractical, whilst the descriptive decision-making is more subjective, prone to bias, and depends largely on clinicians' levels of knowledge and experience and can be affected by numerous influences.

2.3.3 Influences on clinicians' decisions

In clinical practice, the clinician cannot analyse a clinical condition solely in terms of risks and likelihoods to make a decision. This is because there are usually too many variables or unknowns in the clinical setting that may influence the clinician, consciously or subconsciously, during the decision-making process (Croskerry and Sinclair, 2001; Croskerry, 2005a). Potential influences on clinicians' decision-making include both clinical (related to medical condition) and non-clinical (not directly related to medical condition) factors. While it is not always possible to categorise the influential factors into either 'clinical' or 'non-clinical' due to overlap (e.g., patient's age, clinician's specialty), the non-clinical influences are grouped in the literature into three general categories related to characteristics of patient, clinician, and practice

(McKinlay *et al.*, 1996; Hajjaj *et al.*, 2010). The three inter-relating factors are depicted in Figure 2.18, in which, the clinician as the decision-maker is the central player in the clinical decision-making process but the decision-maker is not isolated from the patient and environmental factors (Kay and Nuttall, 1995a).

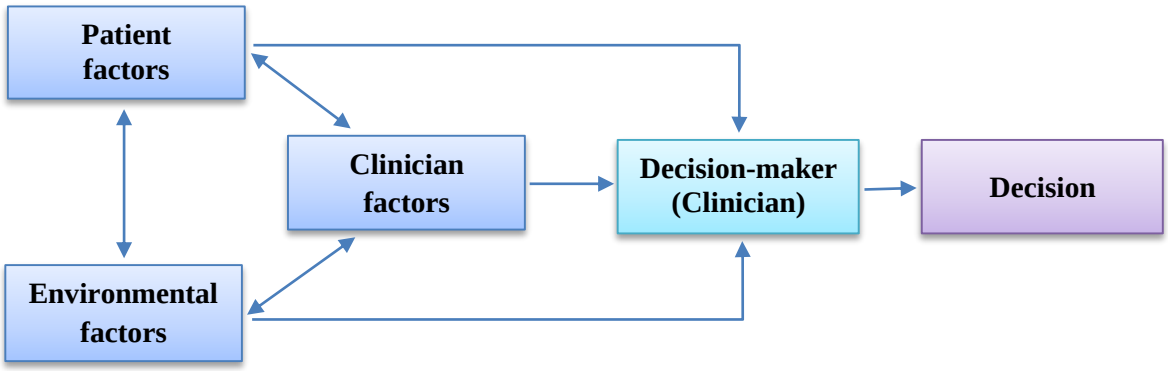


Figure 2.18: Influences on clinical decision-making process. Modified from Kay and Nuttall (1995a) with permission from Nature Publishing Group.

Patient characteristics

Different patient characteristics have been identified to consistently influence the clinical decisions including: patients' age, gender, race, health insurance, education, and socioeconomic level (Perkoff and Anderson, 1970; Verbrugge and Steiner, 1985; Hohmann, 1989). In addition to these, each individual patient has unique characteristics that differ from others. Studies have shown that all the following factors can influence the clinicians' decisions: the patient-clinician relationship, patient attendance pattern, patient's level of involvement, patient's level of trust in clinician, patient personality, and patient preferences, values, wishes, attitudes, and expectations (Kay and Nuttall, 1995b; Luker *et al.*, 1998; Levinson *et al.*, 2005). Therefore, the patient characteristics should always be taken in consideration in decision-making process.

Clinician characteristics

Various characteristics of clinicians can influence their decisions. The clinicians' experience has been shown to be the most important influential factor on clinicians' decision-making process in several studies (Stolley *et al.*, 1972; Hadsall *et al.*, 1982; Croskerry, 2005a). In fact, many studies have shown that the clinicians' experiences are intrinsic to decision-making because the clinicians often use their past experiences in the decision-making process "by comparing the current situation to previously

experienced situations held in their memory" (Cioffi, 2001) and, therefore, they often perform better over time (Benner, 1982; Dawson *et al.*, 1988).

In addition to experience, the clinician's knowledge also plays an important and integral part in decision-making process. Specifically, the clinician's speciality, level of qualification and education, and level of training influence their decisions (McCaul *et al.*, 2001). Furthermore, clinicians' interactions with their professional community and their accumulated knowledge about their patients also influence the clinical decision-making process (Hemminki, 1975; Hjortdahl, 1992).

Ideally, the clinicians' personal characteristics such as age, gender, race or ethnicity, and character or personality should not typically influence decision-making process with respect to diagnosis and treatment of a medical condition (McKinlay *et al.*, 1996). In reality, however, as the clinicians are human, these personal characteristics do influence their decision-making process (Sexton *et al.*, 2000; Cyran *et al.*, 2001; Tracy *et al.*, 2005; Risberg *et al.*, 2008).

Furthermore, different forms of diagnostic and treatment biases have been described in the literature to influence clinicians' decisions (Tversky and Kahneman, 1974; Dawson, 1993; Croskerry, 2000; Croskerry, 2003a; Croskerry, 2005b). These come in multiple forms and are in a steady increase. A total in excess of 100 cognitive biases have been identified and reported in the literature and there are probably more (Croskerry *et al.*, 2010; Croskerry and Nimmo, 2011). Table 2.13 represents the summary of common biases discussed by authors in this area (Bornstein and Emler, 2001; Croskerry, 2002; Croskerry, 2005a).

Types of biases affecting decision-making process*		
Aggregate bias	Gambler's fallacy	Psych-out error
Anchoring bias	Gender bias	Regret/outcome bias
Anticipated regret	Hindsight bias	Zebra retreat
Ascertainment bias	Posterior probability error	Search satisfying
Availability	Premature closure	Sutton's slip
Base-rate neglect	Omission bias	Triage-cueing
Commission bias	Order effects	Unpacking principle
Confirmation bias	Outcome bias	Vertical line failure
Diagnosis momentum	Overconfidence bias	Visceral bias
Ego bias	Playing the odds	Ying-Yang out
Framing	Ignoring negative evidence	Representativeness restraint
Fundamental attribution error	Number of alternatives bias	Cognitive/affective biases and other biases

* For further details, please see Croskerry (2002).

Table 2.13: Different types of biases affecting decision-making process. Adapted from (Bornstein and Emler, 2001; Croskerry, 2002; Croskerry, 2005a).

Practice characteristics

The environment of clinical practice in which care is provided can also have an influence on a clinician's decision. Different characteristics of clinical practice can be involved in clinical decision-making process including: practice setting features such as geographical location, the organization of the practice, and type of practice (e.g., private versus public); environmental circumstances such as work load or pressure, time constraints, and resources availability; financial issues such as type of clinicians' compensation (entrepreneurial or salaried), insurance schemes for management and reimbursement, clinicians' financial investment, and management policies and therapy cost (Mechanic, 1975; Luker and Kenrick, 1992). The latter financial factor can play a major role in changing clinicians' practice (Chaix-Couturier *et al.*, 2000; Brocklehurst *et al.*, 2013) especially for TMD management (Katsoulis *et al.*, 2012). In the UK NHS system, the splint therapy cost and the current lack of financial incentives for the clinicians to compensate for the relatively long time required to manage TMD is a major barrier for primary TMD care (Durham *et al.*, 2007). The ongoing process for changing the current dental contracts in addition to 'smart' healthcare commissioning may expectedly help change, and probably improve, healthcare delivery if implemented in the future (NHS Commissioning Board, 2013; DOH, 2015).

In summary, numerous non-clinical factors can influence the clinician decision-making process. These are summarised in Table 2.14.

Examples of non-clinical influences on clinical decision-making process
Patient-related factors - Patient's demographic features such as age, gender, race or ethnicity, and socioeconomic status - Patient's health insurance - Patient's education - Patient's personal characteristics such as patient personality, attitudes, and behaviour - Patient's preferences, values, wishes, expectations - Patient's concerns and worries (medical and non-medical concerns) - Patient-clinician relationship, patient's level of involvement, and patient's level of trust in clinician - Patient's attendance pattern and adherence to treatment - Others influences of patient's family members and friends, faith, culture, and quality of life
Clinician-related factors - Clinician's personal characteristics such as age, gender, culture, faith, and race or ethnicity - Clinician's knowledge and experience - Clinician's accumulated knowledge about their patients - Clinician's interaction with professional community such as relationship with colleagues, hospital staff and with pharmaceutical industry
Practice-related factors - Practice setting features such as practice organization, geographical location, size, and type (e.g. private vs. public 'NHS' practice) - Environmental circumstances such as work load or pressure in the clinic, time factor, and availability of health resources - Financial issues such as type of clinicians' compensation (entrepreneurial or salaried), insurance schemes for management and reimbursement, clinicians financial investment, and management policies/ implication of treatment cost

Table 2.14: Non-clinical influences on clinical decision-making process. Adapted from reviewing the relevant literature, mainly (Kay and Nuttall, 1995c; McKinlay *et al.*, 1996; Hajjaj *et al.*, 2010).

2.3.4 Improving clinicians' decisions

In clinical decision-making, there are some factors that can be enhanced to improve clinicians' decisions thereby improving patients' care. While some perceived factors can improve clinician decision-making over time (e.g., clinician's experience), other factors can be used to enhance clinician decision-making (e.g., reducing uncertainty and bias).

Experience in clinician decision-making is very important (Cioffi, 2001). This, however, is not a thing that can be learned 'theoretically' but rather gained 'practically' over time. Despite the fact that there is no substitute for clinical experience, simulation practical courses (e.g., simulated patients and then receiving feedback) may help the

clinicians to imagine and hold the 'non-experienced' events in their memory to be used during the clinical decision-making process (Bornstein and Emler, 2001; Croskerry, 2005a). Apart from the clinician's experience, other influential methods can also be used to improve clinical decisions, most commonly, reducing uncertainty and bias.

Reducing bias

In clinical practice, several biases can affect clinicians' decisions (Table 2.13). To minimise the effect of these biases, a variety of cognitive 'de-biasing' strategies have been suggested in the literature (Bornstein and Emler, 2001; Croskerry, 2003a; Croskerry, 2003b; Croskerry and Nimmo, 2011). Each strategy is specified to avoid a particular bias but all strategies, in general, are based simply on the assumption that educating the clinicians about these biases and making them aware of their existence will permit them to monitor their decision-making (metacognition) and to avoid these biases in their clinical decisions, thereby improving the decision-making process (Gruppen *et al.*, 1994; Bornstein and Emler, 2001). Recently, checklists have been proposed for use in clinical practice to help reduce clinicians' diagnostic errors (Ely *et al.*, 2011). These checklists can be useful in reducing clinicians' biases in decision-making process as they can provide an alternative to overreliance on intuition and memory in situations of high uncertainty and/or limited time (Ely *et al.*, 2011).

Reducing uncertainty

Uncertainty is inevitable in clinicians' decision-making process and can never be entirely eliminated (Logan and Scott, 1996; Hall, 2002) but it is to some extent discipline-specific and there are different levels of uncertainty in each medical speciality and each clinical setting (Croskerry, 2005a). Reducing uncertainty can be difficult to achieve in clinical practice but different methods have been suggested to reduce it (Logan and Scott, 1996). One of the main methods used in the last few decades to decrease uncertainty is the application of "evidence-base" concept (Sackett *et al.*, 1996).

Evidence-base concept

In clinical practice, treatment plans are traditionally based on a mixture of clinician knowledge gained through education, training, practice traditions, and subjective perception of past clinical experiences and the opinions of 'authorities' which can

include charismatic champions of particular forms of management (Forssell and Kalso, 2004; Tegelberg *et al.*, 2007). Clearly, this traditional clinical practice may result in variable treatments of the same condition, some of which rely on subjective experience (experiential-based knowledge) rather than on scientific rationale (research-based knowledge) (Niederman and Badovinac, 1999) which means that ineffective, expensive, or more importantly even harmful treatments can be sometimes implemented.

To move from tradition-based care to evidence-based care, Sackett and colleagues in the mid-1990s introduced the concept of Evidence-Based Medicine (EBM): "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients" (Sackett *et al.*, 1996). Apparently, the main goal of EBM is to support the use of the most accurate, safe, and effective intervention for patients in order to optimise patients' healthcare (Haynes and Haines, 1998).

Evidence-based medicine, or 'dentistry' (EBD) in our case, focuses mainly on determining the best research evidence relevant to a clinical problem and applying that evidence to resolve this problem (Haynes *et al.*, 2002a). However, the clinician's ability to make a sound clinical decision depends largely on the quality of evidence and his/her ability to evaluate this evidence (Gordon and Dionne, 2005). The levels of evidence for the effectiveness of therapeutic interventions are graded on the basis of study design with the highest levels of evidence coming from systematic reviews (SRs) and meta-analyses based on high-quality randomised controlled trials (RCTs) as illustrated in Table 2.15 (Levels of Evidence, 2009).

Level	Type of evidence
1a	SR (with homogeneity) of RCTs
1b	Individual RCT (with narrow Confidence Intervals)
1c	All or none study
2a	SR (with homogeneity) of cohort studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)
2c	"Outcomes" Research; Ecological studies
3a	SR (with homogeneity) of case-control studies
3b	Individual Case-Control Study
4	Case-series (and poor quality cohort and case-control studies)
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

Table 2.15: Levels of evidence about the effectiveness of a therapeutic intervention or treatment. Adapted from Levels of Evidence (2009).

The outcomes of systematic reviews and meta-analyses in evidence-based medicine or dentistry (e.g., Cochrane Collaboration) are evidence-based recommendations and guidelines (e.g., UK National Institute of Clinical Excellence 'NICE') to be applied in clinical practice (evidence-based practice 'EBP'). For example, the change in the management of patients with impacted third molars within the UK NHS following NICE guidelines publication (McArdle and Renton, 2012). Clinical decision-making, however, cannot rely on evidence alone (Straus, 2002) because "evidence does not make decisions, people do" (Haynes *et al.*, 2002b). Furthermore, dependence on research evidence solely by ignoring the traditional influences on clinical decisions (Section 2.3.3) may not depict the real clinical practice. Evidence-based decision-making models, therefore, have emphasised that research evidence alone is not an adequate guide to make decisions.

Evidence-based clinical decisions

An evidence-based decision-making model has been proposed by Haynes and Haines (1998) to demonstrate a path from the generation of evidence to the application of evidence (Figure 2.19). This path begins with biomedical research to generate the evidence (the wedge shape), followed by three subsequent steps that are needed to implement research evidence to clinical practice (the boxes) including synthesising the evidence, developing clinical guidelines from research evidence, and applying the guidelines at the right place, time, and way. This is followed by making decisions by the clinicians via integrating the research evidence with the patient's clinical circumstances and wishes to provide the 'evidence-based' clinical decisions (Haynes and Haines, 1998).

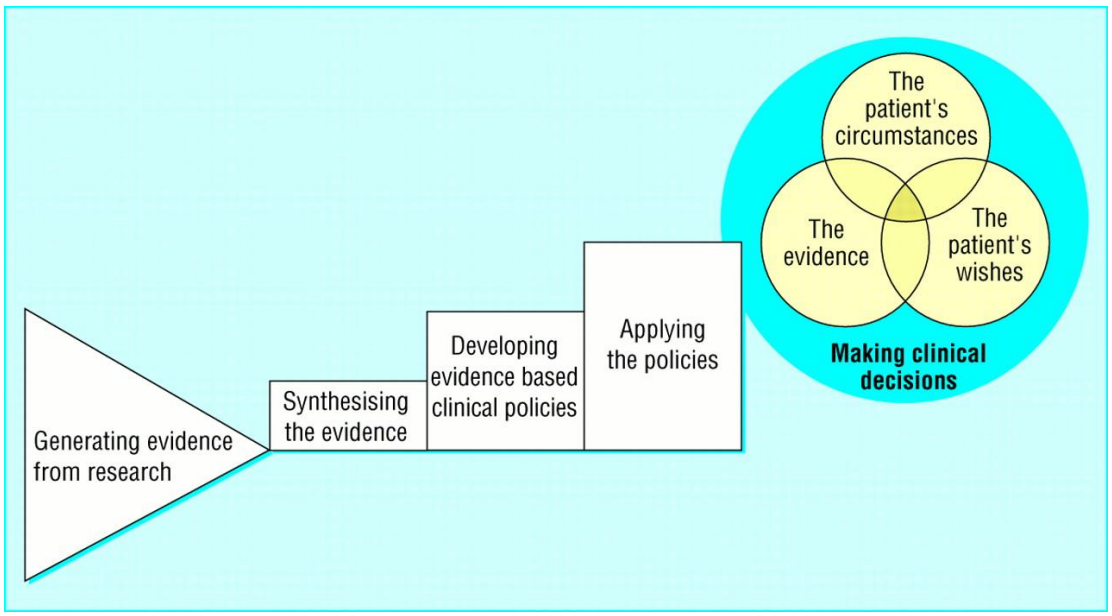


Figure 2.19: The path from the generation of evidence to the application of evidence. Reproduced from Haynes and Haines (1998) with permission from BMJ Publishing Group Ltd.

The updated evidence-based clinical decision-making model described by Haynes *et al.* (2002a) demonstrates the integration of three needed key elements (Figure 2.20): evidence, preferences, and circumstances, but takes into consideration the central role of clinician's expertise as the experience and skill that encompass and balance clinical state and circumstances, patients' preferences and actions, with the best research evidence to make evidence-based decisions. This approach can help reduce clinicians' biases because it allows the clinicians to rely more on research evidence rather than relying 'solely' on their intuition and experience to make decisions (Bornstein and Emler, 2001).

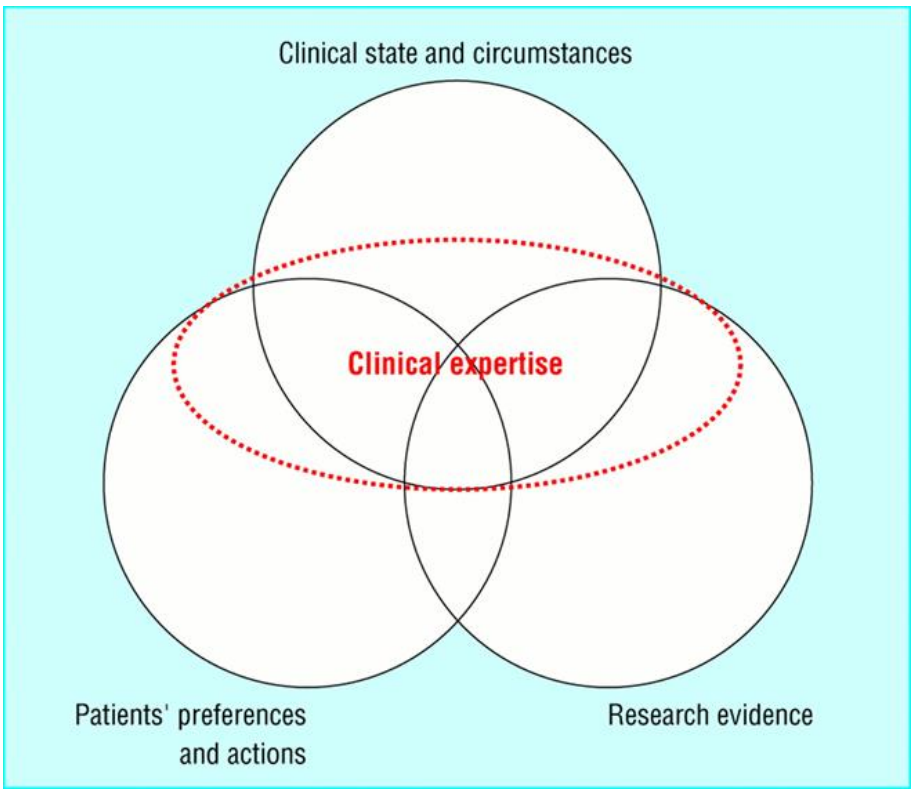


Figure 2.20: Evidence-based clinical decision model. Reproduced from Haynes *et al.* (2002b) with permission from BMJ Publishing Group Ltd.

This model, for an individual decision, can accommodate different weights for each key element of the decision and can be depicted visually by varying the sizes of the circles. In other words, for making evidence-based clinical decisions, the clinicians must apply their expertise (i.e., the clinicians' basic clinical skills as well as their past experience) to assess the patient's clinical state and personalise the best available evidence (preferably from patient-centred clinical research) to fit a specific patient's circumstances and must also incorporate the research evidence with the individual patient's preferences, values, concerns, expectations, or likely actions before making a decision (Haynes *et al.*, 2002a). This model has, therefore, a greater emphasis on shared decision-making because it incorporates the patients' preferences and values. The evidence-based model, however, is rather 'conceptual than practical' and it is prescriptive rather than descriptive because it can only be used as a guidance of how evidence-based decisions should be made rather than how the decisions are actually made (Haynes *et al.*, 2002a). In real life practice, implementation of research evidence has been found to be more complex than is suggested by the rational process of evidence-based model (Lipman *et al.*, 2004).

In fact, the incorporation of evidence-based research findings and guidelines into clinical decision-making is not a simple straightforward process as demonstrated in evidence-based decision-making models because it depends on several aspects. Firstly, it depends largely on the availability and quality of clinical evidence itself (Turp *et al.*, 2004), as pointed out by Gordon and Dionne (2005) that "therapeutic decision-making process is highly dependent on the quality of evidence that is considered in making a judgment and application of that evidence to patient care". Secondly, it requires the clinician to develop specific skills before being able to practice EBM/D efficiently and effectively and make evidence-based decisions in clinical practice. These are in brief: asking a clinically answerable question; searching the best available evidence to answer the question; critically appraising the evidence quality; integrating the evidence with clinical expertise and individual patient's needs and values; evaluating performance (Sackett, 1997; Straus and Sackett, 1998). Thirdly, non-clinical influences on clinical decision-making (Table 2.14) can be a major challenge to practice EBM/D in 'real' clinical practice (Hajjaj *et al.*, 2010). Finally, it requires frequent reviewing to each sequential step in the development, dissemination, implementation, and evaluation of guidelines to be effective (Thomson *et al.*, 1995) and there can be several different factors impeding the successful implementation of research evidence into clinical practice 'evidence-based practice' (EBP). Implementation of research evidence in clinical practice, therefore, is not simple and may not succeed despite the availability of high-quality evidence. This will be discussed further in the next section (Section 2.4).

2.3.5 Conclusion

The clinical decision-making is an adaptive process with various factors influencing the clinician decision at various levels during the decision-making process. In clinical practice, neither prescriptive nor descriptive approaches are optimal to make a decision and "one approach does not fit all" (Croskerry, 2005a). Rather than being one or the other, the processes of decision-making may require both approaches at different stages of decision-making processes. Currently, the cognitive processes of decision-making are not yet well understood and there is always a risk of oversimplification of the clinical decision-making process. At the moment, clinicians' decisions are generally related, to some extent, to their practical experience as well as to the degree of uncertainty and evidence quality. Evidence-based practice can improve clinicians' decision-making

performance but there are numerous influences on decision-making process. The next section will discuss the implementation research of evidence in practice.

2.4 Implementation of behaviour change interventions

2.4.1 Introduction

Implementation research is defined as the scientific study of methods that promote the uptake of research evidence in clinical practice to reduce inappropriate care (Eccles *et al.*, 2007). Several reports showed that the clinicians accept the concept of 'evidence base' and agree to practice it to improve patients' care (McColl *et al.*, 1998). In clinical practice, however, many clinicians base their management of TMD patients on subjective experiential-based practice rather than on evidence-based knowledge (Durham *et al.*, 2007).

Implementation of evidence-based research findings into clinical practice is not a simple straightforward process and may occasionally fail and, therefore, may not always result in optimum healthcare outcomes (Haines and Donald, 1998). This 'implementation failure' is not always related to the content or quality of research evidence or guidelines but rather attributed to two main issues hindering implementation's success. First, a failure to identify barriers and facilitators of evidence base implementation (Baker *et al.*, 2010). Second, a lack of theoretical basis for behavioural interventions involved in changing the behaviour of healthcare professionals to support evidence base implementation (Davis and Taylor-Vaisey, 1997; Grimshaw and Eccles, 2004; Bonetti *et al.*, 2005). This section will discuss these implementation challenges and the development of complex behavioural interventions to facilitate implementation.

2.4.2 Barriers and facilitators of evidence base implementation

Implementing research evidence in clinical practice is a highly complex process that can be hindered by lots of barriers (Garner *et al.*, 1998; Haines and Donald, 1998). It is necessary to identify these barriers in order to develop strategies to overcome them (Spallek *et al.*, 2010).

The potential barriers for dissemination and implementation of evidence-based guidelines in various disciplines in medicine and dentistry have been identified in several studies using different quantitative and qualitative research methods (Davis and Taylor-Vaisey, 1997; Haines and Donald, 1998; Tracy *et al.*, 2003; Kao, 2006; Hannes *et al.*, 2008; Spallek *et al.*, 2010; Stone *et al.*, 2014). The identified barriers are many and can arise at different elements of healthcare including: healthcare provider, patient,

practice, guidelines themselves, healthcare organisation, or wider environment. Most of these barriers, however, influence directly or indirectly the healthcare professionals' attitude and behaviour and prevent professionals to change their decision-making behaviour. According to Cabana *et al.* (1999), most of the barriers to clinicians' adherence to practice guidelines are related to professionals' attitude and behaviour as demonstrated in Figure 2.21. This accentuates the necessity to develop implementation strategies for professionals' behaviour change. Designing and applying behaviour change interventions, however, is a complex process that requires several steps (French *et al.*, 2012; Porcheret *et al.*, 2014) including:

- Identifying the targeted clinical behaviour that needs changing.
- Understanding the influences on the targeted behaviour.
- Selecting the relevant techniques to change the behaviour.
- Defining the intervention contents and active components.
- Choosing the style or mode of intervention delivery that is likely to be effective.
- Addressing the practical issues for implementation intervention delivery.

All these steps are discussed below.

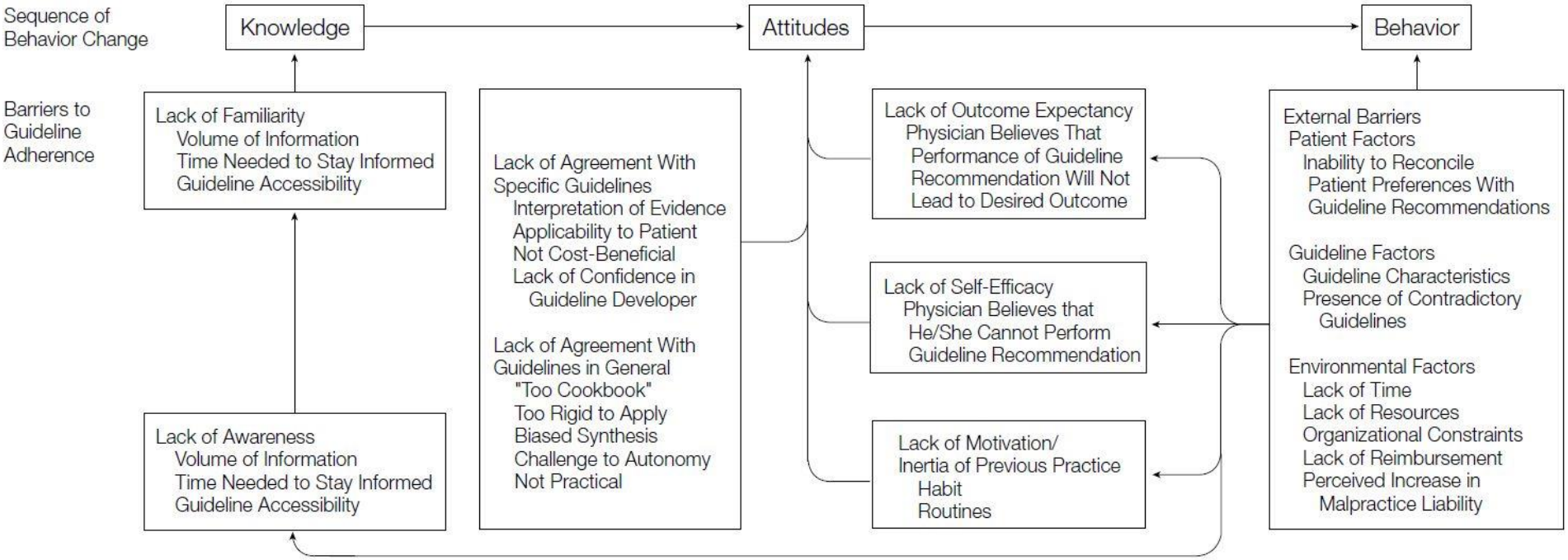


Figure 2.21: Barriers to clinicians' implementation of practice guidelines in relation to behaviour change. Reproduced from Cabana *et al.* (1999) with permission from American Medical Association.

2.4.3 Clinical behaviour

Before discussing how to intervene to change behaviour it is necessary to understand what 'behaviour' means? Behaviour has been defined as "anything a person does in response to internal or external events. Actions may be overt (motor or verbal) and directly measurable, or covert (e.g., physiological responses) and only indirectly measurable; behaviours are physical events that occur in the body and are controlled by the brain" (Davis *et al.*, 2014). Behaviour can consist of a simple, specific action or more complex sequences of actions (Michie and Johnston, 2012).

To understand 'behaviour' further and to provide a basis for designing effective behaviour change interventions, a model of behaviour has been proposed by Michie *et al.* (2011b). The proposed behaviour system or 'COM-B system' involves three interacting components:

1. Capability: "the individual's psychological and physical capacity to engage in the activity concerned".
2. Opportunity: "all the factors that lie outside the individual that make the behaviour possible or prompt it".
3. Motivation: "all those brain processes that energise and direct behaviour, not just goals and conscious decision-making".

The three components can interact to generate behaviour that in turn can influence these components as depicted in Figure 2.22 (Michie *et al.*, 2011b).

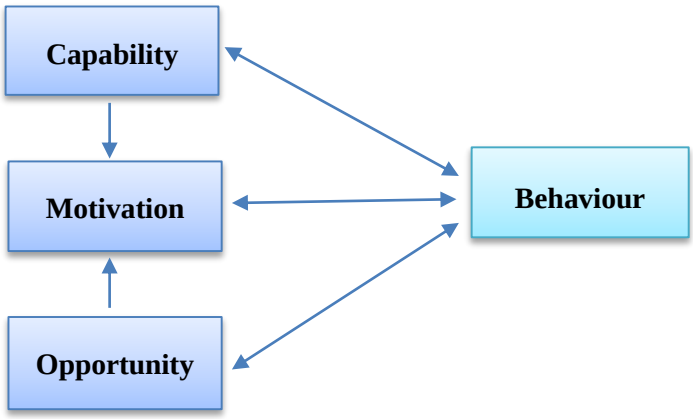


Figure 2.22: The COM-B system: A framework for understanding behaviour. Modified from Michie *et al.* (2011b) with permission from BioMed Central Publisher.

Implementation research involves studying what influences healthcare professionals' behaviour in order to enable them to use the research evidence in clinical practice (Eccles *et al.*, 2007). In fact, attempting to change professionals' behaviour is one of the important methods to improve the implementation of research evidence. Professionals' behaviour, however, as has been shown, is likely to be influenced by a variety of clinical and non-clinical factors. Understanding the behaviours of healthcare professionals, and understanding the various factors underpinning the clinical behaviour to be targeted in changing clinical practice, plus understanding the theoretical basis that informs about the mechanisms for changing or modifying their clinical behaviour are all crucial steps for designing an effective implementation intervention to improve clinical practice towards 'evidence-based practice' (Grol, 2001; Eccles *et al.*, 2007; Mazza *et al.*, 2013). Changing clinical behaviour, however, is not easy and there is no "magic bullet" to change and improve the professionals' clinical practice (Oxman *et al.*, 1995). Nevertheless, designing behavioural change interventions that target behavioural determinants and is based on theoretical principles of behaviour change is more likely to be effective for improving healthcare (Michie *et al.*, 2008).

2.4.4 Behaviour change interventions

Behaviour change interventions have been defined as "coordinated sets of activities designed to change specified behaviour patterns" (Michie *et al.*, 2011b). Interventions for changing behaviour can be delivered at different levels: population, community, organisation, and individual levels (Michie, 2008). Interventions used to change professionals' behaviour are typically complex and involve several interacting components (Craig *et al.*, 2008b), some of which are active functioning components (Michie *et al.*, 2013). Craig *et al.* (2008b) identified the characteristics which make an intervention complex. These are: the number of interacting components involved within the intervention; the number and level of difficulty of behaviours required by those delivering or receiving the intervention; the number of groups or organisational levels targeted by the intervention; the number and variability of outcomes; the degree of flexibility or tailoring of the intervention permitted. The components of behaviour change intervention have been described by Davidson *et al.* (2003) and are summarised in Table 2.16.

Intervention component	Intervention question addressed
Content/elements	What was the content or elements of the intervention? How was it delivered (i.e., mode of delivery such as oral communication, written material, videos, interactive computer programs, others)?
Provider	Who delivered it? (i.e., characteristics of intervention deliverers)
Format	What were the method(s) of intervention administration (e.g., self-help, individual, group, telephone, other)?
Setting	Where and when was the intervention delivered? (i.e., characteristics of intervention setting)
Recipient	To whom was the intervention delivered? Was the recipient also the target of the intervention? (i.e., characteristics of intervention recipients)
Intensity	How many different clinician contacts and how much total contact time was involved? (e.g., contact time)
Duration	Over what time period were intervention contacts conducted and how were they spaced? (e.g., number of sessions over a given period)
Fidelity	Was the intervention delivered as intended? How was this monitored and measured?

Table 2.16: Minimal intervention detail to be described in research records. Adapted from Whitlock *et al.* (2002) and Davidson *et al.* (2003).

Recently, the template for intervention description and replication (TIDieR) for behaviour change has been developed to involve all the information needed in order to be used as a checklist guide for better reporting and describing of behaviour change interventions (Table 2.17) (Hoffmann *et al.*, 2014).

Item	Description
Brief name	Provide the name or a phrase that describes the intervention
Why	Describe any rationale, theory, or goal of the elements essential to the intervention
What	*Materials:* Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL) *Procedures:* Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities
Who provided	For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given
How	Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group
Where	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features
When and How Much	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose
Tailoring	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how
Modifications*	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)
How well	*Planned:* If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them *Actual**:* If intervention adherence/fidelity was assessed, describe the extent to which the intervention was delivered as planned

*If checklist is completed for a protocol, these items are not relevant to protocol and cannot be described until study is complete.

Table 2.17: Items included in the Template for Intervention Description and Replication (TIDieR) checklist. Information to include when describing an intervention adapted from Hoffmann *et al.* (2014).

As shown in Table 2.16 and Table 2.17, there are different components of behavioural intervention. Currently, however, a simplified consensus framework of interventions have been suggested by Colquhoun *et al.* (2014). The framework involves four key components as follows:

- Active ingredients (strategies and techniques),
- Causal mechanisms (how they function),
- Mode of delivery (how they are delivered/applied),

- Intended targets (what they aim to change).

The ‘active ingredients’ of the intervention are the key components that target the determinants of behaviour and have the capacity to change the targeted behaviour (Davidson *et al.*, 2003; Colquhoun *et al.*, 2014). Therefore, interventions aiming to change healthcare professionals’ behaviour should contain ‘active ingredients’ or components that effectively overcome the specific barriers encountered in relation to a specified ‘targeted’ behaviour (Craig *et al.*, 2008b; Michie *et al.*, 2013). Identifying the 'active ingredients' responsible for behaviour change in behavioural interventions, therefore, is a mandatory crucial step for designing, applying, evaluating, and reporting behaviour change interventions.

2.4.5 Designing and applying behaviour change interventions

Implementation interventions are designed to change professionals’ behaviour and improve their uptake of evidence into practice (French *et al.*, 2012). The UK Medical Research Council (MRC) established guidance for developing (Campbell *et al.*, 2007; Craig *et al.*, 2008a; Craig *et al.*, 2008b) and evaluating (Moore *et al.*, 2015) complex interventions.

The MRC guidance is a useful generic approach to design an implementation intervention informed by theory. It illustrates a systematic process for developing a complex intervention through to its implementation in terms of four inter-related phases: development, feasibility and piloting, evaluation, and implementation (Figure 2.23) (Craig *et al.*, 2008b). In practice, however, the phases may not follow in a linear or even cyclical sequence.

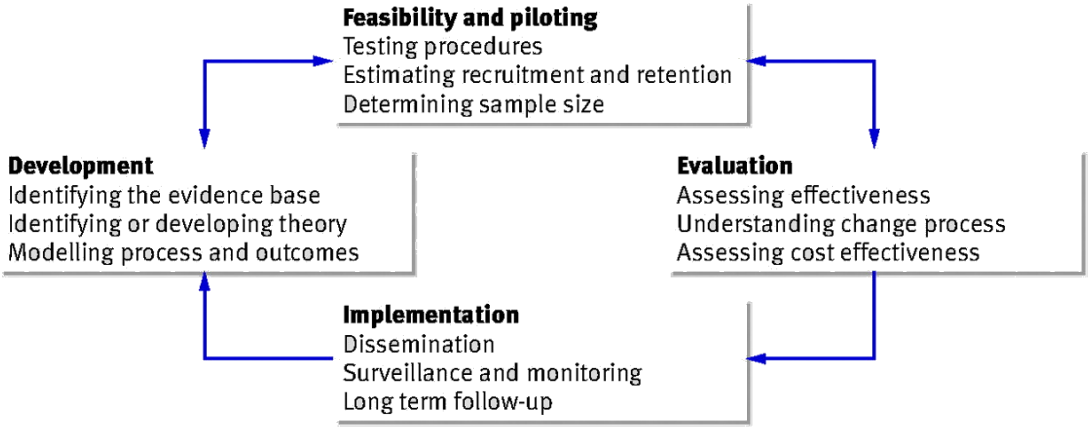


Figure 2.23: Key elements of the development and evaluation process of complex intervention. Reproduced from Craig *et al.* (2008b) with permission from BMJ Publishing Group Ltd.

The MRC guidance suggests the use of theoretical bases to identify influences on clinical behaviour as this will increase the possibility of selecting the appropriate active ingredients of intervention for a 'targeted' behaviour, thereby increasing its chances of success. The MRC framework, however, has been critiqued for not providing thorough guidance on how to use theory to progress through the early phases of the process for complex interventions development (Michie, 2008). Hardeman *et al.* (2005) proposed a framework to make the early phases of complex interventions development process more explicit. The framework involves three essential steps (Figure 2.24): Step 1, identifying the determinants of behaviour; Step 2, identifying the techniques of behaviour change; Step 3, identifying the links between the techniques of behaviour change and the determinants of behaviour (i.e. to identify which technique(s) need to be used as part of an intervention to change each 'behavioural determinant'). The proposed framework indicates that the behaviour change can be achieved by targeting the behavioural determinants which can be identified from the theories of behaviour and behaviour change.

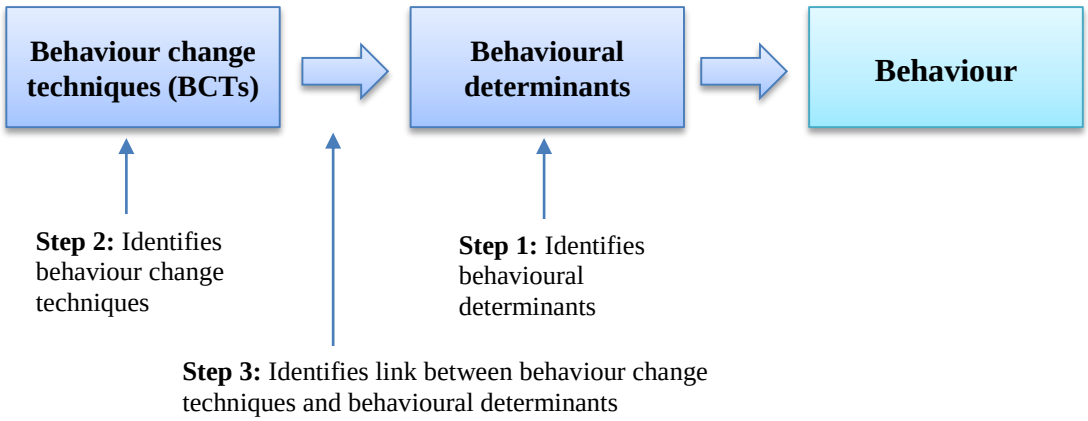


Figure 2.24: Proposed framework for causal modelling approaches. Each arrow represents a step required for the development process of intervention targeting/changing a specific behaviour. Modified from Hardeman *et al.* (2005) and Michie *et al.* (2008) with permissions from both Oxford University Press and John Wiley and Sons.

Recently, French *et al.* (2012) issued a detailed guidance on how to progress through the early phases of intervention development by using a four-step systematic approach consisting of four guiding questions and three illustrative required tasks for each question to direct the selection of the most appropriate components for an implementation intervention. The four steps for developing a theoretically-based intervention designed to change clinical practice (clinician's behaviour) are: Step 1, identifying the problem; Step 2, assessing the problem; Step 3, forming possible solutions; Step 4, evaluating the selected intervention (French *et al.*, 2012). The steps for behaviour change intervention development and their relevance to the current project are summarised in Table 2.18.

Steps	Tasks	Relevance to current project
Step 1: Who needs to do what, differently?	• Identify the evidence-practice gap	Identification of target clinical behaviours for DDwoR management. (Chapters 4 and 5 determined the research evidence for DDwoR management).
	• Specify the behaviour change needed to reduce the evidence-practice gap	Management and/or referral of DDwoR.
	• Specify the health professional group whose behaviour needs changing	Clinicians at the frontline of healthcare service.
Step 2: Using a theoretical framework, which barriers and enablers need to be addressed?	• From the literature, and experience of the development team, select which theory(ies), or theoretical framework(s), are likely to inform the pathways of change	Given the nature of the data as well as the exploratory aims of this study, the theoretical domains framework of behaviour change (TDF) was utilised to inform data collection and analysis.
	• Use the chosen theory(ies), or framework, to identify the pathway(s) of change and the possible barriers and enablers to that pathway	Theories of behaviour change informing the TDF.
	• Use qualitative and/or quantitative methods to identify barriers and enablers to behaviour change	Qualitative TDF-informed method identified domains acting as barriers and others as facilitators for DDwoR management (Chapter 6). The core domains identified to influence clinicians' decisions when initially presented with a patient having acute DDwoR at the frontline were condition-specific knowledge and skills. These had various inter-related effects on all other domains.

Steps	Tasks	Relevance to current project
Step 3: Which intervention components (behaviour change techniques and mode(s) of delivery) could overcome the modifiable barriers and enhance the enablers?	• Use the chosen theory, or framework, to identify potential behaviour change techniques to overcome the barriers and enhance the enablers	As suggested for mapping the behavioural determinants to behavioural change techniques (BCTs) (Michie *et al.*, 2008; Backman *et al.*, 2015), the identified barriers and enablers to behaviour change of DDwoR care, as informed by the qualitative TDF study, can be matched to the BCTs described in the BCT-V1 taxonomy (Michie *et al.*, 2013). Examples of the BCTs that may be involved to address the barriers of DDwoR care in a proposed future intervention are as follows: Shaping knowledge (BCT4.1. Instruction on how to perform the behaviour); Comparison of the behaviour (BCT6.1. Demonstration of the behaviour); Repetition and substitution (BCT8.1. Behavioural practice/rehearsal); Natural consequences (BCT5.6. Information about consequences); Social support (BCT3.2. Social support 'unspecified'); Comparison of outcomes (BCT9.1. Credible source); Reward and threat (BCT10.6. Non-specific incentives); Regulation (BCT11.2. Regulate negative emotions); Self-belief (BCT15.1. Verbal persuasion about capability); Covert learning (BCT16.2. Imaginary reward).
	• Identify evidence to inform the selection of potential behaviour change techniques and modes of delivery	The above BCTs could be the active ingredients that could change the determinants of the behaviour identified as more relevant in the qualitative study. The preferred mode of intervention delivery, as identified in the qualitative study, is both: face-to-face and electronic via eHealth platform.
	• Identify what is likely to be feasible, locally relevant, and acceptable and combine identified components into an acceptable intervention that can be delivered	Not accomplished task yet (future work)
Step 4: How can behaviour change be measured and understood?	• Identify mediators of change to investigate the proposed pathways of change	Future work
	• Select appropriate outcome measures	Future work
	• Determine feasibility of outcomes to be measured	Future work

Table 2.18: Steps for developing a theory-informed implementation intervention and their relevance for the current research. Modified from French *et al.* (2012).

The authors, however, argued that this stepped approach should be used as a 'conceptual aid' rather than a 'rigid prescription' to guide a comprehensive intervention development process and it can be iteratively adjusted and refined according to contexts and settings (French *et al.*, 2012). The authors also discussed the main strengths and potential limitations of this method. Its main strength relies in that it can guide the development of implementation intervention through a systematic 'direct streamlined' approach moving directly from targeting the behaviour to be changed, to identifying theoretical domains influencing the behaviour, to determining relevant behaviour change techniques, to finally implementing and evaluating a 'complete' intervention to change the 'targeted' behaviour. Its potential limitations, however, are related to the subjectivity in process of designing implementation interventions, the directness at the individual rather than organisational level, and the requirement for considerable time and resources (French *et al.*, 2012).

Overall, designing and applying implementation interventions informed by behaviour change theories and models is more likely to be effective than atheoretically-based interventions (Noar and Zimmerman, 2005; Abraham *et al.*, 2009). Therefore, the use of behavioural theories is strongly advocated in implementation research (Eccles et al., 2006).

2.4.6 Psychological theories and models of behaviour change

Theory has been defined as "a system of ideas or statements held as an explanation or account of a group of facts or phenomena" (Michie *et al.*, 2005). Theories of behaviour change provide scientific explanations of the processes of behaviour change and illustrate how, when, and why change occurs. They, therefore, allow researchers to understand how and why interventions succeed or fail and form a basis for designing future behaviour change interventions (Michie and Johnston, 2012).

Previous attempts to understand, predict, and modify the clinicians' behaviour have been either atheoretical (Bero *et al.*, 1998; Ivers *et al.*, 2012) or based on a limited number of theories (Walker *et al.*, 2003; Bonetti *et al.*, 2006; Eccles *et al.*, 2007) with varying effectiveness. In a systematic review of guideline development and implementation studies, only 53 of 235 reviewed studies (22.5%) were judged to have employed theories of behaviour or behaviour change and ten studies used individual constructs from theories whilst the remaining 172 studies were judged to have not

employed theories or constructs (Davies *et al.*, 2010). The majority of the 53 theory-employing studies used only one theory (42 studies) whilst only a few studies employed a maximum of three theories (Davies *et al.*, 2010). Selecting one theory or few theories may lead to omission some of the critical theories to change the targeted behaviour (Francis *et al.*, 2012). In another systematic review on the effectiveness and efficiency of guideline dissemination and implementation strategies (Grimshaw *et al.*, 2004), considerable variation in effects of the reviewed interventions over 235 studies showing modest success was found. This led the authors to recommend the development of 'a coherent theoretical framework' to inform better choice of interventions for professional and organizational behaviour change (Grimshaw *et al.*, 2004).

Michie *et al.* (2008) advocated the use of theory in designing behaviour change interventions for three main reasons. Firstly, to understand and identify the causal determinants of behaviour and behaviour change (i.e., theoretical mechanisms of change) which makes the interventions more likely to be effective by targeting these behavioural determinants. Secondly, to test and evaluate the theory in the theoretically-informed interventions. Thirdly, to understand and evaluate what works and not works in order to develop a better theory and theoretically-informed interventions across different contexts, populations, and behaviours. Besides these, the use of a theoretical basis can also be more cost-effective in developing and implementing an intervention as the mechanisms for its success/failure can be better understood informing the design of future interventions without wasting time and resources (Francis *et al.*, 2009).

There are, however, numerous psychological theories and models available to understand, predict, and change professionals' clinical behaviour (Davis *et al.*, 2014). Moreover, many of these psychological theories share overlapping theoretical constructs as "component parts of theories" (Michie *et al.*, 2005). The presence of a plethora of psychological theories with a wide range of overlapping theoretical constructs between theories causes at least three problems in applying these theories and models to design behaviour change interventions. First, it makes the use of all the potentially relevant theories for behaviour change impossible increasing the risk of missing critical relevant theories or including irrelevant ones. Second, it causes confusion in selecting and applying theory to intervention design. Third, it highlights the problem of lacking the systematic basis for selecting the most appropriate, relevant, important, or useful theories for changing the targeted behaviour among all the available theories (Michie *et*

al., 2005; Francis *et al.*, 2009; Cane *et al.*, 2012; Francis *et al.*, 2012). In an attempt to overcome these problems, Michie *et al.* (2005) developed the theoretical domains framework.

2.4.7 Theoretical Domains Framework (TDF)

The Theoretical Domains Framework (TDF) has been developed in 2005 by Michie and colleagues. The framework encompasses a broad range of psychological theories and constructs relevant to clinicians' behaviour in implementing clinical evidence (Michie *et al.*, 2005). It, therefore, provides the researchers a ready access to a definitive 'full' set of theoretical explanations of behaviour change and a tool to identify the relevant theories to particular contexts.

The framework was accomplished through a sequential-stage systematic consensus method using three groups of experts: a main working group of 18 health psychology theorists, in collaboration with a multidisciplinary group of 16 healthcare services researchers including 2 dentists, and a psychological group of 30 health psychologists (Michie *et al.*, 2005). The sequenced-stage consensus approach involved the following:

- Identifying behaviour change theories and theoretical constructs, where a theoretical construct is "a concept specially devised to be part of a theory".
- Simplifying the constructs into theoretical domains, where a theoretical domain is "a group encompassing a set of related theoretical constructs".
- Evaluating the importance of the theoretical domains.
- Conducting an interdisciplinary evaluation.
- Validating the domain list.
- Piloting interview questions.
- Identifying the theoretical framework, where a framework is "a structure composed of parts framed together".

The resulting consensus identified a theoretical framework consisting of 12 theoretical domains from 33 theories covering 128 theoretical constructs that could help to understand, predict, and change the healthcare professionals' clinical behaviour (Michie *et al.*, 2005). The 12 behavioural change domains of the TDF are:

1. Knowledge.
2. Skills.
3. Social/Professional role and identity.
4. Beliefs about capabilities.
5. Beliefs about consequences.
6. Motivation and goals.
7. Memory, attention and decision processes.
8. Environmental context and resources.
9. Social influences.
10. Emotions.
11. Behavioural regulation.
12. Nature of the behaviour.

Each domain was associated with exemplar questions in the theoretical domains interview (TDI) (Michie *et al.*, 2005) in order to allow researchers to investigate the domains during interviews, focus groups, or survey questionnaire.

The TDF represents a wide range of theoretical approaches that can achieve comprehensive, effective, and well-rationalised intervention implementation. It has several strengths but it also has some weaknesses.

TDF strengths and weaknesses

Since its development, the TDF has been applied widely in implementation science. Francis *et al.* (2012) reviewed the TDF applications in implementation research and identified two major strengths in the framework: its comprehensive theoretical coverage of potential influences on behaviour and its capability of identifying the key mediators or modifiers of behaviour change (i.e., behavioural determinants that hinder or facilitate the intended change). An additional strength of the TDF is its capability of making links between theories and techniques of behaviour change (i.e., mapping behaviour change techniques onto behavioural determinants). Furthermore, this framework has an additional advantage related to its 'flexible' applicability because it can be applied 'flexibly' in various research designs to collect qualitative (interviews or focus groups) or quantitative (survey questionnaires) data. For example, a generic TDF-based survey questionnaire has been developed recently to help the researchers in identifying factors influencing behaviour on a 'representative' sample in various contexts and settings (Huijg *et al.*, 2014a; Huijg *et al.*, 2014b).

In fact, the TDF, as a newly applied research tool in behavioural change science, is a very beneficial 'multi-functional' tool to understand behaviour change processes and

potential change pathways. Figure 2.25 provides a summary of the several potential 'linked' applications of TDF in implementation science.

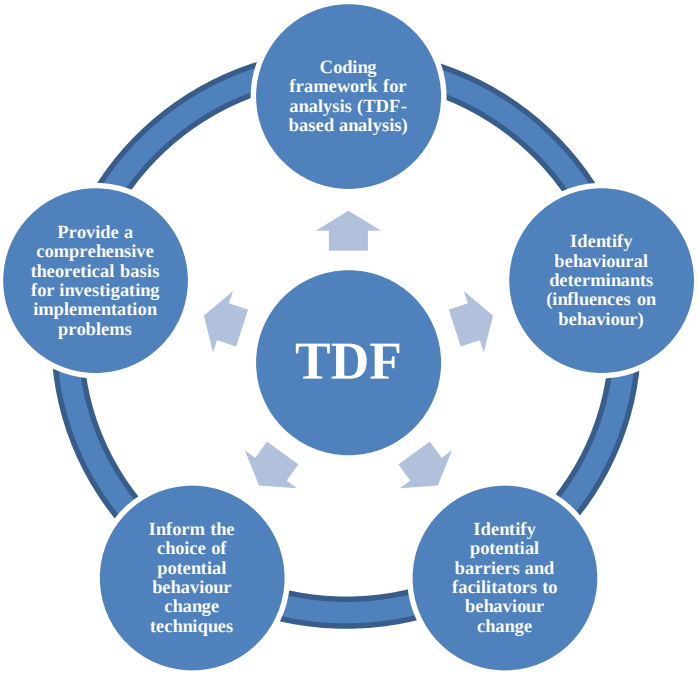


Figure 2.25: The TDF potential multi-uses in implementation research. Depicted from reviewing the relevant literature, mainly (Michie *et al.*, 2005; Francis *et al.*, 2012).

One of the main aims of developing the TDF is to simplify and integrate a plethora of behaviour change psychological theories and make theory more accessible to, and usable by, disciplines involved in evidence base implementation other than psychologists; thereby, communicating the psychological constructs to an interdisciplinary audience (Michie *et al.*, 2005). The cross-disciplinary implementation of the TDF means that it can be used to understand and change the healthcare professionals' behaviour by 'lay' researchers other than psychologists. Obviously this is a major advantage for the TDF but it can be a disadvantage too if researchers applying the TDF have no training or experience in behavioural theory as the depth of meaning of the domains may not be evident to the 'lay' researchers with the possibility of having the TDF poorly or superficially applied (Francis *et al.*, 2012). To use the framework thoroughly, Francis *et al.* (2012) advised the researchers to 'dig deep' beyond a superficial interpretation of the theoretical domains and, therefore, recommended for interdisciplinary research teams using the TDF for the first time to include a health psychologist on the team.

In the literature, the TDF has been used in a variety of contexts to explain implementation problems and to inform implementation interventions. In a review of TDF applying studies, Francis *et al.* (2012) identified 17 studies used the TDF as a basis for exploration the healthcare professionals' behaviour, and the majority of these used semi-structured interviews' method (Francis *et al.*, 2012). Table 2.19 summarises some examples of the wide TDF applications for guidelines implementation by healthcare providers in a wide range of clinical settings in different parts of the world.

Clinical setting	**Study (year)***	**Country**
Acute lower back pain	McKenzie *et al.* (2008)	Australia
Pediatric and new-born care	Nzinga *et al.* (2009)	Kenya
GDPs guidelines implementation	Clarkson *et al.* (2010)	UK
Human papillomavirus and cervical cancer prevention	McSherry *et al.* (2012)	Ireland
Clinicians' prescribing errors	Duncan *et al.* (2012)	UK
Pre-operative tests for low-risk surgery	Patey *et al.* (2012)	Canada
Diagnostic imaging for spine disorders	Bussieres *et al.* (2012)	USA & Canada
Tobacco use prevention and cessation counselling by dental care professionals	Amemori *et al.* (2013)	Finland
Osteoarthritis patients' self-management	Porcheret *et al.* (2014)	UK
Application of fluoride varnish to children's teeth	Gnich *et al.* (2015)	UK
Neck pain management	Bussieres *et al.* (2015)	Canada

* Studies are in chronological order.

Table 2.19: TDF uses in various clinical contexts in different countries.

This wide applicability of the TDF in investigating various behaviours in different healthcare settings provides evidence of framework success in "making psychological theory useful" (Michie *et al.*, 2005) to researchers from a variety of disciplinary backgrounds across the world.

The TDF, however, has also several limitations. First, it does not specify relationships between the domains and does not generate testable hypotheses (Francis *et al.*, 2009) and, therefore, it is described as "a descriptive framework rather than a theory" (Francis *et al.*, 2012). Second, despite its clarity in specifying the component constructs to each domain, there is some overlap between the theoretical constructs in the domains of the TDF making the boundaries between domains unclear and difficult to identify by the researchers because some constructs are related to more than one domain (Francis *et al.*, 2009). The last point can be especially challenging when the TDF is used as a coding framework for data analysis of qualitative interviews (Islam *et al.*, 2012); nevertheless

there is an acknowledgement that the TDF is a proven efficient and comprehensive method for data analysis (Porcheret *et al.*, 2014; Backman *et al.*, 2015). Third, the TDF can generate ideas about the factors influencing behaviour but it cannot provide evidence about the 'actual' influences on clinical practice (Francis *et al.*, 2012). That is, although the participants' own views are of relevance in determining their perceptions/conclusion and engagement of behaviour change, the identified themes in TDF interviews may reflect only the participants' own and others' views regarding influences on clinical behaviours and may not necessarily reveal the 'actual' causes (Patey *et al.*, 2012). Fourth, there is a possibility of reaching 'premature' data saturation if the selected participants for TDF interviews share similar opinions (Patey *et al.*, 2012). The last two points, however, related more to research methodology used (e.g., qualitative interviews) rather than the TDF shortcomings per se and can be overcome by using different research methodologies or adapting various research methods. Fifth, the TDF interview topic guide is criticised for being more structured, too focused, and too constrained leading the interviewee to discuss only the views and opinions about the topic that fit into the framework. One study, however, confuted this criticism by using randomised designs and making direct comparisons between the results of methods based on the TDF versus atheoretical methods, using interviews, focus groups, and a survey questionnaire (Dyson *et al.*, 2011). The study found considerable overlap in the findings from the theoretical and atheoretical approaches. Furthermore, the data generated using the TDF approach also prompted the identification of beliefs that could not be elicited by the atheoretical approach (Dyson *et al.*, 2011). In a recent systematic review of questionnaire-items used in 50 included quantitative and qualitative studies investigating barriers to change healthcare-related behaviour, 97% of manuscripts' questionnaire-items were found to be covered by the TDF and only about 3% of items identified were not covered by the TDF-questionnaire which confirms the validity of TDF framework in assessing barriers to change (Sarmast *et al.*, 2014). This provides further evidence of the comprehensive inclusive theoretical coverage of the TDF. Nonetheless, all the identified limitations are worth consideration and highlight the necessity for further refining and improving the current framework.

TDF refining and validation

In a refining and validation study of the TDF, Cane *et al.* (2012) tested the validity of the original 12 domains framework developed by Michie *et al.* (2005) using a three-stepped approach: Step 1, identify domains; Step 2, establish domain content; Step 3, finalise domain labels.

The three-step validation process examined specifically structure, content, and labels of the domains by using card sort task methodology (closed and open), fuzzy cluster analysis, and discriminant content validation methods. The study's results showed good support for the basic structure but led to two main changes of the original framework. First, a separation and clarification of a number of existing domains and constructs (e.g., 44 constructs have been removed in the refined version of the 128 constructs in the 'original' TDF; 3 additional domains have been added). Second, a dropout to the 'nature of the behaviour' domain with the reason being that it is a 'dependent' rather than an independent variable and related more to an understanding of the behaviour characteristics rather than to influences on behaviour (Cane *et al.*, 2012). The 'refined' framework, therefore, contains 14 domains involving 84 theoretical constructs as shown in Table 2.20.

Domain	Constructs*
1. Knowledge	Knowledge (including knowledge of condition/scientific rationale); procedural knowledge; knowledge of task environment.
2. Skills	Skills; skills development; competence; ability; interpersonal skills; practice; skill assessment.
3. Social/Professional role and identity	Professional identity; professional role; social identity; identity; professional boundaries; professional confidence; group identity; leadership; organisational commitment.
4. Beliefs about capabilities	Self-confidence; perceived competence; self-efficacy; perceived behavioural control; beliefs; self-esteem; empowerment; professional confidence.
5. Optimism	Optimism; pessimism; unrealistic optimism; identity.
6. Beliefs about consequences	Beliefs; outcome expectancies; characteristics of outcome expectancies; anticipated regret; consequents.
7. Reinforcement	Rewards (proximal/distal, valued/not valued, probable/improbable); incentives; punishment; consequents; reinforcement; contingencies; sanctions.
8. Intentions	Stability of intentions; stages of change model; transtheoretical model and stages of change.
9. Goals	Goals (distal/proximal); goal priority; goal/target setting; goals (autonomous/controlled); action planning; implementation intention.
10. Memory, attention, and decision processes	Memory; attention; attention control; decision-making; cognitive overload/tiredness.
11. Environmental context and resources	Environmental stressors; resources/material resources; organisational culture/climate; salient events/critical incidents; person x environment interaction; barriers and facilitators.
12. Social influences	Social pressure; social norms; group conformity; social comparisons; group norms; social support; power; intergroup conflict; alienation; group identity; modelling.
13. Emotions	Fear; anxiety; affect; stress; depression; positive/negative affect; burn-out.
14. Behavioural regulation	Self-monitoring; breaking habit; action planning.

* Underlined constructs are overlapped in more than one domain.

Table 2.20: Refined theoretical domains framework. Adapted from Cane *et al.* (2012).

The findings from Cane *et al.* (2012) have strengthened the evidence about the appropriateness of structure and content of the theoretical domains, thereby increasing the confidence in the TDF's potential utility in implementation science. There are, however, some limitations of the refined-TDF, one of which is illustrated in the footnote

of Table 2.20, as there are still some overlaps between the theoretical constructs in the domains of the refined-TDF. In their study, Cane *et al.* (2012) discussed two possible limitations of the refined framework. One limitation is the weak clustering of two of the included domains (environmental context and resources; behavioural regulation). Another identified limitation is that the refined-TDF is limited to theoretical constructs identified early in the original-TDF, which despite their extensiveness, they do not cover all the available behavioural change theories (Noar and Zimmerman, 2005). Nevertheless, the TDF is currently the most comprehensive inclusive theoretical approach that can be used to identify the behavioural determinants with good reliability.

2.4.8 Behaviour Change Techniques (BCTs)

Behaviour change techniques (BCTs) are defined as "an observable, replicable, and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour" (Michie *et al.*, 2013). In other words, a BCT is proposed to be an active/effective ingredient within the intervention components (Michie *et al.*, 2011a). BCTs can be used either alone or in combination and in a variety of formats (Michie *et al.*, 2013). For example, an audit and feedback BCT has been identified as an effective technique for interventions to change healthcare professional's behaviour (Ivers *et al.*, 2012).

The science of behaviour change is developing quickly. The first reliable taxonomy of BCTs developed by Abraham and Michie (2008) included only 26 BCTs. Recently an extensive taxonomy of 93 BCTs has been developed by Michie *et al.* (2013). The 'BCT taxonomy version 1' involves 93 BCTs grouped into 16 clusters, namely:

1. Scheduled consequences.
2. Reward and threat.
3. Repetition and substitution.
4. Antecedents.
5. Associations.
6. Covert learning.
7. Natural consequences.
8. Feedback and monitoring.
9. Goals and planning.
10. Social support.
11. Comparison of behaviour.
12. Self-belief.
13. Comparison of outcomes.
14. Identity.
15. Shaping knowledge.
16. Regulation.

The current BCT taxonomy v1 has been described as a reliable, distinct list of clearly defined, non-redundant BCTs and as a 'hierarchical' structure (Michie *et al.*, 2013). The long-term goal of the BCT Taxonomy project is to develop a comprehensive, reliable, and generalisable 'core' BCT taxonomy that: can be used as a tool for identifying, implementing, and evaluating behaviour change interventions, can be applied in various contexts and settings to different types of intervention: individual, organizational, and community interventions, and has international acceptance and multidisciplinary use (Michie *et al.*, 2013).

Michie *et al.* (2013) suggested five potential benefits that will arise from the development of a cross domain, internationally accepted, BCT taxonomy. Firstly, it will promote accurate replication of interventions. Secondly, it will facilitate correct implementation of 'effective' interventions. Thirdly, it will enable systematic reviewers to use a reliable method for extracting information about intervention content, thus identifying and synthesizing discrete, replicable, potentially active ingredients (or combinations of ingredients) associated with effectiveness. Fourthly, it will enable the intervention development to draw on a comprehensive list of BCTs to design interventions, and will enable well-defined, clear, and detailed reports of the intervention content. Finally, it will allow the investigation of possible mechanisms of action by linking the techniques of behaviour change with the theories of behaviour change.

2.4.9 Linking behaviour change techniques to behaviour change theories

Different behaviour change techniques can address different behavioural determinants. The current BCT taxonomy v1 is a methodological tool that can be used in specifying the detailed content (i.e., active components) of a wide range of behaviour change interventions but it does not, however, make links with theory (Michie *et al.*, 2013). Linking the techniques of behaviour change with the theories of behaviour change is necessary for both developing and evaluating the theoretically-informed interventions (Michie and Johnston, 2012).

Michie *et al.* (2008) identified three factors required for effective mapping of theoretical constructs to behaviour change techniques. First, examine the wide range of theoretical frameworks available. Second, identify the range of techniques available to change

behavioural determinants. Third, develop a basis for selecting and mapping relevant techniques to differing behavioural determinants.

A preliminary attempt at linking BCTs with theoretical constructs of TDF (i.e. behavioural determinants informed by psychological theory) has been done by Michie *et al.* (2008) and found to be useful but needs further work to optimise its benefits. In this preliminary study, 35 BCTs were identified first and then mapped (linked or matched) to relevant theoretical domains and constructs by consensus of four independent experts. The results of this consensus mapping showed a reasonable inter-rater agreement (71%) and identified the possible techniques that can be used for changing each behavioural/causal determinant in the original-TDF (Michie *et al.*, 2008). The number of behavioural change techniques agreed by the experts to be useful for changing each domain was as follows:

- One technique to change knowledge; environmental context and resources; social/professional role and identity.
- Two techniques to change social influences; emotions.
- Three techniques to change memory, attention, and decision processes.
- Four techniques to change beliefs about consequences.
- Five techniques to change action planning.
- Nine techniques to change beliefs about capabilities; motivation and goals.
- Ten techniques to change skills.

This mapping process adds further evidence and support for the use of the TDF to identify the behavioural determinants (i.e., domains) that can be linked to appropriate behaviour change techniques for designing behaviour change interventions. The authors, however, discussed that this mapping attempt is only an illustration of what can be achieved further by a larger sample of experts' consensus (Michie *et al.*, 2008). The limitation of this initial mapping attempt is attributed to its subjective agreement as it was based on authors' opinion (subjective experiences and knowledge) not on evidence of actual effectiveness of the techniques and the fact that the task was completed without definitions of BCTs. Nevertheless, this mapping identified several advantages. Firstly, there is substantial consensus in agreeing about the inappropriate technique(s) for changing specific determinants which could be used as evidence to avoid wasting resources on interventions that are likely to be unsuccessful. Secondly, there is also

substantial consensus in agreeing the appropriate technique(s) for changing each of the theoretical domains despite the uneven distribution of techniques across the causal determinants. Thirdly, this identification of the 'appropriate' techniques to change each behavioural determinant can be utilised as a basis for conducting intervention trials and undertaking systematic reviews to provide evidence about the most effective BCTs (Michie *et al.*, 2008).

2.4.10 Modes of delivery

Various methods have been proposed in the literature to enhance the dissemination and implementation of evidence in clinical practice. These are many ranging from simple dissemination strategies enhancing accessibility to information resources such as mailing the clinical guidelines or educational materials to more complex implementation strategies using different modes of delivery, including: using opinion leaders or mass media campaigns; using reminder systems; educational outreach visits and academic detailing; developing continuing educational programmes with different educational strategies and educational activities such as educational meetings, courses, conferences, seminars, workshops, interactive group meetings and multi-professional collaboration; receiving audit and feedback; using computerised clinical decision support systems (CDSS) and tools; and combined multifaceted approaches (Oxman *et al.*, 1995; Grimshaw *et al.*, 2001; Grol and Grimshaw, 2003; Mettes *et al.*, 2010; Squires *et al.*, 2014).

In a systematic review about the effectiveness and efficiency of guideline dissemination and implementation strategies (Grimshaw *et al.*, 2004), 235 RCTs reporting 309 comparisons were identified. Of these, 73% comparisons were multifaceted interventions whilst the remaining were single interventions, most commonly reminders (16% comparisons), educational materials (9% comparisons), and audit and feedback (4% comparisons) (Grimshaw *et al.*, 2004). The review found that about 87% of the reviewed interventions resulted in improvements in healthcare but the majority were modest to moderate improvements (Grimshaw *et al.*, 2004). Dyson *et al.* (2011) argued that the success of delivery strategies depends primarily on the type of change being implemented. French *et al.* (2012) suggested the choice of delivery mode should be made and guided by the 'particular' context and practical issues of intervention delivery, mainly, what is feasible according to available resources and what is acceptable in the relevant clinical setting to the targeted group of healthcare

professionals. In other words, several inter-related factors need to be taken into consideration when selecting the mode of delivery of an intervention such as: targeted behaviour, targeted population, setting, resources, as well as feasibility, practicability, scalability, and acceptability of the intervention itself. The choice of the appropriate mode or style of delivery can be informed by evidence on the effectiveness of strategies for changing practice from the Cochrane Effective Practice and Organisation of Care Group (EPOC, 2002).

Currently, technological advances in developing computerised clinical decision support system (CDSS), whether via electronic computer technology (eHealth) or mobile technology (mHealth) platforms, may help dissemination and implementation of research evidence into clinical practice. The CDSS has been defined as "any computer program designed to help health professionals make clinical decisions" (Shortliffe, 1987). These systems are designed to provide clinicians and patients with relevant clinical knowledge and patient-related information with an optimum goal to improve the quality of healthcare and reduce errors in practice (Davis, 2008; Vikram and Karjodkar, 2009). They have several advantages related mainly to their practicality, feasibility, and economical issues (Nhavoto and Gronlund, 2014). A systematic review on the impact of health information technology on quality, efficiency, and costs of healthcare found three major benefits from using the CDSS: increasing adherence to evidence-based care, enhancing surveillance and monitoring, and decreasing decision-making errors (Chaudhry *et al.*, 2006). According to Newman (2007), these electronic systems can assist clinicians in making decisions in several ways: detect potential clinical errors; suggest risk factors and approaches to patient differential diagnosis and management; suggest 'optimal' clinical strategies on the basis of the best available evidence and cost-benefit and harm-benefit considerations; organise treatment plan details; gather and present data required to perform a treatment plan; communicate to third party payers.

There are, however, a multitude of requirements for these electronic systems. In one study, ten technical elements were discussed to be required for 'optimal' CDSS (Bates *et al.*, 2003). In addition to technical requirements of these tools, Straus (2002) recommended three elements that are needed to be available in the CDSS to help the clinicians individualising their treatment decisions and incorporating the patients' values and circumstances in their decision-making process. Hence, CDSS should: express the risks and benefits of treatments in valid, concise, and intelligible formats to

patients as well as to clinicians; allow the clinicians to individualise treatment according to patients' unique values and expectations; be feasible for use on busy clinical services (Straus, 2002). In one systematic review about these systems, four features were identified that should be available in CDSS to be effective in improving healthcare, including: provides decision support automatically as part of clinician workflow; delivers decision support at the time and location of decision-making; provides usable recommendations; and uses a computer to generate the decision support (Kawamoto *et al.*, 2005). These four features share generally a common theme to make the clinicians easily applying and using the electronic tool with minimum efforts during the clinical practice.

In addition, there are several potential challenges and concerns that may restrict the wide adoption of these supporting systems by clinicians. These are many but related mainly to users (i.e., clinicians) such as: lack of familiarity, lack of acceptability, lack of trust, lack of relevance, lack of time, lack of incentives, lack of functionality of 'cookbook' approaches, fear of reduced autonomy or increased liability, and fear of legal liability. Other factors that might restrict adoption are related to systems themselves such as: financial considerations for development and maintenance, lack of knowledge maintenance and update, and lack of necessary and continuous evaluation (Newman, 2007; Hochadel, 2008; Vikram and Karjodkar, 2009). More importantly, these CDSS have theoretical limitations because most of the times they do not have a theory base and do not identify mechanisms of behaviour change and the BCTs necessary to target the behaviour. Therefore, the majority of CDSS only focus on motivational stages of decision-making (i.e., clinician's knowledge). To change a decision-making behaviour, it is often needed to make the behaviour change intervention broader to encompass and address all the relevant behavioural determinants (e.g., clinician's skills). Nevertheless, despite these requirements, challenges, and limitations, the computerised clinical decision support e-Health and m-Health systems seem very promising tools to improve healthcare in the future.

2.4.11 Conclusion

Implementation of research evidence in practice is hindered by numerous barriers related mainly to healthcare professional behaviour and attitude. Changing healthcare professionals' behaviour towards 'evidence-based practice' is difficult and challenging and the interventions needed to be designed to achieve this change are typically complex. Nevertheless, understanding the behaviours of healthcare professionals; identifying the influences on clinical behaviour; basing the intervention on theoretical principles of behaviour change; mapping the appropriate behaviour change technique to underlying behaviour change theory; disseminating via appropriate mode of delivery; and taking into consideration the practical issues of intervention delivery will more likely lead to effective intervention development and successful implementation.

2.5 Summary Conclusion

Despite the advances in TMD research, TMD topic is still not a fully understood growing subject in terms of aetiology, diagnosis, and treatment. This can be challenging to the clinician 'decision-maker' due to high uncertainty levels. The clinician's decisions, however, can be supported by reducing the uncertainty via research evidence as well as by understanding influential factors that may play a role in the clinical decision-making process for TMD/DDwoR management and developing appropriate interventional strategies to overcome these.

The identified evidence from systematic reviews (Chapters 4 and 5) will be used with the identified influences on clinicians' decisions from qualitative study (Chapter 6) to shape the future intervention that will be developed. This intervention will probably be a complex behavioural intervention to support clinicians to make a decision as well as to execute specific clinical behaviours.

Chapter 3. Aims and Objectives

3.1 Aim

To inform and facilitate the future development of a virtually delivered evidence-informed behavioural intervention for clinicians at the frontline to aid them managing disc displacement without reduction (DDwoR) disorder. This will inform the development of more generic strategies with which to help improve the management of temporomandibular disorders (TMD) in general.

3.2 Objectives

1. To investigate the effects of duration of locking on the clinical outcomes of TMJ closed lock management and its implications for the definitions of acute and chronic DDwoR.
2. To investigate the effects of conservative (non-surgical) and surgical therapeutic interventions used for the management of patients with DDwoR.
3. To explore and build an understanding of professionals' clinical decision-making processes in the management of TMD in general and DDwoR in particular in order to identify factors, as informed by the TDF, influencing the professionals' decisions in DDwoR management at the frontline.

3.3 Programme of work

The three objectives were addressed by conducting three separate consecutive studies:

1. Systematic review of locking duration effects on timing the interventions used for DDwoR management.
2. Systematic review of interventions effects on DDwoR management.
3. Qualitative interview study with dental and medical primary and secondary care professionals who might be expected to be involved in DDwoR management.

Chapter 4. Effects of Locking Duration on Timing the Interventions in TMJ Closed Lock Management: A Systematic Review

4.1 Introduction

TMJ closed lock (CL) is a clinical term often used to describe a 'painful locking' symptom which is usually attributed to disc displacement without reduction (DDwoR) (Weisberg and Friedman, 1981; Okeson, 2007) or less commonly to anchored disc phenomenon (ADP) (Nitzan and Dolwick, 1991; Nitzan and Marmary, 1997). In this chapter, therefore, the 'closed lock' term is used to describe the clinical symptoms of the two clinical conditions: DDwoR and ADP. The duration of locking determines if the CL condition is acute or chronic (Murakami *et al.*, 1995; Sembronio *et al.*, 2008b).

4.1.1 Acute and chronic closed lock duration

The 'acute' and 'chronic' are medical terms usually used to measure the time scale of a disease rather than its severity. In medical dictionaries, the term 'acute' is often linked to a temporary state or condition which may/may not be severe, and the term 'chronic' is linked to a persistent or long lasting state or condition and again does not imply anything about severity (BMA, 2008; CCMD, 2010). In pain conditions, it is generally agreed that "acute pain" is a pain of recent onset with a duration of less than or equal to 1 month (≤ 30 days) and "chronic pain" is a persistent pain with a longer duration of more than or equal to 3-6 months (≥ 90 days) (Carr and Goudas, 1999; Dworkin *et al.*, 2011). In a CL condition, the terms "acute closed lock" (ACL) and "chronic closed lock" (CCL) are also widely used in the literature to describe the chronicity of the condition according to locking duration or time since locking onset. At the moment, however, there is no clear indication about the chronological difference between acute and chronic CL; that is, how long before 'acute' is redefined as 'chronic'? Intuitively, however, there should be a difference if the clinicians intervene in CL early versus if they intervene late. This is not only because of the fact that the disc may be 'replaced' back into its normal anatomic position but also because if symptomatic load is decreased it may be possible to avoid pain-related disability and dysfunction over the longer-term (Gatchel *et al.*, 2006).

4.1.2 Why it is important to differentiate acute from chronic closed lock?

The natural clinical progression of closed lock from 'acute' to 'chronic' in patient with DDwoR has been proposed as follows: it starts as an anteriorly displaced disc obstructing the translation of condyle during mouth opening. This causes restriction in mouth opening often associated with severe pain (acute stage). Thereafter, the repeated attempts to open the mouth by the patient displace the disc gradually farther forward anteriorly so the condyle can slide forward during mouth opening. This causes increase in range of mouth opening over 'time' often associated with reduced pain (chronic stage) (Haketa *et al.*, 2010). From a clinical point of view, the progression from an acute to a chronic CL over time may affect the intervention effectiveness and, therefore, the outcome of treatment. This is in part because patients with CL may respond to a similar therapeutic intervention differently on the basis of locking duration, and in part because the assessment of the effectiveness of interventions in CL is most often based on the two outcomes which tend to improve over time: increased opening and decreased pain. In other words, locking duration may be a potential factor that can both affect treatment effectiveness and help predict treatment outcomes in CL management. Currently, however, the effects of locking duration on CL management outcome is still unknown.

4.2 Aims and objectives

4.2.1 Aim

The primary aim of this systematic review was to investigate the effects of duration of locking on the clinical outcomes of closed lock management and its implications for the definitions of acute and chronic CL.

4.2.2 Objectives

- To investigate the effects of locking duration on the success of therapeutic interventions in closed lock.
- To examine the timing definitions for acute-chronic closed lock stages.

4.3 Methods

4.3.1 Study design

Systematic review.

4.3.2 Criteria for considering studies

The criteria for considering studies followed the PICOS criteria which are: **P**articipants, **I**nterventions, **C**omparators/**C**ontrol, **O**utcomes, and **S**tudies.

Types of studies

Inclusion criteria

As the primary aim of this review was to find the relationship between locking duration and CL management outcome, studies of any design that involve patients with acute or chronic TMJ CL (DDwoR and ADP) and investigating the effects of any form of conservative (non-surgical) and/or surgical interventions were considered as long as the duration of symptoms were reported.

Studies involving other heterogeneous groups of TMD patients (e.g., DDwR, osteoarthritis, or myofacial pain) in addition to patients with CL were considered if separate data (e.g., locking duration and/or success rate) were provided in the study for CL patients, or if the sample consisted of ≥ 80% CL patients. Studies involving patients with a confirmed radiographic diagnosis of DDwoR/ADP associated with comorbid disorders were also included.

Exclusion criteria

Studies were excluded if they addressed diagnoses other than ‘closed lock’ (DDwoR or ADP). CL studies were excluded if they did not report the duration of symptoms of their sample or if they addressed subject matter other than CL management.

Types of participants

Inclusion criteria

Patients of any age, gender, and of different stages of chronicity with clinical and/or radiological diagnosis of acute or chronic DDwoR as diagnosed according to: AAOP criteria for acute or chronic DDwoR (de Leeuw, 2008); RDC/TMD criteria (IIb or IIc)

for DDwoR with/without limited opening (Dworkin and LeResche, 1992); Wilkes early/late intermediate stages (III or IV) of internal derangement (Wilkes, 1989); or any other bespoke study criteria that were compatible with, or comparable to, the aforementioned criteria (Table 2.5) were considered as long as the duration of symptoms were reported. CL patients with a 'static' or 'fixed' disc (i.e., anchored disc 'ADP') (Nitzan and Dolwick, 1991; Rao *et al.*, 1993) were also included as long as the duration of symptoms were reported. Patients with confirmed diagnosis of DDwoR/ADP with comorbid disorders were also considered.

Exclusion criteria

CL patients with systemic diseases were excluded.

Types of interventions

Any form of conservative or surgical intervention was considered. The interventions were divided into different treatment modalities to be considered by their main treatment components such as: education, self-management, splint therapy, physiotherapy, intra-articular injection, arthrocentesis, arthroscopic and open joint surgery. Standardized combination of different treatments was also included.

Types of outcome measures

The main outcome measures considered were the success rates of the included studies in relation to the duration of locking of the studies' samples. Given the lack of agreed valid and reliable criteria to define 'success' in CL management (Schiffman *et al.*, 2014b), the criteria for success of the reviewed intervention were based on the reported criteria used by each individual included study.

As an additional measure considered, the timing definitions for acute and chronic closed lock stages in the studies included were also examined and retrieved.

4.3.3 Search methods for identification of studies

Electronic searches

A systematic search until August 2013 was conducted in Medline database via Ovid. The Medline search strategy is described in Table 4.1. In addition, Google Scholar was also searched using 'disc displacement without reduction' and 'closed lock' keywords.

Ovid Medline(R) <1946 to August Week 1 2013>
1. exp Temporomandibular Joint disorders/
2. exp Temporomandibular Joint/
3. 1 or 2
4. (lock$ adj2 (closed or jaw)).tw.
5. ((displace$ without or dislocat$ without or unreduc$ or nonreduc$ or un-reduc$ or non-reduc$ or derange$ without) adj6 (disc or disk or meniscus)).tw.
6. 4 or 5
7. 3 and 6
8. limit 7 to (English language and humans)
9. limit 8 to "review articles"
10. 8 not 9

Table 4.1: Medline search strategy.

Manual searches

To identify any additional studies, other sources were manually-searched including the reference lists of the included studies and the reference lists of the relevant review articles.

Search limits

English language, Peer reviewed publications.

4.3.4 Data collection and extraction

Selection of studies

Eligible studies were selected by the research student according to the inclusion/exclusion criteria based on the title and abstract (when available) with those identified as clearly irrelevant from their title/abstract were excluded. The full-texts of all potentially eligible studies were then retrieved and examined. Throughout the selection process, any doubt about a study's inclusion meant it was examined by one of the supervisors (JD) and the decision to include or exclude the study was made by discussion with the student to reach a consensus. All studies met the inclusion criteria then underwent data extraction and quality assessment.

Data extraction and management

A standardised table was used by the student to extract and record data from the studies included. The information extracted from each included study involved details about the following:

- Study design
- Participant characteristics (sample size, diagnosis, age, gender, and locking duration)
- Intervention
- Follow-up period
- Study success criteria
- Study findings in relation to locking duration
- Success rate
- Timing definitions for acute and chronic closed lock stages (if stated).

To ensure reliability, one of the supervisors (JD) crosschecked the validity of all extracted data. The data on duration of symptoms, follow-up period, and ACL-CCL timings were standardised in months and the data for the successful pain reduction outcome measured on 0-10 cm scale were standardised, when possible, to 0-100 mm scale. If not provided, the mean of the patients' age and locking duration was calculated from the raw data using the Statistical Package for the Social Sciences (IBM SPSS statistical package v.19 for windows).

Quality assessment of included studies

Given the wide diversity in the design of the studies expected to be included in this review, the quality of included studies was assessed according to study design using the National Health and Medical Research Council (NHMRC) level of evidence guidelines for intervention trials (NHMRC, 2013) with slight modification. The studies were assessed independently by the student and one of the supervisors (JD) and the level of evidence in each study was judged by its design as: (I) highest, (II-1), (II-2), (III-1), (III-2), (III-3), or (IV) lowest as detailed in Table 4.2. Any disagreements concerning the assessment were resolved by discussion to reach a consensus. All data on studies' quality were summarised in the standardised table.

Level of evidence	Study design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II-1	Evidence obtained from at least one properly-designed randomised controlled trial.
II-2	Evidence obtained from at least one poorly-designed randomised controlled trial.
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method of quasi-randomisation).
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group.
IV	Evidence obtained from case series, either post-test or pre-test/post-test.

Table 4.2: A designation of levels of evidence. Modified from NHMRC (2013).

Data analysis

The included studies were grouped according to main treatment components of each therapeutic modality. Given the substantial heterogeneity among studies, the interventions' success rates in relation to locking duration were summarised and tabulated by each individual study and the data were integrated in a narrative synthesis of the main findings from the included studies with a descriptive analysis only.

4.4 Results

4.4.1 Search results

A total of 630 records were identified from electronic and manual searches (426 from Medline and 204 from other sources). Of these, 399 records were found potentially eligible and their full-texts were retrieved and examined. Ultimately, 117 studies of 126 reports met the review inclusion criteria. The study flow diagram is demonstrated in Figure 4.1.

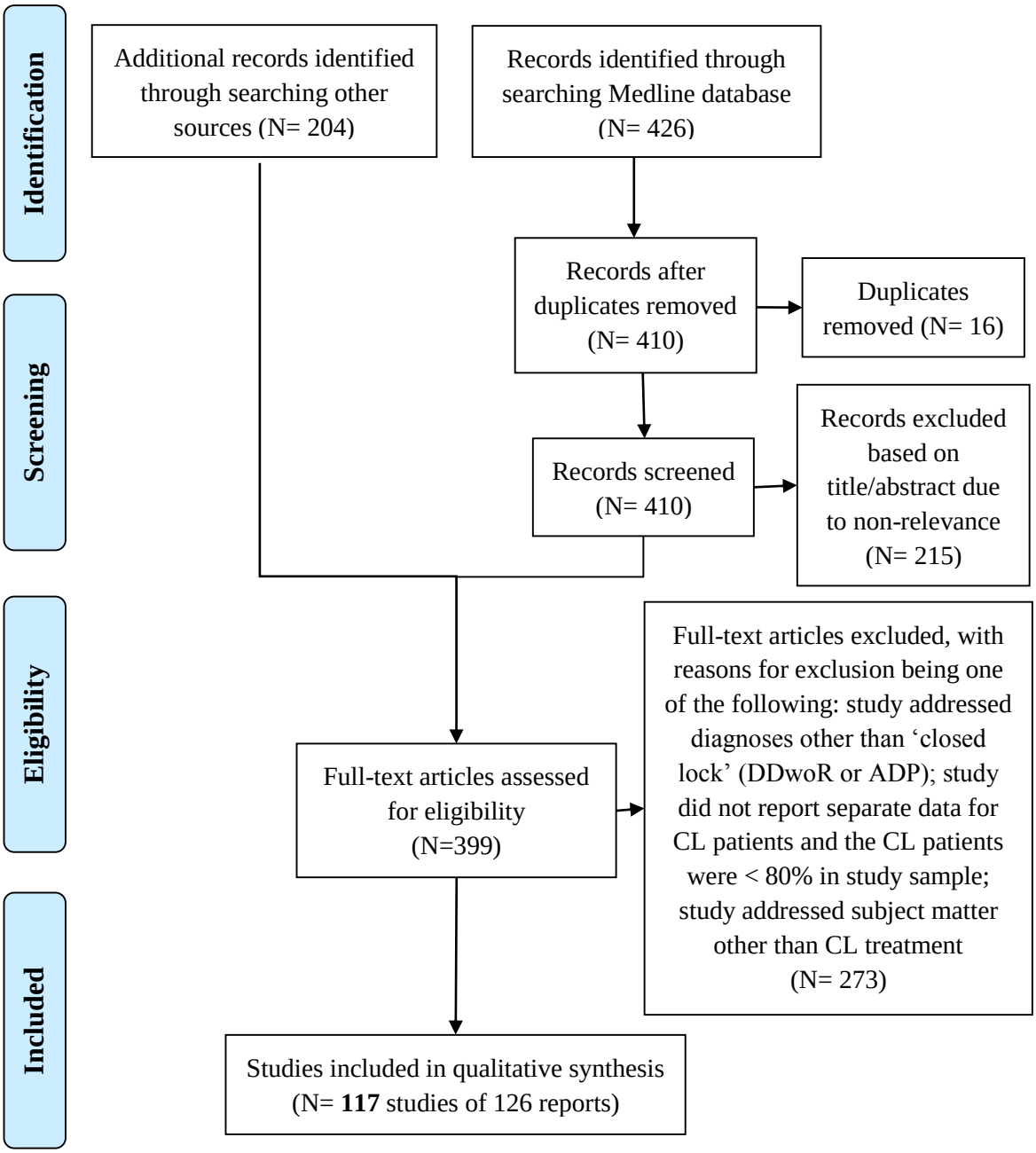


Figure 4.1: Study flow diagram. Adapted from PRISMA 2009 flow diagram (Moher *et al.*, 2009).

4.4.2 Description of included studies

One-hundred seventeen studies of 126 reports met the review inclusion criteria (Appendix A).

Characteristics of study design

Most of the studies included in this review were non-comparative trials (37 studies), case series (33 studies), and case reports (20 studies) whilst only few were comparative trials (10 studies), and randomised clinical trials (17 studies).

The studies were published between 1986 and 2013. Many studies included had a follow-up publication or an overlap published report for the conducted trial. The period of follow-up in the included studies varied considerably, ranging from 10 minutes only (Yoshida *et al.*, 2011) to 13 years (Ozkan *et al.*, 2012).

Characteristics of participants

More than 6000 participants were included in this review. The sample size of the included studies ranged from 1 participant in the case reports to 1506 participants in one retrospective study (Zhang *et al.*, 2009a). Whilst most of the included studies involved participants with DDwoR, eight of the studies involved participants with ADP (N=260) (Nitzan *et al.*, 1991b; Nitzan, 1994; Dimitroulis *et al.*, 1995a; Nitzan *et al.*, 1997; Casares *et al.*, 1999; Dhaif and Ali, 2001; Sanroman, 2004; Kaneyama *et al.*, 2007b).

The majority of participants were females (~86%) resulting in a 6:1 female to male ratio. The age of the participants among all studies ranged from 11 to 77 years (mean patients' age across studies ranged from 20 to 47 years). Data on duration of CL symptoms among all studies ranged from 1 day to 37 years (mean locking duration across studies ranged from 2 weeks to 5 years).

Characteristics of interventions

For the purpose of this systematic review, the reviewed therapeutic interventions were defined according to their main treatment components as follows: mandibular manipulation (MM), self-management (SM), physiotherapy (PT), splint therapy, combination conservative therapy, arthrocentesis (AC), arthroscopy (AS), and open surgery (OS). A detailed description of each intervention is shown in Table 4.3.

Intervention	Description
Mandibular manipulation (MM)	• Unlock manipulation (UM): any manual manipulation technique used to restore the displaced disc into its normal anatomical position. • Pumping manipulation (PM): any adjunctive technique used to inflate the joint space by joint space pumping and hydraulic pressure to assist the manipulation in recapturing the displaced disc.
Self-management (SM)	Any self-management programmes involving self-care instructions + medications (over-the-counter analgesics, muscle relaxants, NSAIDs) ± self-exercises.
Physiotherapy (PT)	• Any active or passive jaw stretching 'repeated' exercises. • Any other physiotherapies such as: ultrasound therapy, short wave diathermy, iontophoresis, transcutaneous electric nerve stimulation (TENS), pulsed electromagnetic fields (PEMF), or low level laser therapy (LLT).
Splint therapy	Any type of splint such as: stabilization splint (SS), anterior repositioning splint (ARS), pivot splint (PS), and soft splint.
Combination therapy	Any splint plus physiotherapy ± self-management.
Arthrocentesis (AC)	Any technique using needles and injections for joint washing and lavage inside the superior joint space.
Arthroscopy (AS)	Any technique using an arthroscope for joint hydraulic pumping and lavage and/or any other operative arthroscopic operations inside the superior joint space.
Open surgery (OS)	Any procedure using a skin incision to approach the TMJ such as discoplasty, discectomy, eminectomy, or condylectomy.

Table 4.3: Description of reviewed interventions.

Characteristics of outcomes

Different objective and subjective outcome measures were assessed in the included studies such as pain intensity and mandibular movements and function. The majority of the included studies considered reduction in pain intensity, usually assessed by the visual analogue scale (VAS), and improvement in mouth opening, commonly measured using a millimetre ruler, as criteria for success of therapeutic interventions. However, the threshold points for the success criteria of these two outcomes differed widely across the studies. For pain outcome, the level of pain intensity on 0-100 scale regarded as 'successful' was: < 20, ≤ 30, ≤ 33, ≤ 40, or pain reduction $\geq 30\%$, $\geq 50\%$, or $\geq 85\%$. For mouth opening outcome, the degree of MMO in millimetres (mm) regarded as 'successful' was: ≥ 30 mm, ≥ 35 mm, ≥ 36 mm, ≥ 38 mm, or ≥ 40 mm.

4.4.3 Quality of included studies

The majority of the included studies had methodological weaknesses in their design. Specifically, most studies were either uncontrolled studies or incompletely controlled the other prognostic factors that might influence the outcome of treatment. Most studies, therefore, were assessed as poor-quality and the level of evidence was generally of a low grade (III-IV).

Further details about the characteristics and quality of all the included studies are tabulated and summarised in Appendix A.

4.4.4 Effects of interventions in relation to closed lock duration

Preliminary synthesis of findings of included studies

Multiple conservative and surgical treatment modalities were used in the included studies. The interventions identified were grouped according to their main treatment components into eight treatments: mandibular manipulation (unlocking or pumping MM), self-management (SM), physiotherapy (PT), splint therapy, combination therapy of splint + PT ± SM, arthrocentesis (AC), arthroscopy (AS), and open surgery (OS). To investigate the effects of these interventions in relation to locking duration, the included studies were tabulated and summarised in Appendix A. The success rates of interventions provided in Appendix A are based on the success criteria used by each individual study. Consequently, the definition of success was highly variable involving both objective and subjective outcomes with the most frequent measures of ‘success’ being degree of mouth opening and level of pain intensity.

Summary of main results

The main findings of intervention effects in relation to locking duration are summarised according to the treatment components of each therapeutic modality in Table 4.4 and discussed further below.

Treatment Modality	No. of studies*	Locking duration (months)	Overall success rate %	Overall evidence quality
		Mean (range)	Mean (range)	
'Unlock' manipulation	20	9 (0.03-180)	68% (9%-100%)	III-IV
Pumping manipulation	8	7 (0.07-120)	66% (45%-100%)	III-IV
Self-management (SM)	7	- (0.5-25)	66% (60%-72%)	III-IV
Physiotherapy (PT)	2	weeks to years	-	II-III
Splint therapy	12	16 (0.25-192)	60% (13%-100%)	III-IV
Combination therapy (Splint + PT ± SM)	11	10 (-)	84% (71%-100%)	III-IV
Arthrocentesis (AC)	36	10 (0.03-109)	73% (22%-100%)	III-IV
Arthroscopy (AS)	32	19 (0.25-163)	79% (50%-100%)	III-IV
Open surgery (OS)	8	22 (0.5-150)	86% (70%-100%)	III-IV

* Some studies compared between different treatment modalities and, therefore, incorporated more than once.

Table 4.4: Summary of findings for the effects of locking duration on the success of interventions used for TMJ CL management.

Mandibular manipulation (MM)

The studies used either manipulation only or manipulation assisted by hydraulic pumping to 'unlock' the jaw. Twenty included studies used unlock manipulation (UM) on DDwoR patients with a mean locking duration of 9 months (range: 0.03-180 months) with a variable success rate ranging from 9% to 100% (mean: 68%). Pumping manipulation (PM) was used in eight studies on DDwoR patients with a mean locking duration of 7 months (range: 0.07-120 months) with a comparable success rate (mean: 66%) to UM.

The included studies applied different manipulation techniques on DDwoR patients. The most commonly applied technique was Farrar's manipulation (Figure 2.8) (Farrar, 1978) and the most commonly used splint after recapturing the displaced disc was the anterior repositioning splint (ARS). Among all the manipulation studies included, only nine studies used post-manipulation imaging to assess disc recapturing with a variable success rate ranging from 4% to 100% (mean: 44%).

Self-management (SM) and physiotherapeutic (PT) interventions

Seven studies used a self-management treatment strategy consisting of education, self-care instructions, self-exercises, and medications on DDwoR patients with a locking duration ranging from 0.5 to 25 months with a mean success rate of 66% (range: 60%-72%). Only two studies used the jaw stretching exercises by physiotherapists as the sole treatment on DDwoR patients with locking duration ranging from several weeks to several years with a 'high' success rate.

Splint therapy

Occlusal splints were either used as a sole treatment or as an adjunct to other interventions in DDwoR management. Twelve studies used different types of splints as a sole treatment with DDwoR patients. These studies' sample had a mean locking duration of 16 months (range: 0.25-192) and a variable success rate ranging from 13% to 100% (mean: 60%). Eleven studies used splints adjunctively with other conservative interventions on DDwoR patients with a mean locking duration of 10 months with a mean success rate of 84% (range: 71%-100%).

Arthrocentesis (AC)

Thirty-six included studies used arthrocentesis and lavage on CL patients with a mean locking duration of 10 months (range: 0.03-109 months) with a mean success rate of 73% (range: 22%-100%). The arthrocentesis success rate, however, was higher in ADP (91%) than DDwoR (65%) studies.

Arthroscopy (AS)

Arthroscopic surgery was used in thirty-two included studies on CL patients with a mean locking duration of 19 months (range: 0.25-163 months) with a success rate ranging from 50% to 100% (mean: 79%).

Open surgery (OS)

Eight included studies used open joint surgery on CL patients with a mean locking duration of 22 months (range: 0.5-150 months) with a mean success rate of 86% (range: 70%-100%).

4.4.5 Acute and chronic closed lock timing definitions

Among the included studies, only 22 studies define the acute or chronic CL stages of their sample. There was, however, considerable variation in the threshold that defines acute and chronic stages of CL among these studies ranging from 1 to 9 months. The variability in studies' timing for acute and chronic CL stages according to locking duration is shown in Table 4.5.

Locking duration	**Timing of Acute-Chronic CL stages**	**Study**
1 month	ACL ≤ 1 mo CCL > 1 mo	Yuasa *et al.* (2001); Sembronio *et al.* (2008b); Saitoa *et al.* (2010); Ghanem (2011)
1.5-2 months	ACL ≤ 1.5-2 mo CCL > 1.5 mo	Van Dyke and Goldman (1990); Dimitroulis (2002)
2 months	ACL < 2 mo CCL ≥ 2 mo	Nadler (1988); Ozawa *et al.* (1996); Holmlund *et al.* (2001); Hamada *et al.* (2005)
3 months	CCL > 3 mo	Kumagai *et al.* (2010)
4 months	ACL < 4 mo CCL ≥ 4 mo	Ness (1996); Casares *et al.* (1999)
3-6 months	ACL < 3 mo, Sub-ACL = 3–6 mo CCL > 6 mo	Stiesch-Scholz *et al.* (2002b)
6 months	ACL < 6 mo CCL ≥ 6 mo	Kuwahara *et al.* (1990); Murakami *et al.* (1995); Hosaka *et al.* (1996); Emshoff and Rudisch (2004); Emshoff (2005); Politi *et al.* (2007); Schiffman *et al.* (2007)
3-9 months	Sub-ACL = 3–9 mo CCL > 9 mo	Clark *et al.* (1991)

Table 4.5: Summary of studies' timing for acute and chronic closed lock stages according to duration of locking.

4.5 Discussion

4.5.1 Summary of main findings

The main aim of this systematic review was to investigate the effects of locking duration on CL management outcome rather than to investigate the therapeutic effectiveness of interventions used for DDwoR management, which will be examined in the next chapter (Chapter 5). In this systematic review, therefore, 117 CL studies of different designs were included.

The studies were grouped on the basis of main treatment modality. Despite this grouping, there was considerable heterogeneity among the studies included. This heterogeneity, however, was anticipated from the wide inclusion criteria of this systematic review, and was attributed to substantial variations in: study design, diagnostic and inclusion criteria, participants' characteristics, interventions' delivery, techniques and their combinations, outcomes measures, success criteria, and follow-up periods.

Given the clinical and/or methodological heterogeneity of studies included, the main findings were summarised by each individual study in Appendix A. Although the success rates of interventions provided in Appendix A were based on the success criteria used by each study, most conservative and surgical interventions had 'acceptable' success rates in managing acute and chronic closed lock. Nevertheless, there were only very few studies that used clear and robust criteria in an attempt to examine treatment effects in relation to duration of symptoms of their sample. Consequently, this permitted only the possibility to examine the 'success' of a wide variety of interventions targeting many different putative predictive factors, in which the locking duration constitutes only one factor amongst all the potential prognostic factors.

In the studies included, numerous predictors other than locking duration and treatment type, frequency, and period were suggested, including: age, gender, level of pain, range of mandibular movements, parafunctional habits (clenching or bruxism), disc mobility, disc displacement direction and severity, joint inflammation, and stage and degree of intra-articular morphological and pathological changes in condyle-disc complex. Despite the proposed effects of these factors on CL management, it is still unclear if any of the suggested prognostic factors can predict the outcome of CL treatment because most studies had the shortcoming of not controlling the other predictors that may have

potential influence on treatment outcome. Amongst all the predictors suggested, only a few can be easily accessed via standard history and/or clinical examination such as patient's age, joint pain, mouth opening, locking duration, and parafunctional habits whereas others require more advanced imaging (e.g., MRI) or investigations (e.g., arthroscopy) to be addressed such as intra-articular adhesion, joint effusion, and cartilage and/or osseous changes. Duration of locking is very simply estimated by self-report, although the accuracy of patient's report may be influenced by several factors including recall bias.

In fact, it is unlikely that a single prognostic factor determines successful outcome when managing the CL patients. This is because many of the suggested 'prognostic' biomedical factors can interrelate or interact with each other to a greater or lesser degree. To give an example, the severity of intra-articular pathological changes and the stage of intra-articular derangement or degenerative changes may increase with the age of the patient and/or the duration of locking. Besides that, there are still no significant data on the role psychosocial factors may have in predicting outcome in CL.

At the moment, it should be accepted that several, as yet undefined, factors probably influence the outcome of CL management including not only the biomedical characteristics of the disorder but also the patients' psychosocial phenotype (Bernstein and Gatchel, 2000; Phaik, 2006; Dougall *et al.*, 2012; Mehalick *et al.*, 2013; Bouloux *et al.*, 2015). However, until there is a better understanding of these biopsychosocial factors, it seems entirely reasonable, within the ethos of modern medicine and consistent with the recent guidance on TMD management (Greene, 2010c), to avoid invasive surgical interventions in the initial phases of CL management.

Overall, one of the findings from this systematic review was that all the conservative or surgical interventions reviewed achieved 'acceptable' success rates in managing both acute and chronic closed lock. Amongst these interventions, mandibular manipulation (MM) is the simplest, quickest, least costly, and most practical and realistic approach that can be attempted first in every CL patient as an initial diagnostic/therapeutic intervention at the first point of contact. There is also some initial evidence to support its efficacy in 'early' intervention for patients with DDwoR (Chapter 5). Similarly, there is some evidence in the orthopaedic literature that early spinal manipulation improves symptoms quickly in patients with mechanical disc herniation causing acute lower back pain of less than 6 weeks duration (Santilli *et al.*, 2006; Kinkade, 2007). Therefore,

there is no reason for not adapting this ‘early’ management approach in mechanical TMJ disorders such as DDwoR. However, many research questions about this intervention remain unanswered and need to be clarified in future research (see Implications for future research in Chapter 8), one of these questions is: How long the time period that the manipulation can be attempted to achieve ‘successful’ outcome of TMJ disc recapturing on post-manipulation MRI? In this review, the time-span from initiation of CL that allows disc ‘repositioning’, as assessed by post-manipulation TMJ imaging investigation, could not be determined. Nonetheless, many studies in this review showed that the MM can be effective in achieving the successful outcome of improving the clinical symptoms of DDwoR patients (i.e., increasing opening and decreasing pain) without necessarily recapturing the displaced disc. Similarly, spinal manipulation has been shown to improve patients’ symptoms even when disc position appears unchanged at follow-up (Santilli *et al.*, 2006). In fact, TMJ manipulation as a treatment modality can aid both diagnosis and treatment and is unlikely to have adverse effects. There are, therefore, few significant contraindications to justify postponement of attempting to treat TMJ DDwoR initially through this simple approach.

Another interesting finding in this review was the considerable controversy in the definition of acute and chronic CL stages in relation to locking duration. This controversy may be attributed to variations in effectiveness of treatments and authors’ findings in their studies due to varying levels of chronicity in their sample. In other words, the progression from ACL to CCL is probably one of the potential reasons for confusing outcomes reported in the literature around CL management. In this review, some of the clinical trials involving patients with DDwoR defined their samples into ACL and CCL based on the chronicity of DDwoR (i.e., locking duration or time since DDwoR onset). The most reliable diagnostic criteria for DDwoR (Dworkin and LeResche, 1992; Schiffman *et al.*, 2014a), however, depend mainly on the patients’ signs and symptoms rather than the duration of symptoms in order to classify acute versus chronic DDwoR. Actually, a more appropriate clinical classification of acute and chronic DDwoR can be based on the time-scale for the possibility of recapturing the displaced disc into its normal anatomical position (i.e., from DDwoR to DDwR) with a non-invasive intervention. In this review, however, the transition point from acute to chronic CL stage and its implications on ‘early’ management could not be identified and needs further investigation. Similarly, the effects of locking duration on CL treatment outcomes remain unproven and need to be investigated in future research.

4.5.2 Overall completeness and applicability of evidence

The majority of studies included in this review were uncontrolled and did not examine the potential effect of placebo and/or the possible resolution of CL symptoms over time (Greene *et al.*, 2009; Yura, 2012). More importantly, only very few studies attempted, with adequate statistical power, to analyse the treatment effects according to duration of symptoms on a large sample size. Similarly, very few studies took in consideration the other potential prognostic factors, whether biomedical or psychosocial, that can influence the treatment outcome. All these shortcomings made it difficult to establish the 'real' effect of locking duration on CL treatment outcome. In this review, therefore, the evidence for the effects of locking duration on treatment outcome was contradictory and inconsistent. This may suggest that the degree of intra-articular pathological changes is more influential than the locking duration on CL treatment outcome but this, currently, cannot be established.

4.5.3 Quality of the evidence

The level of evidence in this review was of a low grade (III-IV) because the included studies were too heterogeneous and most were uncontrolled poor-quality studies. This suggests the need for better quality evidence to understand the effects of locking duration on closed lock management outcomes.

In this review, however, the quality assessment of the included studies was based solely on study design. Despite this was a suitable way to summarise the studies according to their designs (NHMRC, 2013), it did not totally illustrate the strength of the evidence as the study design is only one of numerous components contributing to evidence strength.

4.5.4 Potential biases in the review process

This review, to the best of the research team's knowledge, is the first comprehensive and systematic review that has investigated the effects of locking duration on CL treatment outcome. There were, however, some limitations in the review process related mainly to the review's wide inclusion criteria and possibility of publications and language biases.

The decision to include all the CL studies reporting the locking duration in their sample was made because the main aim of this systematic review was to investigate if there is

any relationship between locking duration and CL treatment outcome. To achieve this aim, however, a systematic search was conducted in only one database for English language publications. Searching multiple databases without language restrictions would help in the future to overcome these potential biases. Furthermore, there were a large number of CL studies that were initially identified but they did not report the duration of symptoms in their study sample and, therefore, were excluded. Similarly, many surgical trials included CL patients' not-responding to conservative interventions for several months (i.e., CCL) but they did not specify the exact duration of symptoms in their study sample and were also excluded. In addition, it should also be taken into consideration that the duration of locking data extracted from studies included may not be precise because they rely on the accuracy of the data reported by the patients with potential recall bias. Nevertheless, the large number of studies included in this review lessens the effects of these biases as the studies encompassed different treatment modalities representing a wide variety of interventions used for acute and chronic CL management.

4.6 Conclusions

The objectives of this systematic review were to assess the effects of duration of locking on the success of therapeutic interventions used in closed lock and to define the acute and chronic CL stages. In this review, all the reviewed interventions, whether conservative or surgical, achieved 'acceptable' success rates in managing both acute and chronic closed lock. Therefore, neither the transition point from acute to chronic CL stage nor the effects of locking duration on treatment outcome/success could be determined in this review and, hence, remained controversial. The studies included, however, were too heterogeneous and most were of poor-quality suggesting the need for better quality studies to understand the effects of locking duration on closed lock management outcomes. Until having a better understanding, management of patients with closed lock should be started initially with the simplest, cheapest, quickest, and most practical first diagnostic and treatment approach for this condition at the earliest given opportunity in the patient's healthcare journey. This intervention based on current evidence would seem to be mandibular manipulation.

The evidence from this review, however, was generally of a low grade because it was based mostly on uncontrolled studies. To identify the best available evidence for the clinical effectiveness of therapeutic interventions used for DDwoR management, a

systematic review on randomised controlled trials for DDwoR management is needed. This will be explored in the next chapter (Chapter 5).

Chapter 5. Effects of Therapeutic Interventions for the Management of TMJ Disc Displacement without Reduction: A Systematic Review

5.1 Introduction

Disc displacement without reduction (DDwoR) disorder as an advanced intra-articular biomechanical disorder is often associated with significant 'painful locking' symptoms (Okeson, 2007). In clinical practice, therefore, a wide variety of conservative and surgical treatment options have been suggested and used in an attempt to alleviate symptoms of patients with DDwoR. The necessity to identify the true effects of these interventions is crucial since to-date there is insufficient evidence to justify the use of many of them.

5.1.1 Contradictory confusing evidence of therapeutic interventions effects

In the literature, a plethora of studies have investigated the therapeutic effects of various conservative and surgical interventions for DDwoR but most, if not all, claim 'success'. This may have led to the multitude of conflicting opinions among authorities on how and when to manage DDwoR: conservatively, because it has a natural remitting course and, therefore, may need only to enhance the adaptive/healing process (de Leeuw *et al.*, 1994; Look *et al.*, 2014), or surgically because it is intuitively a mechanical problem, and, therefore, may need to intervene early by a manipulative/surgical 'mechanistic' solution to improve symptoms 'quickly' (Sembronio *et al.*, 2008b; Murakami, 2014). The contradictions in the evidence base for DDwoR management also occur within each group of conservative and surgical interventions with opinions divided over the role of physiotherapy (Nitzan *et al.*, 1997; Kurita *et al.*, 1999; Nicolakis *et al.*, 2001; Yuasa *et al.*, 2001; Stiesch-Scholz *et al.*, 2002a; Haketa *et al.*, 2010; Craane *et al.*, 2012b), splint therapy (Lundh *et al.*, 1992; Linde *et al.*, 1995; Sato *et al.*, 1995; Stiesch-Scholz *et al.*, 2002b; Minakuchi *et al.*, 2004; Stiesch-Scholz *et al.*, 2005), or use of adjunctive medication in arthrocentesis or arthroscopy (Alpaslan and Alpaslan, 2001; Aktas *et al.*, 2010a; Sipahi *et al.*, 2015). When treating patients with DDwoR, however, the mechanism of natural improvement in DDwoR signs and symptoms (Chapter 2, Section 2.2.5) must always be taken in consideration before evaluating the actual therapeutic effect of a particular intervention.

5.1.2 Why it is important to identify the therapeutic effects of these interventions?

In terms of clinical decision-making in the management of DDwoR, the competing concepts and diverse opinions in the literature may increase the degree of uncertainty in the therapeutic decision-making process among clinicians. This therapeutic decision-making is dependent on evidence quality (Gordon and Dionne, 2005). The lack of evidence on the most appropriate treatment for DDwoR may lead the management to be based more on experience than evidence (Durham *et al.*, 2007). In clinical practice, the variation in the management of DDwoR, may result in subjective decisions which may decrease the probability of making optimal therapeutic risk-benefit and/or cost-benefit decisions. As a consequence, patients may receive unnecessary investigations which delays their active management or may not receive the most appropriate treatment with the possibility of receiving unnecessary or even harmful treatment not supported by scientific evidence being applied.

One solution to overcome this problematic controversial issue is by applying the concept of 'evidence-based management'. Conti *et al.* (2003) stated that "the concept of Evidence Based Dentistry (EBD) must always guide clinical procedures, especially in a field where invasive and irreversible procedures with poor scientific evidence historically comprised standard management strategies". As seen in the previous chapter, different interventions of varying levels of invasiveness have been used for managing patients with DDwoR. Their clinical effectiveness, however, remains unclear. From the previous chapter (Chapter 4), there are some indications for the need to intervene initially by non-invasive conservative interventions. However, the most efficacious/effective approach is still unclear and needs to be clarified based on up-to-date best available evidence in order to optimise patients' healthcare and avoid any harmful or unnecessary treatment.

5.2 Aim

The aim of this systematic review was to investigate the effects of different conservative (non-surgical) and surgical therapeutic interventions used for the management of patients with DDwoR.

5.3 Methods

5.3.1 Study design

Systematic review.

5.3.2 Protocol and registration

This systematic review was conducted in accordance with the guidance of Cochrane Collaboration (Higgins and Green, 2011) and Centre for Reviews and Dissemination (CRD) (Akers *et al.*, 2009), and is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher *et al.*, 2009). The student was trained by attending a course in Cochrane systematic review methods. The review protocol was peer-reviewed by two TMD experts and registered at the international Prospective Register of Systematic Reviews (PROSPERO) database and, therefore, all the methods of inclusion/exclusion criteria and data collection/analysis were pre-specified and documented in advance. The protocol is available in Appendix B (Al-Baghdadi *et al.*, 2012).

5.3.3 Criteria for considering studies

The criteria for considering studies followed the PICOS criteria. A summary table for the inclusion/exclusion criteria is available in Appendix C.

Types of studies

Inclusion criteria

Randomised clinical trials (RCTs) involving patients with TMJ DDwoR and comparing any form of conservative or surgical interventions against each other, placebo or no treatment were considered. Quasi-randomised clinical trials (qRCTs), such as those allocated patients by using alternate days of the week, birth date, or consecutive attendance were considered only if the baseline demographic details (e.g., severity of condition) of each comparable group were approximately similar.

Studies involving other heterogeneous groups of TMD patients (e.g., DDwR, osteoarthritis, and myofascial pain) in addition to patients with DDwoR were considered if separate data for DDwoR patients were provided in the study. If separate

data were not provided but the percent of DDwoR patients in the study sample was more than 70%, the study was examined to be included.

Exclusion criteria

Studies comparing different types or techniques of the same treatment modality were excluded such as trials comparing different techniques of arthroscopy, different techniques of arthrocentesis, or those comparing different types of occlusal splints. In addition, studies evaluating interventions after an initial surgical modality such as trials evaluating different medications or splints after arthroscopy or arthrocentesis were also excluded.

Types of participants

Inclusion criteria

Patients of any age, gender, and of all degree of severity with clinical and/or radiological diagnosis of DDwoR as diagnosed according to: AAOP criteria for acute or chronic DDwoR (de Leeuw, 2008); RDC/TMD (IIb or IIc) criteria for DDwoR with/without limited opening (Dworkin and LeResche, 1992); Wilkes early/late intermediate stages (III or IV) of internal derangement (Wilkes, 1989); or any other compatible criteria for DDwoR diagnosis (Table 2.5) were considered. Confirming the disc position by soft tissue imaging was not a prerequisite to include the study.

Studies which involve participants with confirmed diagnosis of DDwoR disorder with comorbid disorders were also considered.

Exclusion criteria

DDwoR patients with systemic diseases were excluded.

Types of interventions

Inclusion criteria

Different forms of conservative or surgical therapeutic interventions for DDwoR were considered. The control was any alternative intervention, placebo, or no treatment.

The interventions were divided into different treatment modalities to be considered by their main treatment components such as: education, self-management, splint therapy,

physiotherapy, intra-articular injections, arthrocentesis, arthroscopic and open joint surgery. Studies that evaluate these groups of therapeutic interventions against each other, placebo or no treatment were included. Standardized combination of different treatments was also included.

Types of outcome measures

The main outcome measures considered were reduction in pain intensity and improvement of mouth opening. The outcomes were evaluated over short-term (≤ 3 months) and long-term (> 3 months) follow-up periods according to the International Association for the Study of Pain's definition of 'chronic pain' (Merskey and Bogduk, 1994; Dworkin *et al.*, 2011).

Primary outcomes

The primary outcomes focus on the main clinical symptoms of DDwoR:

- Pain (associated with the TMJs): patient assessed using any recognized validated pain scale (e.g., visual analogue scale 'VAS', numerical rating scale 'NRS', or multi-dimensional pain scale) either at rest or during jaw function (e.g., chewing). For this review, TMJ pain intensity during jaw function was considered as a primary outcome.
- Maximum mouth opening (MMO): this is the inter-incisal distance on maximum mouth opening (preferably including vertical incisal overbite), which could be assessed using any suitable instrument such as ruler, caliper, kinesiograph either actively (the patients open their jaw themselves) or passively (the clinician opens the jaw of the patient). For this review, the quantitative measurement for active/unassisted maximum mouth opening (aMMO) outcome was considered as a primary outcome.

Secondary outcomes

- Other mandibular movements: these include passive/assisted maximum mouth opening (pMMO), comfortable/painless maximum mouth opening (cMMO), laterusion, and protrusion, which could be assessed using any suitable instrument such as ruler, caliper, kinesiograph.

- Any self-assessed patient's satisfaction, quality of life, or mandibular function evaluated with a validated questionnaire such as OHIP-TMD or mandibular function impairment questionnaire (MFIQ).
- Operation/admission duration in studies involving surgical interventions: the operating time was recorded in minutes/hours and the duration of hospital admission was recorded in hours/days.
- Costs of therapy: the currency was recorded in £ or $.
- Adverse events: Any complications that happened during the therapy or thereafter were considered and their severity were examined. Some examples include: hypersensitivity or other adverse reactions to medications; post-treatment complications of occlusal interventions; post-surgical complications.

5.3.4 Search methods for identification of studies

Electronic searches

Four bibliographic databases were electronically-searched up to 1st November 2013:

- Cochrane Central Register of Controlled Trials (CENTRAL) (via the Cochrane Library, November 2013 issue)
- Medline via Ovid (1966-November 2013)
- Embase via Ovid (1980-November 2013)
- Scopus via SciVerse (1966-November 2013).

Detailed search strategies were developed for each database in order to identify the studies to be included or considered for this review. The search strategies were developed primarily for the Medline and then revised appropriately for each database to take into account the differences in controlled vocabulary and syntax rules. A detailed description of Medline search strategy is shown in Table 5.1.

Ovid Medline (R) <1966 to October Week 4 2013>

1. exp Temporomandibular Joint disorders/
2. exp Temporomandibular Joint/
3. 1 or 2
4. (temporomandibular joint or tmj).tw.
5. (derangement adj6 (disorder$ or condition$)).tw.
6. (derangement adj2 internal).tw.
7. (lock$ adj2 (closed or jaw)).tw.
8. ((displace$ or dislocat$ or unreduc$ or nonreduc$ or un-reduc$ or non-reduc$ or derange$) adj6 (disc or disk or meniscus)).tw.
9. or/4-8
10. 3 and 9

The above subject search was linked to the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised controlled trials (RCTs) in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the Cochrane Handbook for Systematic Reviews of Interventions version 5.1.0 (updated March 2011) (Lefebvre *et al.*, 2011):

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

Table 5.1: Medline search strategy.

Manual searches

Other sources were manually-searched to identify any additional studies including: citation search of included studies, reference lists of included studies, along with the reference lists of relevant review articles and textbooks' chapters. In addition, the following journals were identified as being potentially important to be hand-searched for this review as they were highly likely journals to contain relevant studies to the review topic:

1. Journal of Oral and Maxillofacial Surgery (from 2010 to October 2012).
2. Cranio: Journal of Craniomandibular Practise, currently Journal of Craniomandibular & Sleep Practice (from 1996 to October 2012).
3. Journal of Prosthetic Dentistry (from 1999 to September 2012).
4. Journal of Oral Rehabilitation (from 2004 to October 2012).

5. Journal of Orofacial Pain, currently Journal of Oral & Facial Pain and Headache (from 1987 to December 2012).
6. Oral Surgery, Oral Medicine, Oral Pathology, and Oral Radiology (from 2004 to February 2012).
7. International Journal of Oral & Maxillofacial Surgery (from 2003 to October 2012).

The tables of contents in these journals, including the journals' list of future publications, were hand-searched by the student to identify eligible studies from their title/abstract. All the journals were hand-searched according to dates not already have been hand-searched as part of the Cochrane worldwide hand-searching programme (i.e., according to Master List of journals completed search by the Cochrane Oral Health Group up to October 2012).

Personal contact

All the authors of eligible studies were contacted by electronic mail and asked for clarification and missing data as necessary.

Search limits

English language, Peer reviewed publications. Conference proceedings and abstracts were not included in this review.

5.3.5 Data collection and analysis

Data collection and analysis was performed in accordance with the Cochrane Collaboration guidelines using the review manager software (V. 5.2) (RevMan, 2012).

Selection of studies

Eligible studies were selected by the student according to the inclusion/exclusion criteria based on the title and abstract (when available) of all reports identified through the electronic and manual searches. Clearly irrelevant reports were identified by their title/abstract and were excluded by the student. If it is unclear whether a study should be included the full-text was consulted. The full-texts of all potentially eligible studies were then retrieved and independently examined in-duplicate by the student and one of the supervisors (JD) to establish eligibility. To ensure reliability, blinding procedures

were used for the supervisor (JD) regarding the author's names, institutions, and/or journal. Disagreements about inclusion/exclusion between the two were resolved through discussion to reach consensus or, when necessary, by discussion with another supervisor (JS) to reach consensus. All studies that met the inclusion criteria were then underwent quality assessment and data extraction. Studies excluded at this stage or subsequent stages were identified and the reasons for exclusion were recorded in the "characteristics of excluded studies" table.

Data extraction and management

Data extraction was informed by the standard extraction strategies set out in the Cochrane Handbook for Systematic Reviews of Interventions and study details were entered into the "characteristics of included studies table". A standardised, pre-piloted form based on Cochrane recommendations was used to extract data from the included studies. The extraction form is available in Appendix D. In brief, the information extracted from each included study involved details about the following:

- Trial methods
- Participant characteristics
- Interventions
- Control
- Outcomes
- Results
- Authors' conclusions
- Sources of funding and conflicts of interest (if stated).

The data were extracted by the student and their validity was crosschecked by one of the supervisors (JD 'blinded'). Any disagreements between the two were resolved through discussion to reach consensus or, when necessary, by discussion with another supervisor (JS) to reach consensus. Authors of the studies included were contacted via e-mail to clarify study design and/or request missing data as required.

Assessment of risk of bias in included studies

Before data analysis, the methodological quality of all studies included was appraised and assessed independently and in-duplicate by the student and one of the supervisors

(JD ‘blinded’) using the Cochrane risk of bias tool (Higgins *et al.*, 2011a): random sequence, allocation concealment, blinding, incomplete data, selective reporting, and other potential sources of bias. Each domain in the tool was allocated one of the following judgments: low risk of bias, unclear risk of bias, or high risk of bias. Disagreements over the risk of bias in particular studies were resolved by discussion between the two to reach consensus or, when necessary, by discussion with another supervisor (JS) to reach consensus. All data on quality were tabulated and summarised appropriately. Sample size calculation for statistical power was also examined using G*3 Power statistical package (v. 3.1.7).

Data analysis

The main data analysis for this review was performed according to the Cochrane statistical guidelines (Higgins and Green, 2011) using Review Manager software (V. 5.2) (RevMan, 2012) comparing between the effects of different interventions (i.e., between-group statistical differences). P value < 0.05 for between-group difference was considered statistically significant.

Measures of treatment effect

The estimates of effect of an intervention were expressed as risk ratios (RR) with 95% confidence intervals (CI) for dichotomous data, and as mean differences (MD) with 95% CI for continuous data.

Unit of analysis issues

The units of primary outcomes (pain and MMO) were measured in millimetres. For uniformity, data were analysed and presented for pain intensity by rescaling the 0-10 cm VAS or NRS to 0-100 mm scale.

Dealing with missing data

The authors of the included studies were contacted to request missing data whenever possible. If the data were unobtainable, attempts were made (using SPSS ‘v. 22’ or Excel spread sheets ‘v. 14’) to calculate the missing data from the available reported data as suggested by the Cochrane handbook for dealing with missing data (Higgins *et al.*, 2011b). The analyses involved the available/obtainable data but no statistical

methods were used to impute for missing continuous data related to withdrawals or drop-outs (i.e., attrition).

Assessment of heterogeneity

Clinical and statistical heterogeneities were assessed across the studies prior to pooling. Clinical heterogeneity was determined by examining the clinical characteristics of the included studies. This includes examining any clinical diversity or variation in: types of interventions (e.g., dosage, technique, and mode of delivery), severity/chronicity of condition (i.e., acute vs. chronic), and treatment outcomes (e.g., pain, MMO) in each study as these may have an effect on the intervention effect-size. Statistical heterogeneity was examined by Chi^2 and I^2 statistics (Higgins and Thompson, 2002). Substantial heterogeneity was considered to be present when there was a significant p value < 0.05 for Chi^2 test and an I^2 statistic $> 50\%$ (Deeks *et al.*, 2011).

Data synthesis and investigation of heterogeneity

The included studies were grouped according to type of therapeutic interventions. Pooling of clinically and statistically homogeneous trials to provide estimates of the effects of the interventions was attempted. If there were two trials pooled, a fixed-effect model was used; but if there were more than two trials, a random-effects model was used. Meta-analysis was not undertaken when there was substantial heterogeneity among studies; instead, the review data were integrated in a narrative synthesis of the findings from the included studies structured around types of interventions with a descriptive analysis only. The available results for the outcomes of interest were tabulated if they could not be included in a proper meta-analysis.

Assessment of reporting biases

A test for funnel plot asymmetry to assess publication bias (Egger *et al.*, 1997) was planned to be performed only if a sufficient number of included studies suitable for inclusion in a meta-analysis were identified. However, it was not performed due to insufficient numbers of studies pooled in the meta-analyses.

Subgroup analysis

A subgroup analysis based on chronicity of closed lock condition (acute or chronic) was conducted when possible. The time-span from onset of DDwoR that allows disc 'recapture' is probably the most suitable way for determination the transition time-point from acute to chronic closed lock. Although this was undetermined in the previous systematic review (Chapter 4), in this review, the threshold of acute DDwoR was estimated at a cut-off point of 1 month duration of locking as suggested in many previous studies (Sembronio *et al.*, 2008b; Saitoa *et al.*, 2010; Ghanem, 2011). This estimated period was also based on the 'assumption' that the disc may be less likely 'recapture' after 1 month as suggested in the available literature (Farrar, 1978); although this requires further investigation to be proven.

Sensitivity analysis

A sensitivity analysis was performed, when appropriate, to demonstrate if there was any effect of the wide diagnostic inclusion criteria decision on primary outcomes in the meta-analyses. This was performed by excluding the trials that did not radiographically confirm DDwoR clinical diagnosis by soft tissue imaging.

Additional analysis

A supplementary data analysis was also performed by examining the change from baseline in primary outcomes for each individual intervention at short- and long-term follow-up periods (i.e., within-group statistical difference from baseline). If mean change and standard deviation (SD) for mean change was not reported in the studies, differences in means and SD for differences were calculated according to guidance in the literature (Cohen, 1988; Markiewicz *et al.*, 2008; Fritz *et al.*, 2012; Katsnelson *et al.*, 2012) using an Excel sheet (v. 14). If within-group statistical difference (p value < 0.05) from baseline was not reported in the studies, it was calculated by the paired t test for summarised data (mean differences) using the Minitab statistical package (v. 16). This separate analysis was performed to help better understand and interpret the potential clinical significance of improvement from baseline for the primary outcomes of each intervention.

5.4 Results

5.4.1 Search results

A total of 3333 records were identified from all databases. The search strategy identified 3307 records from electronic searches (477 CENTRAL, 1347 Medline, 689 Embase, and 794 Scopus) which after removal of duplicates resulted in 2288 records. After the initial screening of the titles and abstracts of these records, 2116 records were excluded as irrelevant to the topic of this review. Full-text copies of potentially eligible papers were then retrieved and 26 additional reports were obtained through hand-searching other sources resulted in a total of 172 full-texts being reviewed. Of these, 86 were eliminated and excluded from further assessment for two main reasons: non-randomised trials or trials' participants received no specific TMD diagnosis or other diagnosis than DDwoR. This left 86 potentially relevant studies which their full-text copies were re-examined carefully and after close reading, 52 further studies (of 62 reports) were excluded for different reasons summarised in the characteristics of excluded studies' table. Finally, 24 reports represented 20 studies met the review inclusion criteria. Figure 5.1 illustrates the screening process.

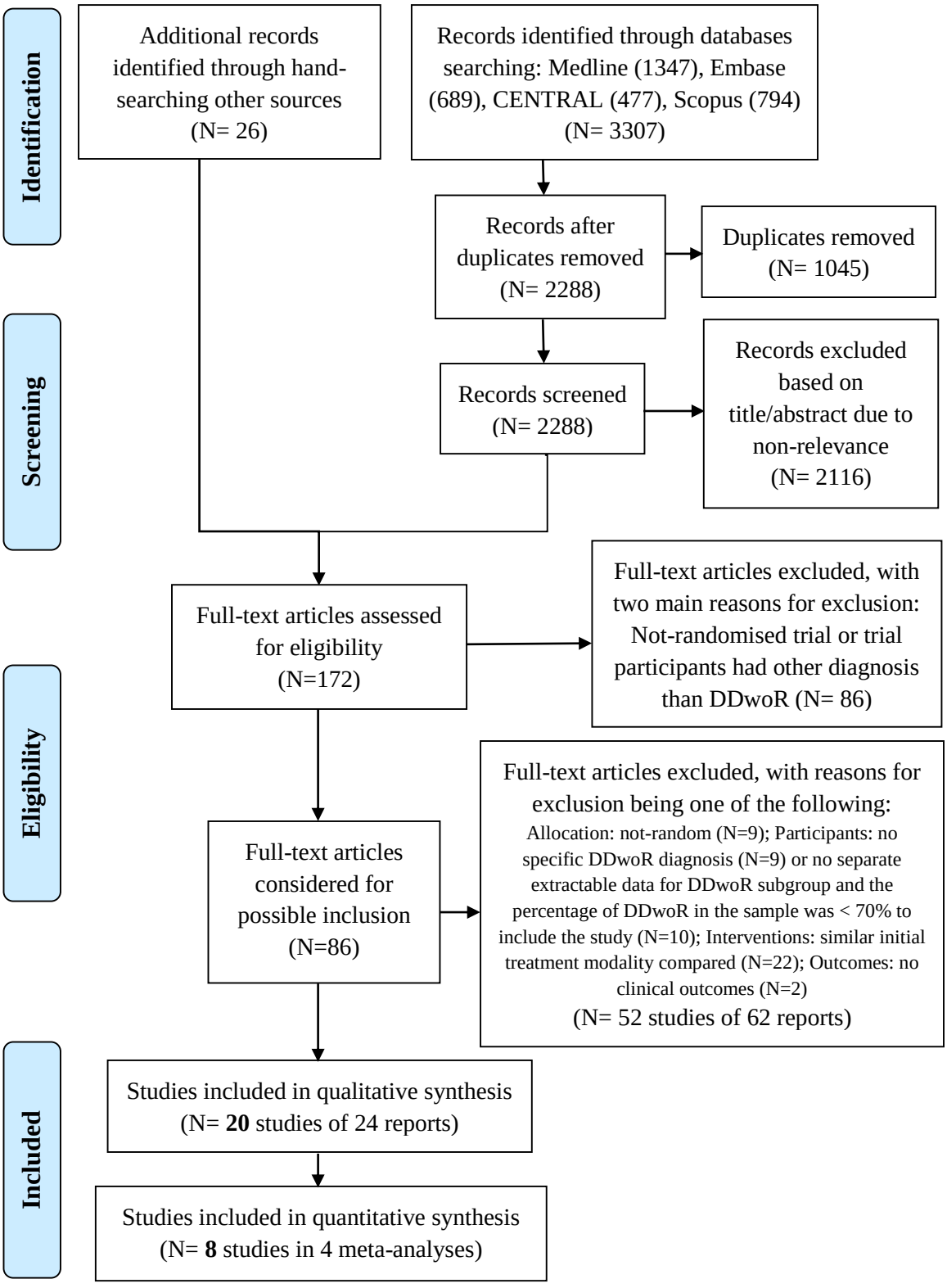


Figure 5.1: Study flow diagram. Adapted from PRISMA 2009 flow diagram (Moher *et al.*, 2009).

5.4.2 Description of studies

Included studies

Twenty studies (of 24 reports) fulfilled the review inclusion criteria (Lundh *et al.*, 1992; Petersson *et al.*, 1994; Linde *et al.*, 1995; Fridrich *et al.*, 1996; Schiffman *et al.*, 1996; Goudot *et al.*, 2000; Holmlund *et al.*, 2001; Minakuchi *et al.*, 2001; Yuasa *et al.*, 2001; Maloney *et al.*, 2002; Yuasa *et al.*, 2003; Minakuchi *et al.*, 2004; Peroz *et al.*, 2004; Yoshida *et al.*, 2005a; Ismail *et al.*, 2007; Politi *et al.*, 2007; Schiffman *et al.*, 2007; Diracoglu *et al.*, 2009; Haketa *et al.*, 2010; Yoshida *et al.*, 2011; Craane *et al.*, 2012a; Sahlstrom *et al.*, 2013; Yoshida *et al.*, 2013; Schiffman *et al.*, 2014b). The characteristics of included studies are described below and summarised in the characteristics of included studies' table available in Appendix E.

Characteristics of trial design and setting

Of the 20 trials, 19 had a randomised study design whilst one trial had a quasi-random study design (Diracoglu *et al.*, 2009). Of the included trials, one trial had 4 parallel arms (Schiffman *et al.*, 2007), four trials had 3 parallel arms (Schiffman *et al.*, 1996; Minakuchi *et al.*, 2001; Maloney *et al.*, 2002), whilst the remaining trials had 2 parallel arms. Blinding was attempted in 11 trials at least in one step (Petersson *et al.*, 1994; Schiffman *et al.*, 1996; Minakuchi *et al.*, 2001; Yuasa *et al.*, 2001; Peroz *et al.*, 2004; Schiffman *et al.*, 2007; Diracoglu *et al.*, 2009; Haketa *et al.*, 2010; Craane *et al.*, 2012a; Sahlstrom *et al.*, 2013).

Of the 20 included trials, five trials were conducted in Japan (Minakuchi *et al.*, 2001; Yuasa *et al.*, 2001; Yoshida *et al.*, 2005a; Haketa *et al.*, 2010; Yoshida *et al.*, 2011), five in Sweden (Lundh *et al.*, 1992; Petersson *et al.*, 1994; Linde *et al.*, 1995; Holmlund *et al.*, 2001; Sahlstrom *et al.*, 2013), four in the USA (Fridrich *et al.*, 1996; Schiffman *et al.*, 1996; Maloney *et al.*, 2002; Schiffman *et al.*, 2007), two trials in Germany (Peroz *et al.*, 2004; Ismail *et al.*, 2007), and one trial conducted each of Belgium (Craane *et al.*, 2012a), France (Goudot *et al.*, 2000), Turkey (Diracoglu *et al.*, 2009), and Italy (Politi *et al.*, 2007).

The included trials were published between 1992 and 2013, with 16 trials were published from 2000 onward. Four trials had a follow-up publication for the conducted trial (Yuasa *et al.*, 2003; Minakuchi *et al.*, 2004; Yoshida *et al.*, 2013; Schiffman *et al.*,

2014b). Eight of the trials received funding (Lundh *et al.*, 1992; Petersson *et al.*, 1994; Schiffman *et al.*, 1996; Minakuchi *et al.*, 2001; Maloney *et al.*, 2002; Peroz *et al.*, 2004; Schiffman *et al.*, 2007; Haketa *et al.*, 2010) and two trials did not (Craane *et al.*, 2012a; Sahlstrom *et al.*, 2013), whilst the remaining 10 trials did not report about funding.

The period of follow-up in the included trials were ranged from 1 day to 5 years with just one trial conducted follow-up for 5 years (Schiffman *et al.*, 2007). Twelve trials had withdrawals or loss to follow up (Petersson *et al.*, 1994; Linde *et al.*, 1995; Fridrich *et al.*, 1996; Holmlund *et al.*, 2001; Minakuchi *et al.*, 2001; Yuasa *et al.*, 2001; Peroz *et al.*, 2004; Schiffman *et al.*, 2007; Diracoglu *et al.*, 2009; Haketa *et al.*, 2010; Craane *et al.*, 2012a; Sahlstrom *et al.*, 2013), whilst 7 trials had no dropouts (Lundh *et al.*, 1992; Schiffman *et al.*, 1996; Goudot *et al.*, 2000; Maloney *et al.*, 2002; Politi *et al.*, 2007; Yoshida *et al.*, 2011), and one trial had unclear follow-up period and dropouts (Yoshida *et al.*, 2005a).

Characteristics of participants

A total of 1305 participants were included in this review, of which, 1288 had a DDwoR diagnosis. The sample size of the included trials varied widely. The smallest trial had 19 participants (N = 15 DDwoR) (Fridrich *et al.*, 1996) and the largest had 305 participants (Yoshida *et al.*, 2005a). While most of the included trials were conducted using a homogenous sample of DDwoR diagnosis, five of the included trials had heterogeneous samples. Of these 5 trials, separate data for DDwoR subgroup were obtained and/or extracted from 2 trials (Maloney *et al.*, 2002; Peroz *et al.*, 2004), whilst the other 3 trials had more than 70% DDwoR patients in their sample and, therefore, were included (Fridrich *et al.*, 1996; Goudot *et al.*, 2000; Ismail *et al.*, 2007).

The majority of participants were females (~86%) resulting in a 6:1 female to male ratio. The age of the participants ranged from 14 to 81 years (mean = 35 years). Data on duration of DDwoR symptoms were not always reported, but ranged from 1 day to 16 years in the fifteen trials reporting data on duration of symptoms. According to 'estimated' 1 month duration of locking cut-off point for acute-chronic DDwoR, six trials included patients with chronic DDwoR (Goudot *et al.*, 2000; Holmlund *et al.*, 2001; Minakuchi *et al.*, 2001; Peroz *et al.*, 2004; Politi *et al.*, 2007; Sahlstrom *et al.*, 2013), eight trials included acute-chronic mixed DDwoR patients (Linde *et al.*, 1995; Yuasa *et al.*, 2001; Yoshida *et al.*, 2005a; Ismail *et al.*, 2007; Schiffman *et al.*, 2007;

Haketa *et al.*, 2010; Yoshida *et al.*, 2011; Craane *et al.*, 2012a), whilst only one trial included exclusively acute DDwoR patients (Diracoglu *et al.*, 2009).

Five of the included trials reported using the RDC/TMD (Maloney *et al.*, 2002; Peroz *et al.*, 2004; Ismail *et al.*, 2007; Craane *et al.*, 2012a; Sahlstrom *et al.*, 2013) whilst the remaining 15 trials recruited patients using criteria compatible with the RDC/TMD diagnosis for DDwoR. Of the included trials, 15 trials confirmed DDwoR clinical diagnosis by soft tissue imaging, specifically: 11 trials by MRI (Fridrich *et al.*, 1996; Goudot *et al.*, 2000; Minakuchi *et al.*, 2001; Yuasa *et al.*, 2001; Maloney *et al.*, 2002; Ismail *et al.*, 2007; Politi *et al.*, 2007; Schiffman *et al.*, 2007; Diracoglu *et al.*, 2009; Haketa *et al.*, 2010; Sahlstrom *et al.*, 2013), 2 trials by MRI in some patients (Peroz *et al.*, 2004; Craane *et al.*, 2012a), and 2 trials by arthrography (Lundh *et al.*, 1992; Petersson *et al.*, 1994).

Characteristics of interventions

It was anticipated in advance in the review protocol (Appendix B) that a wide variety of interventions were being used for DDwoR management. Grouping the interventions to summarise the main findings related to each treatment modality used for DDwoR was necessary but it was difficult decision to make due to different combinations of interventions used, which differed sometimes from the pre-specified treatment grouping in the protocol. Nevertheless, for the purpose of this review, the treatment strategies of reviewed therapeutic interventions were classified into three levels of invasiveness involving different treatment modalities considered by their main treatment components as demonstrated in Table 5.2.

Accordingly, twenty-one comparisons were made between different interventions as follows: 12 comparisons among non-invasive conservative interventions; 3 comparisons between minimally-invasive surgical interventions and non-invasive conservative interventions; 4 comparisons between invasive surgical interventions and non-invasive conservative interventions; 1 comparison between minimally-invasive and invasive surgical interventions; and 1 comparison among invasive surgical interventions.

Intervention	Description
1. Non-invasive	Involves any conservative (non-surgical) interventions.
• Patient education	Includes information, explanation, and reassurance only.
• Self-management	Includes self-care instructions and advice plus pharmacotherapy (any topical or oral medication such as: over-the-counter analgesic, NSAIDS, muscle relaxants) ± self-exercises (home exercise programmes).
• Splint therapy	Includes different types of occlusal splints such as: stabilisation splints, repositioning splints, or soft splints.
• Physiotherapy	Includes different approaches of physical therapy such as: - Mandibular manipulation (MM): a 'singular' manual mandibular manipulation technique to 'unlock' the jaw and recapture the displaced disc (disc repositioning). - Jaw exercises: 'repeated' jaw 'stretching' exercises applied either by the patients themselves (home exercise programme 'self-exercises') or by clinicians (professional exercise therapy 'active or passive jaw exercises'). - Other physiotherapeutic modalities: ultrasound therapy, short wave diathermy, iontophoresis, transcutaneous electric nerve stimulation (TENS), pulsed electromagnetic fields (PEMF), or low level laser therapy (LLT).
• Combination therapy	Includes splints plus jaw exercises ± (self-care/medication/ education ± psychosocial 'cognitive behavioural' therapy 'CBT').
2. Minimally-invasive	Involves any intra-articular intervention by needles only.
• Arthrocentesis	A technique using needles and injections for joint hydraulic pumping and lavage inside the superior joint space.
3. Invasive	Involves any surgical interventions.
• Arthroscopic surgery	A technique using an arthroscope for joint hydraulic pumping and lavage and/or any other operative arthroscopic operations inside the superior joint space.
• Open joint surgery	A technique using a skin incision to approach the temporomandibular joint such as discoplasty, discectomy, eminectomy, or condylectomy.

Table 5.2: Description of interventions.

Characteristics of outcomes

All bar one trial (Yoshida *et al.*, 2011) considered pain intensity of the TMJ as an outcome and all bar two trials (Lundh *et al.*, 1992; Schiffman *et al.*, 2007) assessed/reported the mouth opening outcome whilst only 11 trials assessed the daily activity interference and/or jaw functional limitation (Fridrich *et al.*, 1996; Schiffman *et al.*, 1996; Holmlund *et al.*, 2001; Minakuchi *et al.*, 2001; Yuasa *et al.*, 2001; Peroz *et al.*, 2004; Politi *et al.*, 2007; Schiffman *et al.*, 2007; Haketa *et al.*, 2010; Craane *et al.*, 2012a; Sahlstrom *et al.*, 2013).

In the included trials, the objective 'clinician-measured' outcomes of mandibular movements such as mouth opening, protrusive, and laterusive movements were usually measured by a ruler and expressed in millimetres. The subjective 'patient-reported' outcomes of pain intensity and functional limitation, however, were measured using different tools and scales. For pain intensity, the visual analogue scale (VAS) was the most frequently used scale to assess pain intensity in 17 trials, but it was sometimes calibrated differently, either 0-10 cm or 0-100 mm, across different studies. Other alternative or additional tools were also used to assess pain including: numerical rating scale (NRS) (Maloney *et al.*, 2002); McGill pain questionnaire (MPQ), total pain rating index (PRI), and total number of words chosen (NWCtotal) (Craane *et al.*, 2012a); characteristic pain index (CPI) and graded chronic pain scale (GCPS) (Sahlstrom *et al.*, 2013); symptoms severity index (SSI) (Schiffman *et al.*, 1996; Schiffman *et al.*, 2007). For functional limitation, different tools were also used by the 11 trials including: mandibular function impairment questionnaire (MFIQ) (Holmlund *et al.*, 2001; Politi *et al.*, 2007; Craane *et al.*, 2012a); jaw functional limitation scale (JFLS) (Sahlstrom *et al.*, 2013); restriction of daily life activities (by VAS) (Peroz *et al.*, 2004); interference with daily life (by VAS) (Yuasa *et al.*, 2001); daily activity limitation (DAL) (Minakuchi *et al.*, 2001), limitation of daily functions (LDF) (Haketa *et al.*, 2010); jaw mobility and dietary alterations (Fridrich *et al.*, 1996); craniomandibular index (CMI) (Schiffman *et al.*, 1996; Schiffman *et al.*, 2007).

The operative/admission duration was reported in two surgical trials (Holmlund *et al.*, 2001; Politi *et al.*, 2007) and the cost of interventions was reported in a follow-up report of one trial (Schiffman *et al.*, 2014b).

Adverse effects of interventions were observed and reported in 6 trials (Linde *et al.*, 1995; Schiffman *et al.*, 1996; Goudot *et al.*, 2000; Holmlund *et al.*, 2001; Politi *et al.*, 2007; Schiffman *et al.*, 2007), whilst no adverse events were observed in 4 trials (Petersson *et al.*, 1994; Fridrich *et al.*, 1996; Yuasa *et al.*, 2001; Haketa *et al.*, 2010). The remaining 10 trials did not report about adverse events.

Excluded studies

All 52 studies (of 62 reports) which did not meet the inclusion criteria of this review were excluded and the reasons for their exclusion are detailed in the characteristics of excluded studies' table available in Appendix F. The main reasons for exclusion of

many of these studies were related to the characteristics of the enrolled participants, the comparative interventions, and/or study design:

- Other TMD than DDwoR or no specific DDwoR diagnosis (Gray *et al.*, 1991; Gray *et al.*, 1994b; Carmeli *et al.*, 2001; Nguyen *et al.*, 2001; Wahlund *et al.*, 2003; Sanroman, 2004; Nunez *et al.*, 2006; Oliveras-Moreno *et al.*, 2008; Ziegler *et al.*, 2010).
- Mixed TMD sample with no separate data reported/obtained for patients with DDwoR and the percent of DDwoR patients in the study sample was less than 70% to include the whole trial (Bertolami *et al.*, 1993; Stegenga *et al.*, 1993b; Reid *et al.*, 1994; McNamara *et al.*, 1996; Ekberg *et al.*, 1998; Kulekcioglu *et al.*, 2003; Nilsson *et al.*, 2009; Marini *et al.*, 2010; Nascimento *et al.*, 2013; Katyayan *et al.*, 2014). Three of these excluded studies (Bertolami *et al.*, 1993; Reid *et al.*, 1994; Marini *et al.*, 2010) were originally included but after further assessment, no numerical data were obtained for DDwoR subgroup and the number of patients with DDwoR was less than 70% in the trial sample size and were eventually excluded.
- Similar treatment modality of the comparable groups (Miyamoto *et al.*, 1999; Schmitter *et al.*, 2005b; Stiesch-Scholz *et al.*, 2005; Long *et al.*, 2009; Matsumoto *et al.*, 2011).
- Similar initial surgical treatment modality of the comparable groups (McCain *et al.*, 1989; Bryant *et al.*, 1999; Alpaslan and Alpaslan, 2001; Furst *et al.*, 2001; Prager *et al.*, 2007; Zuniga *et al.*, 2007; Alpaslan *et al.*, 2008; Arinci *et al.*, 2009; Aktas *et al.*, 2010b; Aktas *et al.*, 2010a; Morey-Mas *et al.*, 2010; Ghanem, 2011; Hamed, 2012; Elsholkamy *et al.*, 2013; Emes *et al.*, 2013; Hammuda *et al.*, 2013).
- Study design not eligible for this review (non-randomised trials) (Murakami *et al.*, 1995; Sato *et al.*, 1997b; Sato *et al.*, 2001a; Stiesch-Scholz *et al.*, 2002a; Hall *et al.*, 2005b; Sato and Kawamura, 2008; Machon *et al.*, 2012; Yucel *et al.*, 2014).
- Not a treatment study (Kaplan *et al.*, 1989).
- Outcomes not relevant (Gu *et al.*, 1998; Hirota, 1998).
- Poor quality and protocol violation (Bertolucci and Grey, 1995b).

5.4.3 Risk of bias in included studies

The authors of all included studies were contacted for clarification about study design and/or missing data by electronic mail. Useful information and further clarification of study design were obtained on six of the included trials (Petersson *et al.*, 1994; Schiffman *et al.*, 1996; Holmlund *et al.*, 2001; Yuasa *et al.*, 2001; Schiffman *et al.*, 2007). The individual domain risk of bias assessment for each study is shown in Figure 5.2 and the risk of bias judgements for the included studies are detailed below.

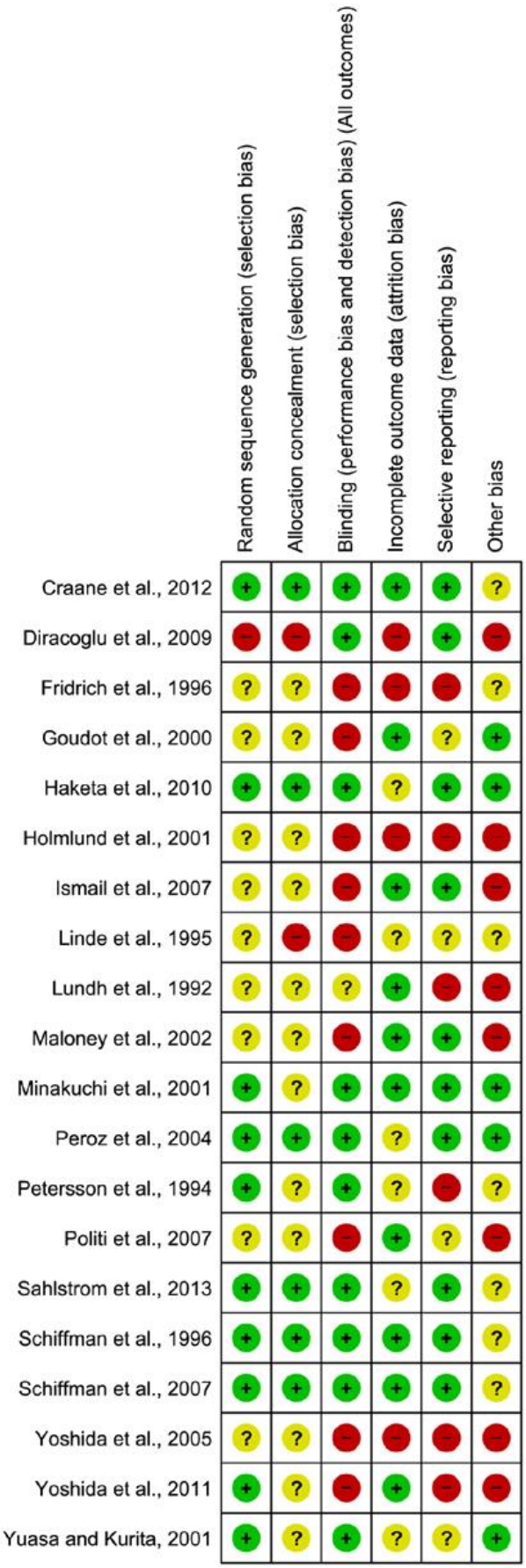


Figure 5.2: The individual domain risk of bias for each study. Symbols: + Low risk of bias, ? Unclear risk of bias, - High risk of bias.

Allocation (selection bias)

Sequence generation

Of the included trials, only 10 had adequate sequence generation and were assessed as being at low risk of bias for this domain. Of these 10 trials, three trials used random number tables (Schiffman *et al.*, 1996; Haketa *et al.*, 2010; Sahlstrom *et al.*, 2013), and each one of the remaining 7 trials used either third party randomisation (Schiffman *et al.*, 2007), shuffling envelopes (Peroz *et al.*, 2004), computer-generated-random-number (Minakuchi *et al.*, 2001), lottery system (Petersson *et al.*, 1994), truncated binomial design (Yoshida *et al.*, 2011), electronically generated blocks (Craane *et al.*, 2012a), or stratified block randomisation (Yuasa *et al.*, 2001). Apart from the others, one trial had inadequate sequence generation by alternate allocation (Diracoglu *et al.*, 2009) and assessed as being at high risk of bias for this domain, whilst the remaining 10 trials provided insufficient details about the method of sequence generation and were assessed as being at unclear risk of bias for this domain.

Allocation concealment

Six trials described adequate allocation sequence concealment and were assessed as being at low risk of bias for this domain (Schiffman *et al.*, 1996; Peroz *et al.*, 2004; Schiffman *et al.*, 2007; Haketa *et al.*, 2010; Craane *et al.*, 2012a; Sahlstrom *et al.*, 2013). Two trials had no concealed allocation and assessed as being at high risk of bias for this domain (Linde *et al.*, 1995; Diracoglu *et al.*, 2009). For the remaining 12 trials allocation concealment was not reported or described in enough detail and these studies were assessed as being at unclear risk of bias for this domain.

Blinding (performance bias and detection bias)

It is notable that due to the nature of most of the interventions being studied, blinding was not feasible for participants or healthcare providers except in 2 double-blinded studies. Furthermore, blinding of outcome assessors was not always possible for patient-reported outcomes. Therefore, the overall risk of bias in blinding of participants, personal, outcome assessors, and data analysts for all outcomes was evaluated under a single domain.

Two trials were double-blinded (Schiffman *et al.*, 1996; Peroz *et al.*, 2004), and 8 trials were single-blinded (Petersson *et al.*, 1994; Minakuchi *et al.*, 2001; Yuasa *et al.*, 2001; Schiffman *et al.*, 2007; Diracoglu *et al.*, 2009; Haketa *et al.*, 2010; Craane *et al.*, 2012a; Sahlstrom *et al.*, 2013). Consequently, 10 of the included trials were assessed as being at low risk of performance and detection bias. Only one trial was assessed as being at unclear risk of bias for this domain due to unfeasible blinding for the patients-reported outcomes (Lundh *et al.*, 1992). The remaining 9 trials did not provide any information about the blinding which is assumed to be not attempted and were assessed as being at high risk of bias for this domain.

Incomplete outcome data (attrition bias)

Ten of the 20 included trials were assessed as being at low risk of bias with regard to incomplete outcome data. In these 10 trials, seven trials had no dropouts (Lundh *et al.*, 1992; Schiffman *et al.*, 1996; Goudot *et al.*, 2000; Maloney *et al.*, 2002; Ismail *et al.*, 2007; Politi *et al.*, 2007; Yoshida *et al.*, 2011), and the other 3 trials had dropouts but adequately applied the intention-to-treat (ITT) analysis (Minakuchi *et al.*, 2001; Schiffman *et al.*, 2007; Craane *et al.*, 2012a). Six of the included trials were assessed as being at unclear risk of bias for this domain due to two main reasons: too few patients (one or two) dropped-out and excluded from analysis without reporting the reason for withdrawals in 3 trials (Petersson *et al.*, 1994; Linde *et al.*, 1995; Peroz *et al.*, 2004); or the ITT principle was either partially or inadequately applied in 3 trials (Yuasa *et al.*, 2001; Haketa *et al.*, 2010; Sahlstrom *et al.*, 2013). The remaining 4 trials were assessed as being at high risk of bias for this domain due to patient withdrawals related to the interventions' adverse effects and/or high or unclear dropouts without applying ITT analysis (Fridrich *et al.*, 1996; Holmlund *et al.*, 2001; Yoshida *et al.*, 2005a; Diracoglu *et al.*, 2009).

Selective reporting (reporting bias)

It was difficult to assess a trial's selective reporting in the absence of its protocol. Nevertheless, the assessment for this domain was based largely on two main issues: First, whether all the pre-specified outcomes described in the methods section of the published report were addressed in the results section of the report. Second, whether the planned assessed outcomes in the trial would reasonably be expected in such a clinical trial for DDwoR management.

Half of the included trials (10/20) were judged as free of selective reporting bias, as they reported and/or provided all the expected, clinically important outcomes pre-specified in their methods sections and were consequently assessed as being at low risk of reporting bias (Schiffman *et al.*, 1996; Minakuchi *et al.*, 2001; Maloney *et al.*, 2002; Peroz *et al.*, 2004; Ismail *et al.*, 2007; Schiffman *et al.*, 2007; Diracoglu *et al.*, 2009; Haketa *et al.*, 2010; Craane *et al.*, 2012a; Sahlstrom *et al.*, 2013). In another 4 trials, there was insufficient information to make a clear judgment and they were assessed as being at unclear risk of reporting bias (Linde *et al.*, 1995; Goudot *et al.*, 2000; Yuasa *et al.*, 2001; Politi *et al.*, 2007). The remaining 6 trials either did not report the data of planned outcomes adequately or did not report/assess an expected, clinically important outcome and were assessed as being at high risk of bias for this domain.

Other potential sources of bias

This domain represents any other apparent bias in the trial design or conduct other than the already-assessed biases in the risk of bias tool (i.e., selection, performance and detection, attrition, and reporting biases). It involves any concerns about bias in the included studies, such as: baseline imbalance, blocked randomization in unblinded trials, or effects of funding sources or conflicts of interest.

Five of the included trials were considered to be free of other sources of bias and were assessed as being at low risk of bias for this domain (Goudot *et al.*, 2000; Minakuchi *et al.*, 2001; Yuasa *et al.*, 2001; Peroz *et al.*, 2004; Haketa *et al.*, 2010). For 7 trials, the other sources of bias were unclear (Petersson *et al.*, 1994; Linde *et al.*, 1995; Fridrich *et al.*, 1996; Schiffman *et al.*, 1996; Schiffman *et al.*, 2007; Craane *et al.*, 2012a; Sahlstrom *et al.*, 2013). The remaining 8 trials were suspected to have other potential sources of bias and were assessed as being at high risk of bias with regard to this domain.

Overall risk of bias

None of the studies included in this review were assessed as at low risk of bias across all domains. Eight studies were assessed as being at unclear overall risk of bias because there was either insufficient information in the trial report and/or available from the authors or because it was not possible to make a definite judgement to determine risk of bias in at least one domain of the bias assessment tool (Schiffman *et al.*, 1996;

Minakuchi *et al.*, 2001; Yuasa *et al.*, 2001; Peroz *et al.*, 2004; Schiffman *et al.*, 2007; Haketa *et al.*, 2010; Craane *et al.*, 2012a; Sahlstrom *et al.*, 2013). The remaining 12 studies were assessed as being at high overall risk of bias because each of these studies was at high risk of bias in one or more domains (Lundh *et al.*, 1992; Petersson *et al.*, 1994; Linde *et al.*, 1995; Fridrich *et al.*, 1996; Goudot *et al.*, 2000; Holmlund *et al.*, 2001; Maloney *et al.*, 2002; Yoshida *et al.*, 2005a; Ismail *et al.*, 2007; Politi *et al.*, 2007; Diracoglu *et al.*, 2009; Yoshida *et al.*, 2011). The summary assessment for the overall risk of bias is shown in Figure 5.3.

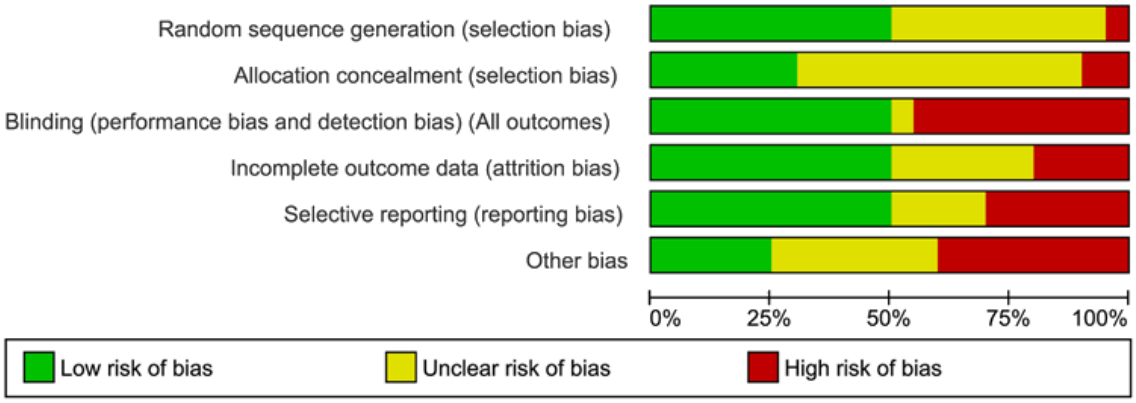


Figure 5.3: Summary assessment for the overall risk of bias.

Additional considerations

- All the authors of the included studies were contacted, and more than half of them replied (12/19 ‘same first author in 2 trials’ 63%).
- Of the twenty studies included, seven presented *a priori* sample-size calculation whilst thirteen did not report/perform *a priori* sample-size calculation. Of the examined thirteen studies, five had adequate statistical power (≥ 80%) whilst eight had inadequate statistical power (< 80%) (Appendix E).
- The main criticism was the lack of homogenous comparable groups which made it difficult to pool the results.

5.4.4 Effects of interventions

Preliminary synthesis of findings of included studies

All the included studies except one study (Yoshida *et al.*, 2005a) had extractable numerical data for statistical analysis. For uniformity across the studies included, data were analysed and presented by rescaling pain VAS or NRS on 0-10 cm to a 0-100 mm scale in five studies (Goudot *et al.*, 2000; Holmlund *et al.*, 2001; Maloney *et al.*, 2002; Politi *et al.*, 2007; Diracoglu *et al.*, 2009).

The reviewed interventions varied widely in invasiveness. For the purpose of this review, the interventions were grouped according to their level of invasiveness into three groups: non-invasive, minimally-invasive, and invasive interventions (Table 5.2). The data are presented by grouping the interventions to compare between non-invasive, minimally-invasive, and invasive treatment modalities. As a result, twenty-one comparisons among interventions were made. Data for between-group statistical analyses of the 21 comparisons for the primary outcomes (pain at jaw function, active/unassisted aMMO) are presented at short- and long-term follow-up time-points for each comparison in the summary of findings table (Table 5.3). The summary of findings for all secondary outcomes is available in Appendix G. Data for within-group statistical analyses of differences from baseline for the two primary outcomes at short- and long-term follow-up time-points are tabulated and summarised in Appendix H to help in assessment of the potential clinical significance of differences.

Comparison (Study)	Primary outcome	Follow-up (short/long-term)	No. of Patients (Trials)	Relative effect (95%CI) [a]	*p* value for between-group difference [b]	Overall Risk of Bias	Outcome measuring tool/scale [c]
1. MM *vs.* No treatment (Yoshida *et al.*, 2011)	MMO	10 min (ST)	148 (1 RCT)	RR 16.67 (5.44 to 51.06)	$p < 0.0001$ favours MM	High	MMO>38mm
2. Jaw exercises *vs.* Education only (Craane *et al.*, 2012a)	Pain [d]	3 mo (ST)	42 (1RCT)	MD 3.81 (-6.15 to 13.77)	NS	Unclear	VAS (0-100)
	Pain [d]	13 mo (LT)	42 (1 RCT)	MD 0.62 (-5.46 to 6.70)	NS	Unclear	VAS (0-100)
	MMO	3 mo (ST)	45 (1 RCT)	MD -3.10 (-6.96 to 0.76)	NS	Unclear	aMMO (mm)
	MMO	13 mo (LT)	42 (1 RCT)	MD -3.80 (-7.68 to 0.08)	NS ($p = 0.05$ towards Educ)	Unclear	aMMO (mm)
3. Self-management *vs.* Education only (Minakuchi *et al.*, 2001)	Pain	2 mo (ST)	44 (1 RCT)	MD -4.40 (-19.54 to 10.74)	NS	Unclear	VAS (0-100) on chewing
	MMO	2 mo (ST)	44 (1 RCT)	MD -1.40 (-6.90 to 4.10)	NS	Unclear	aMMO (mm)
4. Self-management *vs.* No treatment (Yuasa *et al.*, 2001)	Pain & MMO	1 mo (ST)	60 (1 RCT)	RR 1.80 (1.00 to 3.23)	NS ($p = 0.05$ towards SM)	Unclear	No. improved patients for: VAS pain & MMO
	Subgroup analysis	1 mo (ST)	15 Acute	RR 1.05 (0.57 to 1.94)	NS		
			45 Chronic	RR 2.51 (1.06 to 5.95)	$p < 0.05$ favours SM		
5. Self-management *vs.* Splint (Haketa *et al.*, 2010)	Pain	2 mo (ST)	44 (1 RCT)	MD -15.20 (-31.55 to 1.15)	NS ($p = 0.07$ towards SM)	Unclear	VAS (0-100)
	MMO	2 mo (ST)	44 (1 RCT)	MD 6.00 (2.67 to 9.33)	$p < 0.001$ favours SM	Unclear	MMO with pain (mm)
6. Splint *vs.* Control (Lundh *et al.*, 1992)	Pain	12 mo (LT)	51 (1 RCT)	RR 0.49 (0.26 to 0.92)	$p < 0.05$ favour Control	High	No. reduced pain
7. Splint *vs.* TENS (Linde *et al.*, 1995)	Pain	6 wk (ST)	31 (1 RCT)	RR 8.53 (1.21 to 60.33)	$p < 0.05$ favours Splint	High	Reduction in pain≥50%
	MMO	6 wk (ST)	31 (1 RCT)	MD -0.16 (-4.07 to 3.75)	NS	High	Change from baseline mm

Comparison (Study)	Primary outcome	Follow-up (short/long-term)	No. of Patients (Trials)	Relative effect (95%CI) [a]	*p* value for between-group difference [b]	Overall Risk of Bias	Outcome measuring tool/scale [c]
8. Combination therapy [e] *vs.* Education only (Minakuchi *et al.*, 2001)	Pain	2 mo (ST)	46 (1 RCT)	MD -2.80 (-16.12 to 10.52)	NS	Unclear	VAS (0-100) on chewing
	MMO	2 mo (ST)	46 (1 RCT)	MD 1.40 (-3.94 to 6.74)	NS	Unclear	aMMO (mm)
9. Combination therapy *vs.* Self-management (Minakuchi *et al.*, 2001; Schiffman *et al.*, 2007)	Pain	2-3 mo (ST)	97 (2 RCTs)	SMD 0.22 (-0.19 to 0.62)	NS	Unclear	VAS & SSI
	Pain	60 mo (LT)	50 (1 RCT)	MD 0.00 (-0.13 to 0.13)	NS	Unclear	SSI (0-1)
	MMO	2 mo (ST)	48 (1 RCT)	MD 2.80 (-2.95 to 8.55)	NS	Unclear	aMMO (mm)
10. Jaw exercise + splint *vs.* Splint [f] (Maloney *et al.*, 2002; Ismail *et al.*, 2007)	Pain	1-3 mo (ST)	50 (2 RCTs)	MD 0.90 (-12.28 to 14.07)	NS	High	VAS & NRS (0-100)
	MMO	1-3 mo (ST)	50 (2 RCTs)	MD 4.67 (1.80 to 7.55)	$p < 0.01$ favours Exr+Sp	High	aMMO (mm)
11. Active PEMF *vs.* Placebo PEMF (Peroz *et al.*, 2004)	Pain [d]	6 wk (ST)	31 (1 mRCT)	MD 0.23 (-17.96 to 18.42)	NS	Low	VAS (0-100)
	Pain [d]	4 mo (LT)	30 (1 mRCT)	MD 19.49 (0.97 to 38.01)	$p < 0.05$ favour placebo	Unclear	VAS (0-100)
	MMO [d]	6 wk (ST)	31 (1 mRCT)	MD -2.47 (-8.23 to 3.29)	NS	Low	aMMO (mm)
	MMO	4 mo (LT)	30 (1 mRCT)	MD -1.00 (-6.09 to 4.09)	NS	Unclear	aMMO (mm)
12. Active iontophoresis *vs.* Placebo iontophoresis [g] (Schiffman *et al.*, 1996)	Pain	1 wk (ST)	18 (1 RCT)	MD -0.03 (-0.21 to 0.15)	NS	Unclear	SSI (0-1)
	MMO	1 wk (ST)	18 (1 RCT)	MD 1.90 (-5.70 to 9.50)	NS	Unclear	aMMO (mm)
13. Arthrocentesis *vs.* Arthrography only (Petersson *et al.*, 1994)	Pain [h]	2 mo (ST)	33 (1 RCT)	MD -16.02 (-34.79 to 2.75)	NS ($p = 0.09$ towards AC)	High	VAS (0-100) after chewing

Comparison (Study)	Primary outcome	Follow-up (short/long-term)	No. of Patients (Trials)	Relative effect (95%CI) [a]	*p* value for between-group difference [b]	Overall Risk of Bias	Outcome measuring tool/scale [c]
Arthrocentesis vs. Arthrography only	MMO	2 mo (ST)	33 (1 RCT)	MD -3.00 (-9.54 to 3.54)	NS	High	mm
14. Arthrocentesis *vs.* ATN LA block (Sahlstrom *et al.*, 2013)	Pain [d] (no ITT)	3 mo (ST)	37 (1 RCT)	MD 24.60 (6.06 to 43.14)	$p< 0.01$ favours LA	Unclear	VAS (0-100) at movements
	Pain (ITT)	3 mo (ST)	45 (1 RCT)	RR 0.72 (0.46 to 1.14)	NS	Unclear	Reduced pain≥30%
	MMO [d]	3 mo (ST)	37 (1 RCT)	MD -4.90 (-10.00 to 0.20)	NS ($p= 0.06$ towards LA)	Unclear	aMMO (mm)
15. Arthrocentesis *vs.* Combination therapy (Diracoglu *et al.*, 2009)	Pain	3 mo (ST)	110 (1 qRCT)	MD -19.3 (-28.54 to -10.06)	$p< 0.0001$ favours AC	High	VAS (0-100)
	Pain	6 mo (LT)	110 (1 qRCT)	MD -28.80 (-36.56 to -21.04)	$p< 0.0001$ favours AC	High	VAS (0-100)
	MMO	3 mo (ST)	110 (1 qRCT)	MD 1.93 (-0.75 to 4.61)	NS	High	mm
	MMO	6 mo (LT)	110 (1 qRCT)	MD 2.35 (-0.07 to 4.77)	NS ($p= 0.06$ towards AC)	High	mm
16. Arthroscopy *vs.* Self-management (Schiffman *et al.*, 2007)	Pain	3 mo (ST)	50 (1 RCT)	MD 0.01 (-0.12 to 0.14)	NS	Unclear	SSI (0-1)
	Pain	60 mo (LT)	51 (1 RCT)	MD 0.03 (-0.09 to 0.15)	NS	Unclear	SSI (0-1)
17. Arthroscopy *vs.* Combination therapy (Schiffman *et al.*, 2007)	Pain	3 mo (ST)	43 (1 RCT)	MD -0.08 (-0.24 to 0.08)	NS	Unclear	SSI (0-1)
	Pain	60 mo (LT)	47 (1 RCT)	MD 0.03 (-0.09 to 0.15)	NS	Unclear	SSI (0-1)
18. Open surgery *vs.* Self-management (Schiffman *et al.*, 2007)	Pain	3 mo (ST)	48 (1 RCT)	MD -0.07 (-0.20 to 0.06)	NS	Unclear	SSI (0-1)
	Pain	60 mo (LT)	50 (1 RCT)	MD 0.05 (-0.09 to 0.19)	NS	Unclear	SSI (0-1)

Comparison (Study)	Primary outcome	Follow-up (short/long-term)	No. of Patients (Trials)	Relative effect (95%CI) [a]	*p* value for between-group difference [b]	Overall Risk of Bias	Outcome measuring tool/scale [c]
19. Open surgery *vs.* Combination therapy (Schiffman *et al.*, 2007)	Pain	3 mo (ST)	41 (1 RCT)	MD -0.16 (-0.32 to -0.00)	$p < 0.05$ favours OS	Unclear	SSI (0-1)
	Pain	60 mo (LT)	46 (1 RCT)	MD 0.05 (-0.09 to 0.19)	NS	Unclear	SSI (0-1)
20. Arthroscopy *vs.* Arthrocentesis (Fridrich *et al.*, 1996; Goudot *et al.*, 2000)	Pain	12 mo (LT)	62 (1 RCT)	MD 10.00 (-1.20 to 21.20)	NS ($p = 0.08$ towards AC)	High	VAS (0-100)
	MMO	6-24 mo (LT)	81 (2 RCTs)	MD 5.28 (3.46 to 7.10)	$p < 0.0001$ favours AS	High	mm
21. Open surgery *vs.* Arthroscopy (Holmlund *et al.*, 2001; Politi *et al.*, 2007; Schiffman *et al.*, 2007)	Pain	3 mo (ST)	42 (1 RCT)	MD -0.08 (-0.23 to 0.07)	NS	Unclear	SSI (0-1)
	Pain	12 mo (LT)	81 (3 RCTs)	SMD -0.50 (-0.95 to -0.06)	$p < 0.05$ favours OS	High	VAS & SSI
	Sensitivity analysis	12 mo (LT)	61 (2 RCTs)	SMD -0.43 (-0.93 to 0.08)	NS	High	VAS & SSI
	MMO	12 mo (LT)	40 (2 RCTs)	RR 1.07 (0.76 to 1.49)	NS	High	MMO>35mm

Abbreviations: AC: arthrocentesis, aMMO: active (unassisted) maximum mouth opening, AS: arthroscopy, ATN LA block: auriculotemporal nerve local anaesthesia block, CI: confidence interval, Educ: education, Exr+Sp: exercises plus splint, ITT: intention-to-treat analysis, LT: long-term, MD: mean difference, min: minutes, MM: mandibular manipulation, mm: millimetres, MMO: maximum mouth opening, mo: months, mRCT: multi-centre randomised clinical trial, No.: number of patients, NRS: numerical rating scale, NS: non-significant, OS: open surgery, PEMF: pulsed electromagnetic fields, qRCT: quasi-randomised clinical trial, RCT: randomised clinical trial, RR: risk ratio, SM: self-management, SMD: standardised mean difference, SSI: symptoms severity index, ST: short-term, TENS: transcutaneous electric nerve stimulation, VAS: visual analogue scale, wk: weeks.

[a] The risk ratio (RR) is the ratio of the chance of experiencing a particular event that occurs with use of the intervention to that occurs with the use of control. The mean difference (MD) is the difference in means values between two groups in a clinical trial. It estimates the amount by which an intervention changes the outcome on average compared with the control. It can be used as a summary statistic in meta-analysis when outcome measurements in all studies are made on the same scale. The standardized mean difference (SMD) is used as a summary statistic in meta-analysis when the studies all assess the same outcome but measure it on different scales. It expresses the size of the intervention effect in each study relative to its variance (SD). Further details about the statistical analysis used to measure the relative effects of interventions in clinical trials are available in the Cochrane handbook for systematic reviews of interventions (Higgins and Green, 2011) which is accessible online.

[b] Statistical significance (p-value<0.05) for between-group statistical differences.

[c] For uniformity, data were analysed and presented by rescaling pain scales (VAS and NRS) on 0-10 cm (Goudot *et al.*, 2000; Holmlund *et al.*, 2001; Maloney *et al.*, 2002; Politi *et al.*, 2007; Diracoglu *et al.*, 2009) to a 0-100 mm scale.

[d] Unpublished statistical data provided by the contacted authors (personal e-mail communication).

[e] Combination therapy of splint plus jaw exercises (± self-care/education/medication ± cognitive behavioural therapy 'CBT') conservative interventions.

[f] In Maloney *et al.* (2002), Therabite devise + splint group and wooden tongue depressors + splint group were merged as one group: jaw exercises plus splint.

[g] In Schiffman *et al.* (1996), three groups were compared (active iontophoresis by dexamethasone + lidocaine, control iontophoresis by lidocaine only, and placebo iontophoresis by normal saline). In this table, however, only the comparison between active and placebo iontophoresis was considered and reported.

[h] Estimated from figure 2 in the published trial.

Table 5.3: Summary of findings for the primary outcomes (pain at jaw function and unassisted/active maximum mouth opening).

In the following section, data for primary outcomes and adverse effects of interventions over short-term (≤ 3 months) and longest-term (> 3 months) are presented first for each comparison and then summarised on the basis of each treatment modality. All data for secondary outcomes are summarised in Appendix G.

Comparisons of non-invasive interventions

- ***Mandibular manipulation (MM) versus control (Table 5.3, comparison 1)***

Two studies by the same authors compared the short-term effectiveness of single mandibular manipulation (MM) against control with the key difference being the delivery of manipulation: by clinicians (Yoshida *et al.*, 2005a) or by patients themselves (Yoshida *et al.*, 2011).

In Yoshida *et al.* (2005a), the effects of MM (by clinician) in combination with a single dose of NSAID were compared against a single dose medication (NSAID) (control group) on a total of 305 patients randomised by 2:1 ratio into two groups. No extractable data were available from the published report (no variance reported) but the authors reported that 172/204 (84%) patients in the MM group showed decreased pain and increased opening at 1week. Of 172 improvers, 170 had 'acute' (≤ 1 month) and 2 had 'chronic' (> 1 month) DDwoR.

In Yoshida *et al.* (2011), the authors compared the immediate effectiveness of self-MM (by patient) with no treatment (control) 10 minutes after the intervention on a total of 148 patients randomised equally to either group. This study evaluated only the mandibular movements as outcomes. The number of patients with MMO > 38mm was significantly greater 10 minutes after self-MM than no treatment (risk ratio (RR) = 16.67; 95%CI: 5.44 to 51.06; $p < 0.00001$). In a follow-up report of the trial (Yoshida *et al.*, 2013), analysis for the self-MM group showed that the 'improvers' (50/74) had a shorter duration of locking (mostly 'acute' DDwoR: mean = 35 days), whilst the non-improved patients (24/74) had a longer duration of locking (mostly 'chronic' DDwoR: mean = 88 days).

- ***Jaw exercises versus education (Table 5.3, comparison 2)***

Craane *et al.* (2012a) compared active jaw manipulation by physiotherapists to patients' education only (control) for 13 months on a total of 49 patients (completers N = 42)

with DDwoR with and without limited mouth opening. In this study, there was no statistically significant difference between the effect of jaw exercises and patients' education on VAS pain at 3 months (MD = 3.81mm; 95%CI: -6.15 to 13.77; p = 0.45) or 13 months (MD = 0.62mm; 95%CI: -5.46 to 6.70; p = 0.84). Similarly, there was no statistically significant difference between the effect of jaw exercises and patients' education on active MMO at 3 months (MD = -3.10mm; 95%CI: -6.96 to 0.76; p = 0.12) or 13 months (MD = -3.80mm; 95%CI: -7.68 to 0.08; p = 0.05).

- ***Self-management versus control (Table 5.3, comparisons 3 & 4)***

Two studies compared self-management (self-exercises + self-care/medication) to no active treatment (control) for 1 to 2 months on a total of 104 patients (Minakuchi *et al.*, 2001; Yuasa *et al.*, 2001).

Minakuchi *et al.* (2001) compared self-management against patient education only. In this study, there was no statistically significant difference between the effect of self-management and education on VAS pain during chewing (MD = -4.40mm; 95%CI: -19.54 to 10.74; p = 0.57) at 2 months. Similarly, there was also no statistically significant difference between the comparative groups on active MMO (MD = -1.40mm; 95%CI: -6.90 to 4.10; p = 0.62) at 2 months.

Yuasa *et al.* (2001) compared self-management against no treatment. In the published study, all the outcomes were reported as median only with slight favour for the self-management over control. The study's authors combined the measured outcomes VAS and MMO to assess the TMJ dysfunction. By counting the number of 'improved' patients, a greater number of patients experienced decreased pain and increased opening in the self-management group than non-treatment group at 1 month, but the difference was not statistically significant (RR = 1.80; 95%CI: 1.00 to 3.23; p = 0.05). In a subgroup-analysis, however, self-management demonstrated a statistically significant difference in effects over no treatment with 'chronic' (> 1 month) DDwoR (RR = 2.51; 95%CI: 1.06 to 5.95; p = 0.04), but no statistically significant difference in effects on 'acute' (≤ 1 month) DDwoR (RR = 1.05; 95%CI: 0.57 to 1.94; p = 0.88).

- ***Self-management versus splint (Table 5.3, comparison 5)***

Haketa *et al.* (2010) compared self-management involving self-exercises (+ self-care/NSAIDs) to splint (+ self-care/NSAIDs) for 2 months on a total of 52 patients

(completers N = 44). In this study, although there was greater reduction in pain intensity in the self-management group than splint group at 2 months, the difference was not statistically significant (MD = -15.20mm; 95%CI: -31.55 to 1.15; p = 0.07). For mouth opening, however, there was a statistically significant difference in favour of self-management over splint on MMO with pain (MD = 6.00mm; 95%CI: 2.67 to 9.33; p = 0.0004) at 2 months. In this study, no signs of adverse events were observed from the two interventions.

- ***Splint versus control (Table 5.3, comparison 6)***

Lundh *et al.* (1992) evaluated the long-term effects of splints against no treatment (control) for 12 months on a total of 51 patients diagnosed by arthrography and given information and pain medication as needed. This study evaluated only patients' pain as an outcome. The number of patients with no pain or reduced pain was significantly greater in untreated patients than those treated with splints at 12 months (RR = 0.47; 95%CI: 0.25 to 0.88; p = 0.02).

- ***Splint versus transcutaneous electric nerve stimulation (TENS) (Table 5.3, comparison 7)***

Linde *et al.* (1995) compared splints versus TENS for 6 weeks on a total of 33 participants (completers N = 31). In this study, the number of patients with reduction in pain intensity (at rest, chewing, and at opening) by ≥50% was significantly greater in the splint group than TENS group at 6 weeks (RR = 8.53; 95%CI: 1.21 to 60.33; p = 0.03). In contrast, there was no statistically significant difference between the effect of the two interventions neither on the number of patients with MMO >40mm (RR = 1.28; 95%CI: 0.49 to 3.33; p = 0.61) nor on the MMO change from baseline (MD = -0.16mm; 95%CI: -4.07 to 3.75; p = 0.94) at 6 weeks. In this study, TENS reported to cause mild hypersensitivity skin reaction especially in the TMJ area. It was, however, unclear how many patients in the TENS group this sensitivity reaction was observed.

- ***Combination therapy versus education (Table 5.3, comparison 8)***

Minakuchi *et al.* (2001) compared the short-term effects of combined splint plus exercises (+ self-care/medication/education) treatment strategy to education only (control) on 46 participants for 2 months. In this study, there was no statistically significant difference between the effects of combination therapy and education only

neither on VAS pain on chewing (MD = -2.80mm; 95%CI: -16.12 to 10.52; p = 0.68), nor on active MMO (MD = 1.40mm; 95%CI: -3.94 to 6.74; p = 0.61) at 2 months.

- ***Combination therapy versus self-management (Table 5.3, comparison 9)***

The comparison between combination therapy including splint plus jaw exercises (+ self-care/medication/education ± CBT) versus self-management (self-care/medication/education ± self-exercises) was conducted by two studies (Minakuchi *et al.*, 2001; Schiffman *et al.*, 2007) on a total of 102 patients (completers N = 98) for 2 months and 60 months respectively. For pain intensity, pooling the results of the two studies showed no statistically significant differences between the effects of combined treatment strategy over self-management strategy on pain intensity over the short-term (2-3 months) (standardized mean differences (SMD) = 0.22; 95%CI: -0.19 to 0.62; p = 0.29) (meta-analysis 1, Figure 5.4). Similarly, in one study (Schiffman *et al.*, 2007), there was no statistically significant difference between the effects of the two treatment strategies on SSI for pain at 60 months (MD = 0.00; 95%CI: -0.13 to 0.13; p = 1.00). For mouth opening, there was also no statistically significant difference between the effect of comparative groups on active MMO (MD = 2.80mm; 95%CI: -2.95 to 8.55; p = 0.34) at 2 months in one study (Minakuchi *et al.*, 2001). In Schiffman *et al.* (2007), no adverse events were observed from the two interventions.

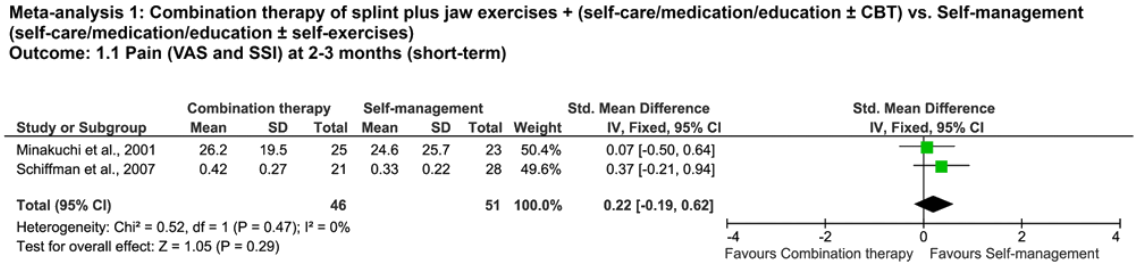


Figure 5.4: Forest plot of pooled data regarding pain outcome for combination therapy vs. self-management.

- ***Combination of splint plus jaw exercises versus splint (Table 5.3, comparison 10)***

This comparison was conducted by two studies (Maloney *et al.*, 2002; Ismail *et al.*, 2007) on a total of 50 patients (45 patients with DDwoR) for 1 and 3 months follow-up respectively with the key difference being the delivery of jaw exercises: by clinicians (Ismail *et al.*, 2007) or by patients themselves using either a mechanical device (Therabite) or wooden tongue depressors (WTDs) (Maloney *et al.*, 2002). For pain

intensity, pooling the results of the two studies showed no statistically significant difference in effects of combined treatment over splint alone on pain intensity over the short-term (1-3 months) (MD = 0.90; 95%CI: -12.28 to 14.07; p = 0.89). For mouth opening, however, pooling the results of the studies showed a statistically significant difference in favour of the combined treatment over splint alone on MMO over the short-term (1-3 months) (MD = 4.67mm; 95%CI: 1.80 to 7.55; p = 0.001) (meta-analysis 2, Figure 5.5).

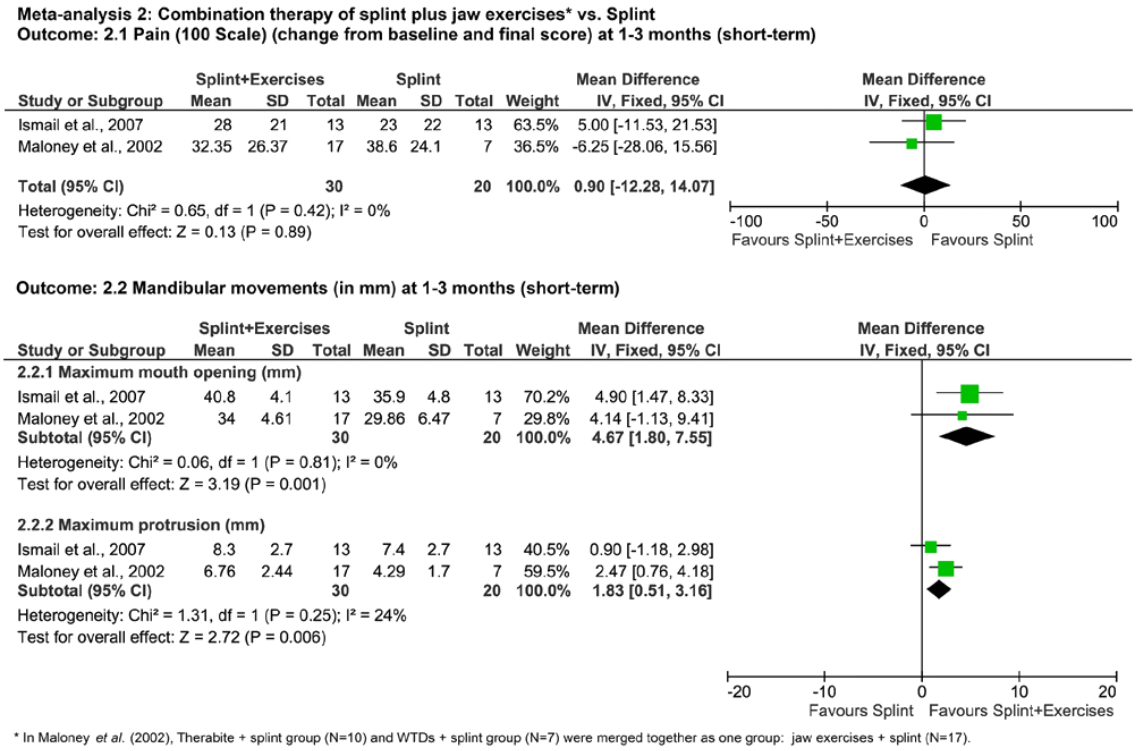


Figure 5.5: Forest plot of pooled data regarding pain and mandibular movements outcomes for combination of splint plus jaw exercises vs. splint only.

- ***Active pulsed electromagnetic fields (PEMF) versus placebo PEMF (Table 5.3, comparison 11)***

Peroz *et al.* (2004) compared active PEMF versus placebo PEMF for 4 months on 31 patients in DDwoR subgroup (completers N = 30). In this multi-centre RCT, there was no statistically significant difference in effects of active and placebo PEMF on VAS pain intensity at 6 weeks (MD = 0.23mm; 95%CI: -17.96 to 18.42; p = 0.98), but the difference was statistically significant in favour of placebo PEMF at 4 months (MD = 14.49mm; 95%CI: 0.97 to 38.01; p = 0.04). For mouth opening outcome, there was no statistically significant difference in effects of active and placebo PEMF on active

(unassisted) MMO at 6 weeks (MD = -2.47mm; 95%CI: -8.23 to 3.29; p = 0.40) and 4 months (MD = -1.00mm; 95%CI: -6.09 to 4.09; p = 0.70).

- ***Active iontophoresis versus placebo iontophoresis (Table 5.3, comparison 12)***

Schiffman *et al.* (1996) compared active iontophoresis (dexamethasone and lidocaine) versus control iontophoresis (lidocaine only) versus placebo iontophoresis (normal saline) for 1 week on a total of 27 patients. In this study, iontophoresis by lidocaine with or without dexamethasone demonstrated greater short-term effects over placebo iontophoresis by normal saline on all measured outcomes but the differences were not statistically significant. For pain, there was no statistically significant difference in effects neither between active and placebo iontophoresis (MD = -0.03; 95%CI: -0.21 to 0.15; p = 0.75) nor between control and placebo iontophoresis (MD = -0.10; 95%CI: -0.25 to 0.05; p = 0.18) on total symptoms severity index (SSI) for pain at 1 week. Similarly, for mouth opening, there was no statistically significant difference in effects neither between active and placebo iontophoresis (MD = 1.90; 95%CI: -5.70 to 9.50; p = 0.62) nor between control and placebo iontophoresis (MD = 2.00; 95%CI: -3.22 to 7.22; p = 0.45) on active MMO at 1 week. In this study, two types of mild transient adverse effects of iontophoresis were reported: skin erythema and dizziness. Skin erythema resolved within 8 hours and dizziness resolved when the power source was turned off. The study's authors, however, did not report how many patients experienced these adverse events and in which group these events occurred.

Comparisons of minimally-invasive versus non-invasive interventions

- ***Arthrocentesis versus control (Table 5.3, comparisons 13 & 14)***

Two studies evaluated the short-term effects of arthrocentesis and lavage to a control group: a diagnostic arthrography (Petersson *et al.*, 1994), or an auriculotemporal nerve (ATN) block as sham treatment (Sahlstrom *et al.*, 2013) on a total of 79 patients (completers N = 70) for 2 to 3 months respectively. For pain intensity, the VAS pain was reported as median (range) in Petersson *et al.* (1994). From Figure 2 in the published trial, the individual VAS pain after chewing could be estimated for each individual patient in both groups. Accordingly, the 'estimated' mean and standard deviation for each comparative group was calculated by SPSS. There was slight favour for arthrocentesis over diagnostic arthrography on reducing the pain after chewing at 2

months but the difference in effects was not statistically significant (MD = -16.34mm; 95%CI: -35.00 to 2.32; p = 0.09). In the study conducted by Sahlstrom *et al.* (2013), there was a statistically significant difference in effect in favour of local anaesthesia (LA) group on VAS pain at jaw movements at 3 months (MD = 24.60mm; 95%CI: 6.06 to 43.14; p = 0.009). By applying the ITT principle by the study's authors, no statistically significant difference between the effect of the two interventions was demonstrated for the reduction of pain intensity ≥ 30% (RR = 0.72; 95%CI: 0.46 to 1.14; p = 0.16) or ≥ 50 % (RR = 0.78; 95%CI: 0.46 to 1.32; p = 0.36). For mouth opening, there was no statistically significant difference in effects of arthrocentesis and arthrography on MMO (MD = -3.00 mm; 95%CI: -9.54 to 3.54; p = 0.37) at 2 months in Petersson *et al.* (1994). Similarly, in Sahlstrom *et al.* (2013), there was also no statistically significant difference in effects of arthrocentesis and LA alone on unassisted (active) MMO with pain (MD = -4.90mm; 95%CI: -10.00 to 0.20; p = 0.06) at 3 months. Pooling the data from both studies to evaluate the overall effect of arthrocentesis against control was not possible due to clinical (unmatched 'control' groups) and statistical ($chi^2 < 0.05$; $I^2 > 50\%$) heterogeneity. No signs of adverse events were observed from the interventions by Petersson *et al.* (1994).

- ***Arthrocentesis versus combination therapy (Table 5.3, comparison 15)***

Diracoglu *et al.* (2009) compared arthrocentesis to a combination of splint plus self-care/self-exercises conservative treatment for 6 months on 120 patients with 'acute' DDwoR (≤ 1 month) (completers N = 110) allocated by consecutive patients' attendance one to each group. In this quasi-randomised trial, arthrocentesis demonstrated a highly significant statistical difference in effects over combination therapy on VAS pain at 3 months (MD = -19.3mm; 95%CI: -28.54 to -10.06; p < 0.0001) and 6 months (MD = -28.80mm; 95%CI: -36.56 to -21.04; p < 0.00001). Although arthrocentesis exerted greater effects on MMO, the difference in effects between the two interventions were not statistically significant at 3 months (MD = 1.93mm; 95%CI: -0.75 to 4.61; p = 0.16) and at 6 months (MD = 2.35mm; 95%CI: -0.07 to 4.77; p = 0.06).

Comparisons of invasive versus non-invasive interventions

- ***Arthroscopy versus conservative treatments (Table 5.3, comparisons 16 & 17)***

Schiffman *et al.* (2007) compared arthroscopic surgery to two conservative treatment strategies: self-management (self-care/medication/education); combination of splint plus exercises (+ self-care/medication/education plus CBT). The comparison of arthroscopy versus self-management was conducted on 55 patients (completers N = 51) and the comparison of arthroscopy versus combination therapy was conducted on 51 patients (completers N = 47) for 60 months. For pain, there was no statistically significant difference in effects of arthroscopy and self-management on SSI at 3 months (MD = 0.01; 95%CI: -0.12 to 0.14; p = 0.88) and at 60 months (MD = 0.03; 95%CI: -0.09 to 0.15; p = 0.63). There was also no statistically significant difference in effects of arthroscopy and combination therapy on SSI at 3 months (MD = -0.08; 95%CI: -0.24 to 0.08; p = 0.31) and at 60 months (MD = 0.03; 95%CI: -0.09 to 0.15; p = 0.63). In this study, no signs of adverse events were observed from these interventions.

- ***Open surgery versus conservative treatments (Table 5.3, comparison 18 & 19)***

Schiffman *et al.* (2007) also compared open surgery with the same conservative interventions: self-management and combination therapy. The comparison of open surgery versus self-management was conducted on 55 patients (completers N = 51) and the comparison of open surgery versus combination therapy was conducted on 51 patients (completers N = 47) for 60 months. Again, there was no statistically significant difference in effects of open surgery and self-management on SSI at 3 months (MD = -0.07; 95%CI: -0.20 to 0.06; p = 0.30) and at 60 months (MD = 0.05; 95%CI: -0.09 to 0.19; p = 0.48). However, open surgery demonstrated a statistically significant difference in effects over combination therapy on SSI at 3 months (MD = -0.16; 95%CI: -0.32 to -0.00; p = 0.04) but not at 60 months (MD = 0.05; 95%CI: -0.09 to 0.19; p = 0.48). In this study, open surgery caused moderate transient motor nerve injury in one patient.

Comparison of invasive versus minimally-invasive interventions

- ***Arthroscopy versus arthrocentesis (Table 5.3, comparison 20)***

Two studies made this comparison (Fridrich *et al.*, 1996; Goudot *et al.*, 2000) on a total of 81 patients with disc displacement with and without reduction (69 patients had DDwoR) for 6 to 24 months. For pain intensity, although the reduction in pain was greater in arthrocentesis group than in arthroscopy group in Goudot *et al.* (2000), the difference in effects between the two interventions on VAS pain intensity at 12 months was not statistically significant (MD = 1.00; 95%CI: -0.12 to 2.12; p = 0.08). In Fridrich *et al.* (1996), the VAS for pain intensity was reported as effect estimate for both interventions over the longest follow-up (range from 6 to 24 months) but no variance was reported. Therefore, pooling the data for this outcome could not be performed. For mouth opening, pooling the data from both studies resulted in a statistically significant difference in effects of arthroscopy and arthrocentesis on MMO in favour of arthroscopy over the long-term (6-24 months) (MD = 5.28mm; 95%CI: 3.46 to 7.10; p < 0.00001) (meta-analysis 3, Figure 5.6). No adverse events were observed by Fridrich *et al.* (1996), while four surgical complications were reported by Goudot *et al.* (2000), two in each group. In the arthroscopy group, one patient had moderate transient facial palsy for 3 months duration, and the other patient had severe cervico-facial oedema required prolonged intubation for 12 hours. In arthrocentesis group, two patients had severe bradycardias [vagal reactions] (one asystole). The asystole recovered after Isoprenalin injection and the other recovered spontaneously when lavage stopped. The risk ratio of adverse events between the two interventions were non-significant (RR = 0.88; 95%CI: 0.13 to 5.85; p = 0.89) but the trial authors reported that the observed adverse effects of arthrocentesis were more serious than the arthroscopic adverse effects.

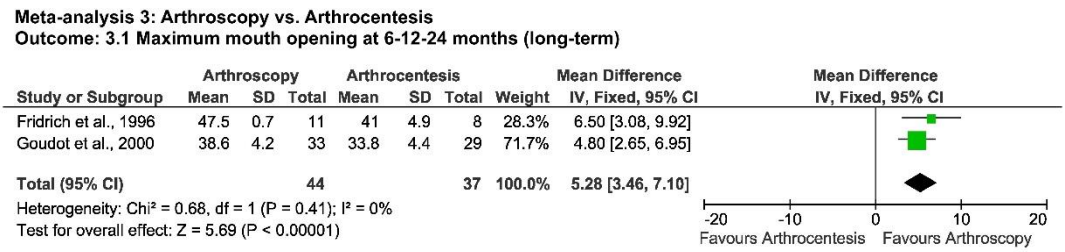


Figure 5.6: Forest plot of pooled data regarding maximum mouth opening outcome for arthroscopy vs. arthrocentesis.

Comparison of invasive interventions

- ***Open surgery versus arthroscopy (Table 5.3, comparison 21)***

Three studies made this comparison on a total of 94 patients (completers N = 88) for a follow-up period ranging from 1 to 5 years (Holmlund *et al.*, 2001; Politi *et al.*, 2007; Schiffman *et al.*, 2007). In terms of the outcome of pain, there was no statistically significant difference in effects of the two surgeries on pain intensity over the longest follow-up in each of the 3 trials. Nevertheless, pooling the data from the three studies showed a statistically significant overall effect for open surgery over arthroscopy on reducing the pain intensity at 12 months (SMD = -0.50; 95%CI: -0.95 to -0.06; p = 0.03). However, by excluding the study not confirming the DDwoR clinical diagnosis by MRI (Holmlund *et al.*, 2001), the sensitivity-analysis showed no statistically significant difference in effects of the two surgical procedures (SMD = -0.43; 95%CI: -0.93 to 0.08; p = 0.10). In relation to mouth opening, pooling the data from two studies (Holmlund *et al.*, 2001; Politi *et al.*, 2007) showed no statistically significant difference between the effects of open joint and arthroscopic surgeries on number of patients with MMO >35mm (RR = 1.07; 95%CI: 0.76 to 1.49; p = 0.71) at 12 months (meta-analysis 4, Figure 5.7). Surgical complications were reported in all the three trials. In Holmlund *et al.* (2001), a small region of hyposensitivity close to the incision was observed in open surgery group. Similarly, mild transient hyposensitivity in the preauricular area was observed by Politi *et al.* (2007) but in both groups. In Schiffman *et al.* (2007), one arthroplasty patient experienced moderate transient motor nerve injury that resolved completely.

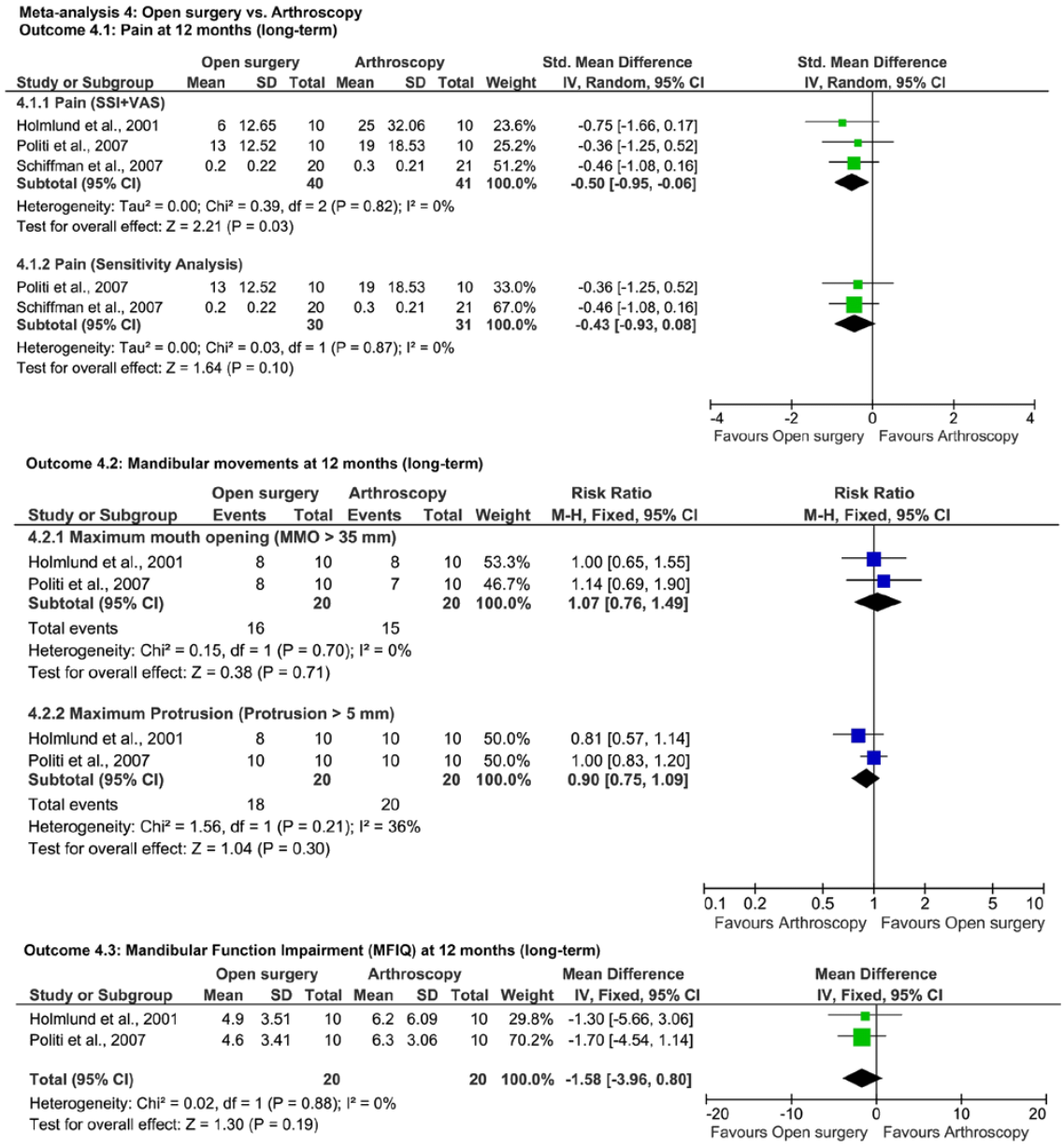


Figure 5.7: Forest plot of pooled data regarding pain, mandibular movements, and function outcomes for open joint surgery vs. arthroscopic surgery.

Summary of therapeutic intervention effects

The treatment modalities used for DDwoR management are summarised according to main treatment components in each therapeutic modality as follows:

Patient education (2 studies)

The effects of patient education and reassurance only as a control group without any active intervention were compared against active therapeutic interventions in two of the included trials (Minakuchi *et al.*, 2001; Craane *et al.*, 2012a) with no additional effects

of active therapeutic interventions over education alone on all the measured outcomes over the short- and long-term.

Self-management (4 studies)

The effects of self-management programmes involving self-care plus medication and education plus/minus self-exercises were compared against other treatment modalities in four trials (Minakuchi *et al.*, 2001; Yuasa *et al.*, 2001; Schiffman *et al.*, 2007; Haketa *et al.*, 2010) with no additional effects of other interventions over self-management on all measured outcomes over both short- and long-term. No adverse effects for this treatment modality were observed in two trials (Schiffman *et al.*, 2007; Haketa *et al.*, 2010) whilst the remaining 2 trials did not report about adverse events.

Splint therapy (5 studies)

Occlusal splint as a solitary treatment modality was evaluated against no treatment or other interventions in five trials (Lundh *et al.*, 1992; Linde *et al.*, 1995; Maloney *et al.*, 2002; Ismail *et al.*, 2007; Haketa *et al.*, 2010). Overall, the splint therapy as a sole treatment approach did not have additional effects over no treatment or other active interventions over the short- or long-term. The adverse effects of splints were not reported in any of the 5 trials.

Physiotherapy (7 studies)

Various physiotherapeutic modalities were evaluated against no treatment or other interventions in six trials (Linde *et al.*, 1995; Schiffman *et al.*, 1996; Peroz *et al.*, 2004; Yoshida *et al.*, 2005a; Yoshida *et al.*, 2011; Craane *et al.*, 2012a). In two trials (Yoshida *et al.*, 2005a; Yoshida *et al.*, 2011), early mandibular manipulation by patients or by clinicians demonstrated initial beneficial effect in decreasing pain and increasing mouth opening over the short-term in patients with ‘acute’ closed lock resulting from DDwoR of short duration of onset. In another trial (Craane *et al.*, 2012a), however, active jaw exercises by physiotherapists on patients with DDwoR with/without limited opening showed no additional effects over patients’ education alone on all measured outcomes over the short- or long-term. No adverse events were reported in these 3 trials. In the other three trials (Linde *et al.*, 1995; Schiffman *et al.*, 1996; Peroz *et al.*, 2004), miscellaneous of electro-physiotherapeutic modalities (TENS, PEMF, Iontophoresis) were evaluated but all demonstrated no additional effects over placebo treatment or

splint therapy on all measured outcomes over the short- and long-term. Electro-physical treatment by TENS and iontophoresis were reported to cause mild adverse events in two trials (Linde *et al.*, 1995; Schiffman *et al.*, 1996), whilst the other trial (Peroz *et al.*, 2004) did not report about adverse effects of PEMF.

Combination therapy (5 studies)

The effects of combination of splint plus physiotherapy (plus/minus any of medication and education or CBT) treatment strategy against other treatments modalities were evaluated in five trials (Minakuchi *et al.*, 2001; Maloney *et al.*, 2002; Ismail *et al.*, 2007; Schiffman *et al.*, 2007; Diracoglu *et al.*, 2009). When compared with the 'less' invasive and more conservative interventions (i.e., patients' education or self-management), the combined treatment strategy had no additional effects on all measured outcomes over the short- or long-term. When compared with the 'more' invasive surgical interventions (i.e., arthrocentesis, arthroscopy, open surgery), the combination therapy improved mandibular movements and function as much as the surgical interventions over the short- and long-term but it was less effective in reducing the pain intensity than arthrocentesis over the short- and longer-term, and open surgery over the short-term. No adverse effects of combination therapy were observed by Schiffman *et al.* (2007), whilst the remaining 4 trials did not report about adverse events.

Arthrocentesis (5 studies)

The effects of arthrocentesis and lavage under LA ± IV sedation were evaluated against sham treatment or other interventions in five trials (Petersson *et al.*, 1994; Fridrich *et al.*, 1996; Goudot *et al.*, 2000; Diracoglu *et al.*, 2009; Sahlstrom *et al.*, 2013). When compared against sham or placebo treatments (control groups) (Petersson *et al.*, 1994; Sahlstrom *et al.*, 2013), arthrocentesis demonstrated no additional effects on all measured outcomes over the short-term. When compared to combination therapy (Diracoglu *et al.*, 2009), however, arthrocentesis had greater effects in reducing the pain intensity but had comparable effects in improving the mandibular movements over both short- and long-term. Nevertheless, when compared to arthroscopy (Fridrich *et al.*, 1996; Goudot *et al.*, 2000), arthrocentesis had less effects than arthroscopy on improving mouth opening but it had comparable effects to arthroscopy on reducing the pain intensity over the long-term. Adverse effects of arthrocentesis were not observed in

two trials (Petersson *et al.*, 1994; Fridrich *et al.*, 1996), and not reported in another two trials (Diracoglu *et al.*, 2009; Sahlstrom *et al.*, 2013), whilst two severe intra-operative adverse events during the lavage procedure were observed in one trial (Goudot *et al.*, 2000).

Arthroscopy (5 studies)

The effects of arthroscopic surgery under GA or LA + IV sedation were evaluated against other surgical and conservative interventions in five trials (Fridrich *et al.*, 1996; Goudot *et al.*, 2000; Holmlund *et al.*, 2001; Politi *et al.*, 2007; Schiffman *et al.*, 2007). When compared with the non-surgical conservative treatment strategies (self-management or combination therapy) (Schiffman *et al.*, 2007), arthroscopy did not have any additional effects on all measured outcomes over the short- or long-term. When compared with arthrocentesis (Fridrich *et al.*, 1996; Goudot *et al.*, 2000), however, arthroscopic surgery under LA or GA was more effective than arthrocentesis under LA on improving the mouth opening but it had equivocal effects on reducing the pain intensity over the long-term. However, when compared with open surgery (Holmlund *et al.*, 2001; Politi *et al.*, 2007; Schiffman *et al.*, 2007), arthroscopic surgery was less effective than open surgery on reducing the pain intensity but had similar effects on mandibular movements over the long-term. No adverse effects of arthroscopic surgery were observed in three trials (Fridrich *et al.*, 1996; Holmlund *et al.*, 2001; Schiffman *et al.*, 2007), whilst three kinds of post-arthroscopic complications were observed in the other two trials (Goudot *et al.*, 2000; Politi *et al.*, 2007).

Open surgery (3 studies)

The effects of open joint surgery versus other therapeutic interventions were evaluated in three trials (Holmlund *et al.*, 2001; Politi *et al.*, 2007; Schiffman *et al.*, 2007). When compared with the non-surgical conservative interventions, open surgery had no additional effects over self-management on all measured outcomes over the short- and long-term. Open surgery, however, demonstrated greater effects on reducing the pain intensity more quickly than the combination therapy over the short-term but had no additional effects over the long-term, and had also no additional effects on improving the mandibular function over both short- and long-term. When compared with closed surgery (arthroscopy) (Holmlund *et al.*, 2001; Politi *et al.*, 2007; Schiffman *et al.*, 2007), open joint surgery demonstrated greater overall effects over arthroscopic surgery

on reducing the pain intensity over the long-term but it had no additional effects on improving the mandibular movements and function over the short- and long-term. Surgical complications of transient sensory or motor nerve injuries from the open joint surgical procedures were observed in all the three surgical trials.

5.5 Discussion

5.5.1 Summary of main findings

The wide range of therapeutic options used in clinical practice for alleviating symptoms of patients with DDwoR is reflected in this systematic review in which 20 trials were included, providing data for 21 comparisons between and among interventions of varying levels of invasiveness.

The main findings from each intervention reviewed will be discussed narratively to help in summarising the evidence behind the effectiveness of each of eight treatment modalities used for DDwoR management. In this review, the analysis for the primary outcomes was conducted both between- and within-group.

When the interventions were compared with each other (between-group), the least invasive conservative intervention by patient education and/or self-management exerted comparable effects to more 'active' (combined splint plus physiotherapy) or 'invasive' (TMJ surgery) treatment approaches over both short- and long-term. This indicates that educating the patients with DDwoR about this disorder with reassurance about its favourable natural course together with self-care instructions had an important role and a beneficial effect during the primary management of DDwoR.

Amongst the physiotherapeutic interventions, early mandibular manipulation by a clinician or by the patient exerted an immediate effect by increasing mouth opening in patients with 'acute' DDwoR over the short-term. These promising results, however, are unstable and the long-term effects of manipulation are questionable due to inadequate follow-up periods. Jaw 'stretching' exercises, whether alone or in combination with others, also increased mouth opening but their short- and long-term effects were varying and inconsistent among studies. Electro-physiotherapeutic modalities, on the other hand, had generally no additional effects over placebo or splint therapy over short- or long-term and could cause mild transient adverse effects.

Splint therapy as a sole treatment had no additional effects over other interventions or no treatment over the short- and long-term; although their use as an adjunct to other interventions helped to alleviate symptoms. This combination of splint plus physiotherapy plus/minus other conservative interventions had comparable effects to both: 'less' invasive and more conservative interventions of education and self-management, and 'more' invasive surgical interventions of arthrocentesis, arthroscopy, or open surgery over the short- and long-term. This combination therapy, however, was less effective in reducing the pain intensity than: arthrocentesis over the short- and longer-term, and open joint surgery over the short-term.

The minimally-invasive surgical intervention of arthrocentesis and lavage had no additional effects over sham treatments or arthroscopic surgery over the short- or long-term. Arthrocentesis, however, reduced pain intensity more than non-invasive conservative combination therapy in 'acute' DDwoR over both short- and long-term in one study (Diracoglu *et al.*, 2009). This study, however, was quasi-randomised based on alternate allocation to intervention groups and, therefore, if excluded from this review, arthrocentesis' effect remains questionable and unproven. Although arthrocentesis is often regarded as simple and relatively 'less' invasive in comparison with other surgical interventions, it could be also associated with rare but severe surgical complications. In one study (Goudot *et al.*, 2000), arthrocentesis caused severe bradycardias in two patients during the lavage procedure, one of which was of a refractory nature and caused a reversible asystole. The study's authors did not explain the mechanism for this presumably lavage-induced bradycardia. Possible factors leading to reflex bradycardia and asystole may be related to trigeminal nerve stimulation resulting in a trigeminal-derived vagal reflex (trigeminocardiac or trigeminovagal reflex bradycardia) (Roberts *et al.*, 1999).

The invasive arthroscopic and open joint surgical interventions generally had no additional effects over non-invasive conservative interventions over the short- and long-term; although open surgery decreased pain intensity significantly more than combination therapy over the short-term only. When surgical procedures where compared with each other, arthroscopic surgery increased mouth opening significantly more than arthrocentesis over the long-term. Open surgery also decreased pain intensity significantly more than arthroscopic surgery over the long-term. However, a sensitivity-analysis did not confirm the significant difference between arthroscopic and open joint

surgery in reducing the pain intensity thereby suggesting this result is unstable and the evidence is not robust. In the former comparison between arthroscopy and arthrocentesis, the significant increase in mouth opening in arthroscopy as compared to arthrocentesis may be due to the fact that arthrocentesis was done under LA whilst arthroscopy was done in most patients under GA. This use of different anaesthetic approaches (LA, IV sedation, GA) in the surgical trials made the circumstances incomparable. Any direct comparison between the different surgical procedures, therefore, is questionable because the magnitude and/or force for manipulating the jaw during the procedure has been proven to vary with the type of anaesthetic approach and is not always easy to control in unconscious versus conscious patients (Mehra and Arya, 2015). Consequently, this might have direct influence on an objective-measured clinical outcome such as mouth opening. In the latter comparison between arthroscopic and open joint surgeries, the significant decrease in pain intensity in open surgery as compared to other interventions may be due to complete disruption of sensory afferent pain pathways in the local TMJ area which probably leads to a decrease in pain. This sensory disruption is less likely to occur in non-surgical conservative therapy or other less invasive closed joint surgical procedures when compared to more invasive open joint surgery. The more invasive nature of open surgery also has the potential to further stimulate and potentiate any central and peripheral sensitisation as opposed to arthroscopic surgery, which due to less tissue damage, may less likely be stimulatory to peripheral and central nociceptive processes. Another explanation for this significant difference may be simply attributed to the fact that the pain intensity is a subjective self-measured outcome and patients receiving more invasive intervention may self-report a greater reduction in pain (patient mind bias). Arthroscopic and open joint surgical procedures could also be associated with surgical complications, most commonly moderate transient motor and/or sensory facial or trigeminal nerve injuries.

Overall, the between-group analysis showed no statistically significant differences in effects between and among the majority of reviewed interventions. In contrast, the within-group analysis for difference from baseline caused by each individual intervention revealed that the majority of reviewed interventions resulted in a statistically significant improvement from baseline in both primary outcomes over the short- and long-term (Appendix H). These findings indicate that most analysed interventions were effective, to a greater or a lesser degree, in alleviating DDwoR

symptoms, specifically decreasing pain and increasing opening. These findings, however, highlight also four important issues:

Firstly, the improvement in patients' symptoms regardless of treatment-specific effects could be explained by placebo effect of interventions (Greene and Laskin, 1972; Laskin and Greene, 1972; Moseley *et al.*, 2002; Dimitroulis, 2015) or TMJ adaptation and possible symptomatic resolution during the 'favourable' natural course of the disorder (Sato *et al.*, 1997a; Kurita *et al.*, 1998b; Yura, 2012). In this review, many included studies did not examine intervention against a 'true' untreated control group. This made it difficult to determine the 'real' effect of reviewed interventions. Therefore, the estimate of the interventions' effect-size should be interpreted with caution because it may be simply due to placebo effects and/or TMJ adaptation over time.

Secondly, the non-specific effects of the reviewed interventions mean that there were potential powerful therapeutic effects of placebo among all interventions reviewed. This raises the question: Is harnessing the power of the placebo effect by any of these interventions for treating patients with symptomatic DDwoR is ethical or unethical? Actually the answer to this question is complicated and controversial (Finniss *et al.*, 2010). According to American Pain Society (APS) position paper, the use of placebo treatment in clinical practice is 'unethical' and should be avoided, but its use is only ethical for clinical research purposes (Sullivan *et al.*, 2005) even for surgical trials (Horng and Miller, 2002). In the TMD field, however, where robust evidence about most treatments is lacking, harnessing the power of the placebo effect seems practical and suggested to be 'ethical' in clinical practice (Greene *et al.*, 2009). In fact, it seems reasonable to harness the power of the placebo effect in TMD patients' management given that the treatment is safe, cheap, reversible, non-invasive, and can enhance the natural healing process.

Thirdly, many studies included in this review were identified to be underpowered for detecting statistically significant differences between the compared interventions. Mostly, this insufficient power indicates 'poor' methodological quality; for example, Petersson *et al.* (1994) would have needed a reasonable sample size (~48 patients in each group) to achieve adequate power. This insufficient power, however, can also confirm the review's finding of the minimal therapeutic differences between the interventions' effects; for example, Holmlund *et al.* (2001) would have needed a very large, and unrealistic, sample size (~132 patients in each group) to achieve adequate

power. This enormous sample size would have been highly impractical and improbable in a single-centre RCT given the low incidence of DDwoR and the difficulty in recruiting patients with DDwoR which may take several years (Schiffman *et al.*, 2007; Sahlstrom *et al.*, 2013).

Finally, although there was an absence of statistically significant differences between interventions, the majority of reviewed interventions resulted in a statistically significant improvement from baseline. This raises the question: is this improvement from baseline clinically meaningful or not? To answer such a question, the clinically important difference (CID) for the primary outcomes of this review must be determined and identified from the patient's perspective (Copay *et al.*, 2007). For pain outcome, the CID was identified in previous studies to be a reduction from baseline of approximately one third (~30%), specifically: 20 mm on a 100 mm VAS (Jensen *et al.*, 2003), or 2 points on an 11-point NRS (Farrar *et al.*, 2001). In the studies included, however, pain intensity was measured via different instruments (tools/scales), which were not always directly comparable (Williamson and Hoggart, 2005). For mouth opening outcome, an increase of at least 9 mm was suggested in a previous study (Kropmans *et al.*, 2000) to demonstrate a statistically and clinically improvement in MMO. Kropmans *et al.*'s study, however, had several methodological flaws and the threshold of 9 mm was determined on the basis of the smallest detectable difference in measurements for assisted/passive MMO in patients with "painfully restricted TMJ disorders" receiving no treatment. This is as opposed to a CID in MMO that requires an assessment from the patient's perspective after receiving a therapeutic intervention (Dworkin *et al.*, 2008). Currently, there is no agreed CID for MMO. Further studies on biopsychosocially representative samples of patients with DDwoR are required in order to address CID for MMO. Nonetheless, if the 9 mm for assisted/passive MMO improvement is considered as perhaps indicative of CID, it could be estimated that an increase from baseline of about 6.5 mm or more would represent the CID for unassisted/active MMO. This is because there is about 2.5 mm difference between unassisted and assisted MMO for DDwoR patients (Hesse *et al.*, 1996) due to joint laxity and passive stretch force. These suggested numerical values can be used as an approximate to help interpret the clinical significance of change from baseline reported in Appendix H.

Notwithstanding the limitations of this review, one issue has become apparent from the review's findings: most interventions appear to alleviate symptoms of DDwoR with no

significant differences between non-invasive conservative interventions and minimally-invasive or invasive surgical interventions. Given the paucity of current evidence and the difficulty in interpreting the clinically important difference, it makes intuitive sense from this finding to suggest a stepped 'timely-management' approach to treat patients with symptomatic DDwoR initially with the most minimal, least invasive, least expensive, and simplest intervention: education and self-management with 'early' manipulation and escalate to more expensive and more active or invasive treatment only if needed (see Implications for clinical practice Section 8.1). This recommendation, however, should be interpreted in the context of a review based mostly on single studies of unclear to high risk of bias. Future well-conducted research may change or confirm this.

5.5.2 Overall completeness and applicability of evidence

The participants included in this review had an average age of 35 years and were mainly females (~86%) thereby mirroring other closed lock reviews (Al-Belasy and Dolwick, 2007; Monje-Gil *et al.*, 2012). The participants, however, represented a heterogeneous patients' sample and had some limitations. Firstly, the patients were mostly recruited from specialised university clinics and hospitals; that is they were most likely referred patients. Other first-point contact clinical settings such as general practice or emergency departments were not used but would provide patients with early DDwoR onset and probably different therapeutic responsiveness. Secondly, the participants differed considerably in the duration of DDwoR symptoms' onset ranging from one day to several years. This clinical point is quite important for DDwoR as the magnitude of treatment effect may differ depending on the chronicity of DDwoR (acute versus chronic) (Chapter 4). Thirdly, the participants differed also in the presence/absence of comorbid disorders which may affect the therapeutic responsiveness. All these factors may have affected the magnitude of treatment effect due to possible variation in the level of pathological changes in the intra-articular tissues amongst other variables. To investigate the effect of one of these variables, a cut-off point of one month locking duration was estimated for acute-chronic DDwoR subgroup analysis. Nevertheless, only very few analyses could be conducted using this threshold and the influence of locking duration on interventions' effectiveness again could not be established.

Another consideration for the participants' characteristics in this review is related to their recruitment or acceptance to participate in the trials included. In a follow-up report

by Yuasa *et al.* (2003), the authors examined the DDwoR patients who refused to participate in their trial (Yuasa *et al.*, 2001). The individuals who refused were found to have more severe symptoms than those accepted the enrolment in the trial. This may make the generalisation of any of the findings from any RCT of DDwoR patients questionable.

5.5.3 Quality of the evidence

This systematic review included studies of various levels of quality but most were identified to have various methodological weaknesses and/or incomplete reporting. For example, some trials had incomplete reporting of their randomisation process; others had incomplete reporting of follow-up results or did not report useful extractable data such as point estimate and/or variance; and some trials had small sample size and were underpowered to detect any statistical significant differences between the interventions. In addition to these, given the subjective nature of the outcomes assessed within the included trials, blinding was not always feasible in all trials to protect against bias in patient-reported outcomes.

Different therapeutic interventions of varying levels of invasiveness were being used in the studies included. Unsurprisingly, therefore, there was high degree of clinical heterogeneity among the studies. Although the interventions were grouped on the basis of their main treatment components, the combination of different interventions and the variations in techniques used and/or the delivery of interventions varied considerably among the studies. This was not only for the conservative non-surgical interventions but also for surgical interventions because, despite their perceived similarity, the surgical procedures also suffered from clinical heterogeneity in applied techniques and important differences were observed in the following: arthrocentesis lavage fluid volumes (50-150 ml), sometimes less than the recommended ideal therapeutic lavage volume (100-400 ml) (Zardeneta *et al.*, 1997; Kaneyama *et al.*, 2004); arthroscopic techniques - lysis and lavage only or operative arthroscopy; open joint surgical procedures – condylectomy, disc repositioning, or disc removal; anaesthetic approaches - local anaesthesia, intravenous sedation, or general anaesthesia; use of intra-articular medications injected - no medication, sodium hyaluronate, or corticosteroids; intra- and/or post-operative jaw manipulation. All these differences made the circumstances incomparable and any direct comparison difficult. In this review, therefore, the majority of comparisons involved only one trial and only four comparisons involved trials having homogenous

comparable groups eligible for pooling, thereby, allowing only four meta-analyses to be performed. However, even within the pooled studies in each comparison, there was some heterogeneity whereby studies did not exactly use the same combination of interventions, or used dissimilar scales/tools to measure the outcomes, or sometimes assessed the measured outcomes at differing time points. The strength of evidence for the reviewed interventions, therefore, could not be clearly established and any conclusion should be interpreted with caution.

Another important limitation in this review is related to variation in outcome variables in the studies included. Regarding the two primary outcomes considered in this review, some studies had wide inclusion criteria and included some patients who did not have limited opening or pain at the baseline. This may bias the results as it affects the effect size of the reviewed interventions. Furthermore, there were also variations in outcome assessments in the studies included which made comparison across trials problematic. In this review, the most common outcomes assessed for DDwoR were: pain intensity, mandibular movements, and functional limitation measures. The objective outcomes of mandibular movements were measured by a ruler and expressed in millimetre, but the subjective outcomes of patient's reported pain intensity and functional limitation were assessed using different tools and scales. For pain intensity, the most widely used scale was the VAS, but it was also calibrated differently, either 0-10 cm or 0-100 mm across studies. For patients' functional limitation, different tools were used across the studies such as: MFIQ, JFLS, DAL, and many others. Furthermore, some of the outcomes were measured by composite variables such as SSI for pain and CMI for jaw dysfunction that made it unclear which symptom or clinical sign was changing. All these variations in measuring the outcomes caused a problem with the comparison of the effects of interventions across various studies because the reported effect-size of the intervention may vary with the type and scale of tool used. In addition, the included trials had generally a narrow focus on certain elements such as the functional limitations on everyday living activities which probably do not encompass all the aspects of quality of life (QoL). None of them captured the broad multidimensional nature of patients' QoL by involving the various subtle psychosocial aspects discussed by Locker (Locker, 1988; Locker and Allen, 2007) which may affect patients with 'chronic' disorders such as TMD. Besides this, only one trial evaluated the cost of therapies used (Schiffman *et al.*, 2014b). Future trials need to address these outcomes and should follow the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)

(Dworkin *et al.*, 2005; Dworkin *et al.*, 2008) and Consolidated Standards of Reporting Trials (CONSORT) (Schulz *et al.*, 2011).

Another noticeable limitation is the application of intention-to-treat principle. Although this was reported to be undertaken by six of the included trials that reported incomplete follow-up, only one study (Minakuchi *et al.*, 2001) used and presented this analysis appropriately by including all the randomised participants (i.e., including all the dropouts according to the last available observation) regardless of receiving the interventions or not in the published report statistical analysis. In the other five trials, the ITT principle was applied and/or presented in different ways, none of which reported the data appropriately according to ITT basis. In Schiffman *et al.* (2007), the randomised participants who refused the treatment were excluded from study analysis and only 8 of 10 dropped-out patients were available at the 5 years evaluation and were re-included in the final analysis. In Haketa *et al.* (2010), only the patients dropped-out after 1 month were re-included in the final analysis (6 out of 14 dropped-out patients). In Yuasa *et al.* (2001), the trial authors used the last observation carried forward (LOCF) for the dropped-out patients, but assuming them to be improved in the final analysis of dichotomous data. In Craane *et al.* (2012a), the ITT analysis was only presented in the linear-mixed-model statistical analysis in the published trial. In Sahlstrom *et al.* (2013), ITT analysis was applied for only one outcome 'pain' (the primary outcome for the trial). These variations may reflect difficulty in applying 'full' ITT analysis or misunderstanding of the definition of ITT analysis and how the trial authors believe it should be implemented (Hollis and Campbell, 1999).

Despite these methodological flaws and clinical variations among the studies, there were also some positive findings from this review. For example, there was increasing in methodological quality in the recently published trials than the earlier trials. Two recently published trials (Craane *et al.*, 2012a; Sahlstrom *et al.*, 2013) followed the CONSORT statement. Another positive finding was that despite the low incidence of DDwoR amongst TMD and difficulty in recruiting patients into trials, more than half of the included trials involved more than 20 participants in each comparative arm group in their sample size. This may reflect the need for patients with symptomatic DDwoR to treatment.

All the aforementioned considerations weaken the validity of the review findings. Overall, the quality of evidence is still weak due to insufficient studies for each

comparison and unclear or high risk of bias amongst the majority of studies included. More high-quality studies are needed to strengthen the emerging evidence for the interventions used for DDwoR management.

5.5.4 Potential biases in the review process

Multiple decisions were made by the research student and the supervisory team during the construction of the review protocol and thereafter during the conduction of this systematic review. These related mainly to setting out the review inclusion/exclusion criteria and other review methods, as follows:

First, one of the main concerns before establishing the review protocol was the diagnostic accuracy of DDwoR and the possible differences in the diagnostic criteria used for DDwoR diagnosis in clinical trials. This made it difficult to set out the review inclusion criteria for different reasons. The inclusion of participants with a generic diagnosis (e.g., painful limited opening) might reduce the validity of the review results regarding the targeted condition 'DDwoR'. Depending on just the RDC/TMD as reliable criteria for DDwoR diagnosis (Dworkin and LeResche, 1992), despite its comprehensiveness and wide use in TMD research, may not be representative since it may not have been widely used in the 'closed lock' trials. In fact, neither depending on multiple diagnostic systems nor depending on just one system is precise. Including different clinical diagnostic approaches for DDwoR may be problematic but more practical as it would include all relevant DDwoR trials so that the concluded evidence will be representative to miscellaneous therapeutic interventions used in clinical practice for DDwoR patients. In this review, therefore, considerations were made for inclusion the most widely used diagnostic criteria for DDwoR in clinical trials such as RDC/TMD, AAOP, and Wilkes staging or any other compatible criteria for DDwoR diagnosis. TMJ soft tissue imaging may be used as an 'optional' adjunct to confirm disc position in patients with DDwoR; however, including such a strict criterion may again lead to exclude some of the relevant DDwoR cases and the evidence will be probably not representative and, consequently, not generalisable. Nevertheless, studies not confirming DDwoR by soft tissue imaging were identified and subjected to a sensitivity analysis (where applicable) to highlight the effect of this wide inclusion decision on the concluded evidence for primary outcomes.

Second, another consideration in the review inclusion criteria was the possibility of including different stages of DDwoR chronicity in the included participants. In fact, there are difficulties in defining the transition point from acute to chronic DDwoR both in terms of the duration of complaint (Chapter 4) and the level of restriction in mouth opening because there may be a gradual resolution of limited mouth opening with the passage of the time. This was taken in consideration by performing subgroup analysis (where possible) for acute-chronic DDwoR stages based on the estimated '1 month' cut-off point for the reported duration of locking in the included trials.

Third, another concern is there were a number of studies that included, in addition to DDwoR patients, other TMD patients in their sample. The decision to exclude them was easy to make but was inappropriate because it may weaken the external validity of the review findings for such a low incidence condition. Two strategies, therefore, were employed to avoid excluding those studies. Firstly, the trials were included if more than '70%' of their sample size diagnosed with DDwoR. Such a decision may introduce bias in the systematic review process and to lessen such a bias, it was made early in the review protocol before reviewing the studies and after consultation with an experienced Cochrane reviewer and a subsequent discussion between the student and the supervisory team to reach a consensus. Given the low incidence of DDwoR amongst TMD, the percentage of DDwoR in the sample must be reasonable and practical. The choice of percent was arbitrary and subjective and, therefore to further minimize the bias, the final decision about the contamination percent (70%) was made by one of the supervisors (VA) who had no prior knowledge in the TMD field and had no idea about any of DDwoR trials. By this set at 70%, three more trials were included in the review (Fridrich *et al.*, 1996; Goudot *et al.*, 2000; Ismail *et al.*, 2007). Secondly, the trials were included if the separate data for DDwoR subgroup were available or obtainable. Therefore, if the identified trials had a DDwoR subgroup in their study sample and separate data for patients with DDwoR were provided in the published report, the trials were included. However, if the trials did not provide separate data for DDwoR subgroup and the percent for patients with DDwoR was less than 70%, the trials' authors were contacted by the student to ascertain if they could provide the separate statistical data for DDwoR in order to include the study. By this method, two more trials were included in the review (Maloney *et al.*, 2002; Peroz *et al.*, 2004).

Fourth, one of the review exclusion criteria was the randomised trials that compared similar therapeutic treatment modality or those compared different kinds of medications or splints after surgical interventions for DDwoR patients. The decision to not include such RCTs related to research team belief that including such trials will not answer the systematic review question about which of the different treatment modalities used in clinical practice have more beneficial effects and less harmful adverse effects to be more appropriate for use in DDwoR management. To give an example, it is more important for patients, clinicians, and policy makers to know first whether arthrocentesis and lavage, a widely used treatment modality for DDwoR management, is an appropriate and more effective treatment modality than conservative interventions rather than knowing which medication or splint should be used 'after' arthrocentesis. This may be only needed to be known if there is robust evidence supporting the use of arthrocentesis for DDwoR management which is currently lacking.

Fifth, an additional consideration in this review was the incomplete reporting in some of the trials' publications. In order to minimise this shortcoming, the student contacted all the authors of the included studies for clarification regarding unclear aspects in study design and/or missing data. This strategy was generally successful as more than half of the authors replied (63%) and most of them were able to provide useful data; although one author could not adequately provide the requested information due to English language barrier. Therefore, some domains in the risk of bias tool remained unclear to make a definite judgment.

Finally, although searching several databases with wide range of synonyms as well as hand-searching relevant journals was employed in an attempt to include all eligible studies, the language bias could not be minimised by including non-English language RCTs due to resources limits. Nonetheless, the large number of included trials is most likely represented the various interventions used for DDwoR management. Furthermore, one non-English language RCT was identified from its abstract (Yuasa *et al.*, 1997) for possible translation and inclusion/exclusion if this review needs to be updated. In addition to this, three recently published RCTs (El-Sayed, 2014; Alajbeg *et al.*, 2015; Nagata *et al.*, 2015) and one follow-up report (Baker *et al.*, 2015) are currently available for inclusion/exclusion if this review needs to be updated in the future. This update, however, seems currently unnecessary as the findings from all the five published reports coincide with the concluded evidence from this review.

5.5.5 Agreements and disagreements with other systematic reviews

In this chapter, the criteria used to include the studies and the methods applied to appraise and analyse the studies included differed from those applied in the previous chapter. This is primarily due to difference in main aim of the two systematic reviews as the aim of the first systematic review (Chapter 4) was to investigate the effects of locking duration on DDwoR management outcome whilst the aim of the second systematic review (Chapter 5) was to investigate the effects of interventions used for DDwoR management.

The findings from the current review had extrapolated the results of more than two decades ago review about DDwoR management (Kropmans *et al.*, 1999). Despite its limitations, Kropmans's review concluded that all the reviewed interventions were effective with little or no significant differences in effects on pain intensity, maximum mouth opening, or mandibular function impairment between splint, physiotherapy, arthrocentesis, and arthroscopy. The results of the current review did not differ in that all the therapeutic interventions seem to be effective with little or no differences in effects between the comparable groups.

The current review's findings concurred also with the previous Cochrane reviews for arthrocentesis (Guo *et al.*, 2009) or arthroscopy (Rigon *et al.*, 2011) in that: non-invasive conservative interventions should be applied first, there is insufficient evidence to support or refute using the minimally-invasive and invasive surgical interventions, and there is a need for more high-quality RCTs. The current review, however, differed in some aspects from the published Cochrane reviews about TMJ disorders management. Given the low incidence of DDwoR amongst TMD, it was quite an interesting and positive finding to include 20 trials in this review in comparison to a recently published Cochrane review about the interventions used for the management of TMJ osteoarthritis (OA) which included a restricted number of trials (only 3 RCTs) (de Souza *et al.*, 2012). The number of studies included in other Cochrane reviews investigating only one treatment modality for TMJ disorders was not dissimilar and ranged from two to seven RCTs (Shi *et al.*, 2003; Guo *et al.*, 2009; Rigon *et al.*, 2011), some of these trials did not meet the present review inclusion criteria.

5.6 Conclusions

The aim of this review was to assess the effectiveness of therapeutic interventions used for DDwoR management. Many of the interventions analysed in this review are commonly used in clinical practice for patients with DDwoR. The main finding from this systematic review suggests that non-invasive conservative interventions were equally effective as minimally-invasive and invasive surgical interventions with no significant differences in therapeutic effects between interventions, but that the most minimal interventions attained their beneficial effects at lower costs and lower risks in comparison to more active or invasive interventions. Evidence levels, however, are currently insufficient for definitive conclusions, because the included studies were too heterogeneous and at an unclear to high risk of bias. The comparable therapeutic effects of reviewed interventions, paucity of high-quality evidence, and the greater risks and costs associated with more complex interventions, suggest the use of the simplest, least costly, and least invasive interventions to initially manage patients with DDwoR. Of the variety of non-invasive conservative interventions reviewed, patient education and self-management with early mandibular manipulation were the least expensive and least risky interventions having the optimum cost-benefit and risk-benefit values to DDwoR patients. Currently, there is insufficient evidence to support or refute the use of minimally-invasive and invasive surgical interventions for DDwoR. There may well be, however, specific clinical cases where a surgical intervention may help, but the body of evidence does not give a clear indication of when this may be.

The evidence identified in Chapters 4 and 5 should be implemented in practice for evidence-based DDwoR management. The clinicians, however, may not implement the available evidence in clinical practice due to several influences on their decisions. The next chapter will explore the clinicians' decision-making processes.

Chapter 6. Professionals' Clinical Decision-Making Processes in the Management of TMD/DDwoR: A Qualitative Study

6.1 Introduction

6.1.1 Qualitative research in healthcare

In recent years, qualitative research has become increasingly important in studying healthcare by introducing new methods to understand the complexity of the system from the point of view of patients and providers (Nicholls, 2009b). The main aim of qualitative research is to develop concepts that can help people to understand a particular phenomenon in a natural rather than an experimental setting (Pope and Mays, 1995). Qualitative research seeks to explore, explain, and understand the phenomenon under study by focusing on the individual experiences, values, attitudes, behaviours, and interactions (Nicholls, 2009a). Therefore, it has become an extremely useful research method for examining the clinical decision-making process by exploring and understanding both the explicit and the implicit clinicians' decisions (Jette *et al.*, 2003; McGinnis *et al.*, 2009).

Qualitative research is more appropriate to answer exploratory questions such as "what?", "how?", and "why?" rather than quantifiable questions such as "how many?" or "how frequently?" (Pope and Mays, 1995; Greenhalgh and Taylor, 1997). For example, the clinicians may advise the patients with DDwoR to perform jaw-stretching exercises at home to improve their mouth opening. Quantitative research is suitable to assess the effectiveness of the self-exercise treatment and to determine the frequency of patients' compliance with treatment and the proportion of comply/not comply patients, whilst qualitative research is more appropriate to examine and explain why some patients do not comply with the self-exercise regimen.

Patients with DDwoR, as for the whole TMD, may present to different dental and medical specialities in clinical practice. Acute DDwoR, however, is one of the most startling and objective presentations of all the TMD presenting often without any warning and causing severe limitation in mandibular movements and moderate to severe levels of pain (Okeson, 2007). It may, therefore, be shocking to the patients who, understandably, often immediately attend their primary care clinician or local emergency service. In the previous chapters, the evidence suggests that patients with DDwoR can be improved by intervening early with simple minimal non-invasive

conservative interventions. There is, however, a lack of understanding in relation to how frontline clinicians behave when they are confronted with such an acute TMD and what clinical decisions they may make. Such questions need answering using a qualitative rather than quantitative study design.

6.2 Aims and Objectives

6.2.1 Aim

The aim of this qualitative study was to explore and build an understanding of professionals' clinical decision-making processes in the management[3] of TMD in general and DDwoR in particular in order to identify influences on professionals' decisions.

6.2.2 Objectives

- To examine the clinicians' decision-making processes in the management of TMD, specifically examining the clinicians' decisions in diagnosing, treating, or referring DDwoR.
- To identify the factors, as informed by the TDF, influencing clinicians' decision-making in the management of TMD, specifically determining the influences on clinicians' decisions in diagnosing, treating, or referring DDwoR.

6.3 Methods

6.3.1 Study design

Qualitative study.

6.3.2 Philosophical assumptions of qualitative methodologies

In qualitative research, it is crucial to identify the philosophical assumptions or stance of the qualitative researcher to produce rigorous meaningful research due to intimate bond between philosophy (philosophical assumptions: the ideas and beliefs that inform research), methodology (a theory of how research will proceed), and methods (the way the research study is conducted) (Nicholls, 2009b; Creswell, 2013).

[3] In this chapter, the term 'management' is used broadly to cover diagnosis and treatment and/or referral of patients during the professionals' clinical decision-making processes.

The researchers' philosophical assumptions of qualitative methodologies depend on how they view reality (ontology) and truth (epistemology).

Ontology is the nature of reality (Denzin and Lincoln, 2011; Creswell, 2013). It has two extreme stances: realism and idealism. Realism is the belief that the reality is entirely independent of the researcher perception and of the research process with no interconnection between them. Idealism is the belief that the reality is only dependent on the researcher perception and it cannot be separated from the researcher or the research process. In between these two stances, there are numerous ontological stances one of which is subtle realism which attempts to represent reality rather than to reproduce it (Mays and Pope, 2000). In other words, subtle realists believe in the social world's reality but they accept that there is no manner in which the researcher can claim to have absolute isolation from the social world studying it.

Epistemology is the theory of knowledge that deals with the nature and status of knowledge (how we know what we know) (Pope and Mays, 1995; Creswell, 2013). It has also two extremes: positivism and interpretivism. Positivism is the belief in single objective reality; that is, reality exists without human involvement and that objects have their own real 'essence' or 'entity' regardless of individual experience or social conventions which is the philosophical basis of the quantitative research (Nicholls, 2009b). Interpretivism is the belief in multiple realities; that is, reality related to individual 'unique' experience and personal and social relations which is one of the philosophical bases of the qualitative research (Van Manen, 1990).

In this qualitative study, my ontological stance is subtle realism and my epistemological stance is interpretivism; by that I mean: I accept the fact that I am a clinician and a researcher with broad knowledge in the field and this may impact on my interpretation of the study data to some extent; however, by recognising and reflecting my position, I realised the potential bias that may bring to the data interpretation and, therefore, every attempt was made to minimise it.

6.3.3 Ethics

Ethical approval was obtained to conduct this study from the Newcastle University-Faculty of Medical Sciences Ethics Committee (FMS: EC 00632/2013; Appendix I) and

from each NHS Trust's Research and Development department (R&D) as appropriate to each individual participant's employment.

6.3.4 Qualitative sampling

Qualitative research assumes that every person is unique. It is, therefore, concerned with a sample that can 'represent' a breadth of human experiences and that can provide appropriate and meaningful insights into the studied phenomenon (i.e., purposive non-probability sampling) rather than a sample that 'represents' the background population (i.e., probability sampling in quantitative research) (Nicholls, 2009a).

Several different qualitative sampling strategies are described in the literature which aim to recruit participants into the study who can add both depth and breadth to understand the studied phenomenon (Coyne, 1997; Patton, 2002). Sampling strategies, however, are determined by the research aim and each strategy serves a particular purpose (Patton, 2002). In this study, the strategy used to identify healthcare professionals for interviews was purposive, criterion-based, maximum variation sampling.

Purposive sampling was used in order to gain a depth and breadth of viewpoints from differing groups of healthcare providers who might be expected to hold differing experiences, attitudes, beliefs, and opinions to understand the phenomenon under study 'DDwoR'. Criterion sampling of five years or more of length of time since graduation (i.e., experience post-qualification) was predetermined as an indication of clinical expertise[4] acquisition according to Benner (Benner, 1982; Dreyfus and Dreyfus, 2009) and was used to stratify the primary care dental practitioners into new GDPs (< 5 years) and experienced GDPs (≥ 5 years). Maximum variation sampling was aimed to reflect diversity in practice settings (urgent care, usual care, and specialist care) and involved clinicians with differing levels (years) of experiences, grades, training, qualifications, and specialties (accident and emergency 'A&E', oral surgery and oral and maxillofacial surgery 'OMFS', and medical and dental 'non-specialist' community services) in different geographical regions of the North of Tyne in the UK as detailed in Table 6.1.

[4] The practitioner's clinical expertise is defined as "the proficiency and judgment that each clinician acquires through clinical experience and practice" (Straus and Sackett, 1998, p.339).

The clinicians in the OMFS specialist service were selected among other secondary care specialities because they are likely involved in managing patients with limited mouth opening conditions including patients presenting with TMJ closed lock (i.e., acute DDwoR) (Field *et al.*, 2013; DeAngelis *et al.*, 2014) and, therefore, may have experienced the studied phenomenon 'DDwoR', thereby being able to provide insight on the DDwoR care pathway. It was also aimed at including clinicians in OMFS specialist service to compare their decision-making processes in DDwoR management with the processes of clinicians at the frontline in emergency and non-specialist community services.

Sampling inclusion criteria	
Frontline emergency and non-specialist community services	• Primary care clinicians registered with the General Dental Council (GDC): new and experienced general dental practitioners (GDP).
	• Primary care clinicians registered with the General Medical Council (GMC): general medical practitioners (GMP).
	• Emergency on-call dentists registered with the community dental service (CDS) or work in the dental emergency clinic (DEC).
	• Accident and emergency (A&E) junior, middle grade, and senior medical staff: foundation trainee F1 and F2, senior house officers (SHO), speciality registrar doctors (StR), staff grade specialty (StG) or Trust doctors, associate specialists (AsSp), and specialists/consultants (Cons).
OMFS specialist service	• Oral surgery and oral and maxillofacial surgery (OMFS) junior, middle grade, and senior team members: foundation trainee F1 and F2, senior house officers (SHO), speciality registrar doctors (StR), staff grade specialty (StG) or Trust doctors, associate specialists (AsSp), and specialists/consultants (Cons).
Sampling exclusion criteria	
• Clinicians unable to give informed consent to participate in the study.	

Table 6.1: Study sample inclusion and exclusion criteria.

Sample identification

Practitioners were identified from the relevant professional registrar and the practice or hospital department and were contacted, either directly or via their gatekeepers. The clinicians were invited to take part in the study by a standard posted or e-mailed letter involving general invitation statement about the 'temporomandibular joint disorders' rather than the specific 'disc displacement without reduction' disorder in order to avoid any possibility of 'biased knowledge' gain prior to interviews. The letter also contained a standardized participant information sheet and a consent form and all are available in Appendix J.

The invited clinicians were left to reflect on whether or not they would like to participate for two weeks. If no reply was received within two weeks a reminder e-mail or telephone call was made. If they were interested in being involved they were contacted by the research student and a mutually convenient time was made to interview them either face-to-face or via telephone. If a practitioner declined the invitation or did not respond, the next individual fitting the study sampling criteria on the registrar/in the department was contacted. Informed written consent was signed and obtained from all participants before their individual interview, but the topic guide was not given to any participant prior to their interview.

Study sample (Participants)

Sampling in qualitative research often continues until data 'saturation' is achieved; that is, when no new concepts are likely to emerge with further data collection (Ellett and Beausang, 2002). Data saturation in previous qualitative studies in the dental field has been seen to occur prior to thirty interviews with healthcare professionals (Durham *et al.*, 2007; Cope *et al.*, 2014; Stone *et al.*, 2014; Vernazza *et al.*, 2015). In this study, saturation across the theoretical domains was achieved following 21 interviews.

The professionals participated in this study were from primary and secondary (emergency and specialist) care Trusts across North East of England. The study sample involved 12 males and 9 females. Sixteen were frontline clinicians who might be the first-point of contact by DDwoR patients and 5 OMFS clinicians who might be mostly involved in their management. Ten primary care dental practitioners participated in this study. Of the ten, 3 were new GDPs and 7 were experienced GDPs. This stratification was planned for the primary care medical practitioners but not used for two reasons: First, it was difficult to achieve because most of the contacted medical practitioners did not respond or declined to participate in this study. Second, with further data collection and analysis it was proven unnecessary due to similarity of knowledge among all the 6 interviewed medically-qualified practitioners (3 GMPs and 3 A&E). The detailed and summary characteristics of interviewed participants are displayed in Table 6.2 and Table 6.3 respectively and can be cross-referenced to the references in parentheses following each quotation in the data and discussion section. Emboldened acronyms from Table 6.3 will be used throughout Section 6.4.

Participants' characteristics		Primary care service			Secondary care service	
		Primary care clinicians			Secondary care clinicians	
		Frontline clinicians (GDP, GMP, A&E)				Surgeons
Identification number	**Range of years of experience**	**Urgent Care**	**Usual Care**		**Urgent care**	**Specialist care**
		Emergency dentists	**GDP**	**GMP**	**A&E**	**OMFS**
1	21-30	✓	✓			
2	11-20	✓	✓			
3	5-10	✓	✓			
4	< 5					✓
5	< 5		✓			
6	< 5				✓	
7	11-20			✓		
8	11-20			✓		
9	5-10			✓		
10	21-30		✓			
11	11-20					✓
12	11-20		✓			
13	> 30		✓			✓
14	< 5		✓			
15	< 5		✓			
16	5-10				✓	
17	21-30			✓	✓	
18	5-10		✓			
19	11-20					✓
20	11-20					✓
21	> 30					✓
Totals	**1 to > 30 years**	**3**	**10**	**4**	**3**	**6**

Table 6.2: Detailed characteristics of the qualitative study's sample.

Healthcare service setting		Background qualification	Type of practitioner	Number
Primary care (PC)	Usual access	Dentally-qualified	New General Dental Practitioner (< 5 years) **(NGDP)**	3
	Usual access	Dentally-qualified	Experienced General Dental Practitioner (≥ 5 years) **(EGDP)**	4
	Emergency access	Dentally-qualified	Emergency General Dental Practitioner **(EMGDP)**	3
	Usual access	Medically-qualified	General Medical Practitioner **(GMP)**	3
Primary care clinicians Total				**13**
Secondary care (SC)	Emergency access represented by accident and emergency departments **(A&E)**	Medically-qualified	A range of professional grades such as: senior house officers, middle grades (service and training), or consultants	3
Frontline (A&E, GMPs, and GDPs) clinicians Total				**16**
	Specialist access represented by oral surgery and maxillofacial surgery departments **(OMFS)**	Dentally- ± Medically-qualified	A range of professional grades such as: senior house officers, middle grades (service and training), or consultants	5
OMFS clinicians Total				**5**
Secondary care clinicians Total				**8**
Cumulative Total				**21**

Table 6.3: Summary characteristics of the qualitative study's sample.

6.3.5 Qualitative data collection

The three methods commonly used for data gathering in qualitative healthcare research are: observation, focus groups, and interviews. In this study, the interview method was chosen because this type of data collection method allows the exploration of individual participant's own ideologies, perceptions, experiences, and rationale in-detail (Fitzpatrick and Boulton, 1994).

Qualitative interviews are of three main types: structured, semi-structured, and in-depth (Britten, 1995). In this study, semi-structured interviews were used to collect the data. Semi-structured interviews are based on a pre-defined set of loosely structured broad themes that define the area to be explored initially using open ended questions and from

which the interviewer or interviewee may diverge in order to chase an idea or thought in more detail using prompts and probes (Britten, 1995; Nicholls, 2009a). Probes are the researcher's responsive questions used to find out more about issues brought up by the interviewee. Prompts are the researcher's directional questions used to raise other issues that might interest the researcher and have not been raised during the course of the interview (Kwortnik, 2003).

Interview questions

An interview topic guide structured around the TDF (Michie *et al.*, 2005; Cane *et al.*, 2012) was used. The topic guide was developed by the student and its content validity was assessed by two of the supervisors: theoretically by a specialist in health psychology (VA) and clinically by a topic expert and experienced qualitative researcher (JD), thereby ensuring that the questions accurately represented the theoretical domains and adequately covered the TMD and DDwoR management topic.

This study was an inductive and iterative piece of research in that as interviews progressed, the topic guide was evolving according to data gathered and analysed. The final version of the interview topic guide is available in Appendix K.

The interviews followed a standard protocol to ensure consistency. Before the interviews, the clinicians were advised that the interview's aim was not to critique their practice or test their knowledge, but to help enhance understanding the problems they may face in relation to managing TMD in order to allow participants to talk freely and give honest frank answers. Furthermore, all the interviewed clinicians did not have professional or personal relationships with the interviewer. During the interviews, the participating professionals described first their qualifications, years of experience, and discipline or practice setting. After that, the participants were asked about their perspectives on chronic orofacial pain (COFP) to facilitate communication and to understand how they conceive COFP and its composing conditions. After this, TMD in general was discussed, and then focus was turned to DDwoR comparing it at the end of the interviews with TMJ dislocation. Prompts were used to change the topic (e.g., COFP, TMD, DDwoR, or dislocation) and probes were used, when necessary, for further clarification.

Interview procedures

All the interviews were undertaken by the research student. The student was trained by attending a number of courses in qualitative research. Furthermore, the first interview conducted by the student was monitored by one of the supervisors (JD), an experienced qualitative researcher, to assess and develop further the student's interview skills.

Most interviews (N = 18) were conducted face-to-face in one of the rooms in Newcastle Dental Hospital and three interviews were accomplished via telephone. The telephone interviews were conducted for clinicians' convenience, either because they were reluctant to participate in a face-to-face interview or because they were unable to attend the Dental Hospital.

The mean duration of the interviews was 45.22 (± SD 14.86) minutes. All the interviews were recorded (with permission from the participants) using a digital voice recorder (Olympus DS-660) and the audio files were anonymised using study numbers and transcribed verbatim by a professional company who had no links with the clinicians involved in the study and with whom we had a confidentiality agreement. Subsequently, each anonymised transcript was cross-checked with the original recording by the interviewer to ensure the accuracy of transcription and then the audio recording was securely deleted. The British Dental Association's guild remuneration rate (£77/hour) was provided from the student's bench fees to the participating clinicians to compensate for their time.

6.3.6 Qualitative data analysis

The data analysis in quantitative research begins after completion of the 'numerical' data collection, whilst the conceptual analytical process in qualitative research begins during the 'textual' data collection (Nicholls, 2009c). Such 'within data collection' continuous analysis in qualitative research has the advantage of allowing the researcher to go back and make sense of the data, refine questions, develop hypotheses, and follow emerging paths of inquiry in more depth throughout the data collection period. It also enables the researcher to look for deviant cases (i.e., the 'outliers' that contradict the emerging propositions or hypotheses) that can be used to refine the emerging concept (Pope *et al.*, 2000).

There are two distinct forms of reasoning to an idea: inductive and deductive reasoning. Quantitative research is concerned with the deductive process of theory testing, whilst qualitative research is largely involved in the inductive process of theory building (theory developing, production, formation, or generation) (Nicholls, 2009b). Inductive reasoning is an iterative process of examining and re-examining the theoretical ideas within the data to develop hypotheses (Bloor, 1978). In other words, it tries to construct a theoretical meaning and understanding of a problem or a phenomenon as a result of exploration (Thomas, 2006). Its ultimate aim is to generate/build theory that explains the problem or the phenomenon under study (Nicholls, 2009b). Qualitative research, however, does not always use an inductive analytical approach. The themes used to describe and explain the phenomenon may be derived inductively (obtained gradually from the data to generate a hypothesis) or used deductively (either at the beginning or during the data collection/analysis) (Pope *et al.*, 2000).

In this study, I used both inductive and deductive iterative approaches in various stages of data analysis. This is because I, the interviewer, am also a clinician; as a result it would be extremely difficult to isolate myself totally from the data. However, given my experience in the field as a researcher and a clinician, I attempted to avoid bias in data analysis by approaching the relevant literature about the factors (barriers) that might influence the clinicians' decisions in TMD/DDwoR management only after the preliminary findings had emerged. Furthermore, I tried to present the data from two points of view: as a researcher and as a clinician.

To analyse the qualitative data, several approaches are available (Rapley, 2011). In this study, the inductive/deductive analysis of healthcare professionals' decision-making processes was conducted following the framework analysis approach (Ritchie and Spencer, 1994) but it was informed by the Theoretical Domains Framework (TDF) of behaviour change (Michie *et al.*, 2005).

The 'framework analysis' approach used in this study is a method developed by Ritchie and Spencer (1994) for applied qualitative research. It involves five analytical stages: familiarization; identifying a thematic framework; indexing; charting; mapping and interpretation. Ritchie *et al.* (2003) pointed out that this framework approach has several advantages: it is grounded and generative, dynamic, systematic, and comprehensive; enables easy original text retrieval; allows within-case and between-case analysis; is accessible to people other than the primary analyst; and can be appropriate to research

that has specific questions, a limited time period, a predetermined sample (e.g., professional participants), and a specific priori issues (e.g., policy issues).

The TDF was employed in this study as an *a priori* analysis framework to examine and understand the influences on professionals' decision-making processes and to unpick and identify the determinants of professionals' clinical behaviour. The identified 'behavioural determinants' can then be used to help inform the design of a behaviour change intervention based on theoretical framework; such 'behavioural determinants' cannot be completely identified if an atheoretical approach was used.

In summary, the TDF was utilised as a coding framework and the framework approach was used to help organise the data and the analysis.

The interview transcripts were analysed in seven stages as follows:

Stage 1- Familiarisation

The first three transcripts were read and re-read several times and their audiotapes were listened to by the student to obtain a general sense of the information provided and for familiarisation with the raw data.

Stage 2- Coding interview transcripts

This is regarded as the first 'formal' step in data analysis in which all the interview transcripts were coded by the student using line-by-line coding, which is the most intensive and productive manner to code the data (Strauss and Corbin, 1990). It was suggested that one of the potential limitations of using the TDF as a coding framework for data analysis is the possibility of preventing themes from emerging 'naturally' if they did not 'fit' the 'pre-defined' theoretical domains (McCluskey and Middleton, 2010; McSherry *et al.*, 2012). To overcome this limitation, the codes were generated initially 'freely' without using the 'pre-defined' domains and then mapped to the theoretical domains and their relevant constructs.

The first three coded interviews were reviewed independently by one of the supervisors (RG), an experienced qualitative clinical researcher, to crosscheck the validity of the used codes. Thereafter, the student coded all the interviews guided by the theoretical framework for subsequent analyses.

Stage 3- Mapping codes into theoretical domains

An *a priori* theoretical framework based on the TDF was used to facilitate data analysis. Excel spreadsheets (v. 14, Microsoft office professional plus 2010, USA) were used to facilitate the organization of the data into relevant theoretical domains and constructs from the TDF thereby allowing immediate comparison of data.

The coded data and their representative quotes were mapped to the relevant constructs within the theoretical domain of the TDF by the student. Codes that initially seemed to be irrelevant to the theoretical domains were placed into a separate 'additional' theme for further analysis. After further analysis, however, the codes in the additional theme were merged with the theoretical domains. To avoid data misrepresentation, the student referred back to the psychological definitions of the domains and constructs and also to the theoretical domains interview (TDI) questions. This process helped to generate the working definitions to describe each theoretical domain for this study as detailed in Table 6.4.

Domain [a]	'Psychological' definition [b]	Working definitions [c] (domain description)
1. Knowledge	An awareness of the existence of something.	This domain describes the professionals' clinical knowledge about TMD/DDwoR disorders and their procedural knowledge to diagnose and treat these disorders. It also describes the professionals' knowledge about the scientific evidence and guidelines for TMD/DDwoR management.
1.1 Experiential knowledge	A 'conscious event' that is lived through, or undergone, that stimulates the acquisition of knowledge (knowledge acquisition from experience).	This is a construct of 'knowledge' domain. It describes the professionals' acquired knowledge through practice on TMD/DDwoR patients.
2. Skills	An ability or proficiency acquired through practice.	This domain describes the professionals' skills and competencies to diagnose and treat TMD/DDwoR.
2.1 Experiential learning	A 'conscious event' that is lived through, or undergone, and that stimulates expertise learning to take place by actively performing and participating in an activity (i.e., learning from experience).	This is a construct of 'skills' domain. It describes the professionals' previous experience and learning through practice in intervening with TMD/DDwoR patients.
3. Social/ Professional role and identity	A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting.	This domain describes the professionals' perceived role and identity as well as their perceived responsibility in managing patients with TMD/DDwoR. It also describes the professionals' boundaries in TMD/DDwoR management.
4. Beliefs about capabilities	Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use.	This domain describes professionals' perceived self-confidence and beliefs about their abilities in TMD/DDwoR management.
5. Beliefs about consequences	Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation.	This domain describes the professionals' beliefs about consequences which are broadly divided into clinicians' expectancy about the disorder progress and their beliefs about potential consequences of certain clinical decisions.
6. Optimism	The confidence that things will happen for the best or that desired goals will be attained.	This domain describes the professionals' optimism/pessimism about TMD/DDwoR management.
7. Reinforcement	Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus.	This domain describes perceived professional incentives or rewards, whether self-reward, social reward, material reward or health-system reward (e.g., CPD hours), associated with managing patients with TMD/DDwoR.
8. Intentions	A conscious decision to perform a behaviour or a resolve to act in a certain way.	This domain describes the professionals' intentions to manage TMD/DDwoR patients and their intrinsic motivation to improve their knowledge and skills in order to implement their intentions.

Domain [a]	'Psychological' definition [b]	Working definitions [c] (domain description)
9. Goals	Mental representations of outcomes or end states that an individual wants to achieve.	This domain describes the professionals' goal setting and action planning for TMD/DDwoR management. This is associated with the priority or importance ranking of a certain behaviour or sets of behaviours for TMD/DDwoR management.
10. Memory, attention, and decision processes	The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives.	This domain describes the professionals' memory for (e.g., forgetting), and attention to (e.g., focussing) TMD/DDwoR disorders as well as to their memory for the disorders' management guidelines. It also refers to specific decision-making relevant to TMD/DDwoR management.
11. Environmental context and resources	Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour.	This domain describes the availability, accessibility, and functionality of resources as well as the environmental barriers and facilitators for TMD/DDwoR management.
12. Social influences	Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours.	This domain describes social influences from other clinicians, patients, as well as healthcare organisations on professionals' decisions for TMD/DDwoR management. Any of these people or systems could cause social support or social pressure and thereby encourage or discourage the management.
13. Emotions	A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event.	This domain describes professionals' emotional responses (positive or negative), stress, fear, or burnout that could be caused by managing patients with TMD or DDwoR.
14. Behavioural regulation	Anything aimed at managing or changing objectively observed or measured actions.	This domain describes the professionals' self-regulatory processes that aim to change their behaviour as a result of specific behaviour change techniques (e.g., self-monitoring, feedback, breaking habit, action planning, and coping planning) and that could lead to change in order to improve TMD/DDwoR management.
15. Nature of behaviour	The nature of the aggregate of all responses made by an individual in any situation.	This domain describes the nature of professionals' behaviour in TMD/DDwoR management.

[a] Data representing the theoretical domains are available in Table 6.9.
[b] All domain definitions, except for the definition of the domain 'Nature of the behaviour' (from Huijg *et al.* (2014b)) and the constructs 'Experiential knowledge' and 'Experiential learning', were based on definitions from the American Psychological Associations' Dictionary of Psychology (APA, 2007) and as defined and used in the TDF (Michie *et al.*, 2005; Cane *et al.*, 2012).
[c] Our study-specific domain description.

Table 6.4: Theoretical domains and their psychological and working definitions. Adapted from Michie *et al.* (2005) and Cane *et al.* (2012).

Stage 4- Generating the theoretical framework

The student generated the initial framework guided by the TDF. To ensure the reliability of the generated framework, two supervisors (VA & JD) crosschecked independently the consistency in coding the representative quotations within and across domains. Thereafter, the student refined the theoretical framework for subsequent analyses. The completed framework was examined then by one supervisor (VA), a specialist in health psychology, to ensure that the coded data were allocated appropriately into the constructs within the relevant domains. Consensus on framework and its representative data was achieved by successive meetings and discussion with the supervisory team. The finalised framework involved 15 theoretical domains and their relevant constructs adapted from the original and revised TDF (Michie *et al.*, 2005; Cane *et al.*, 2012), with some additions, as depicted in Figure 6.1.

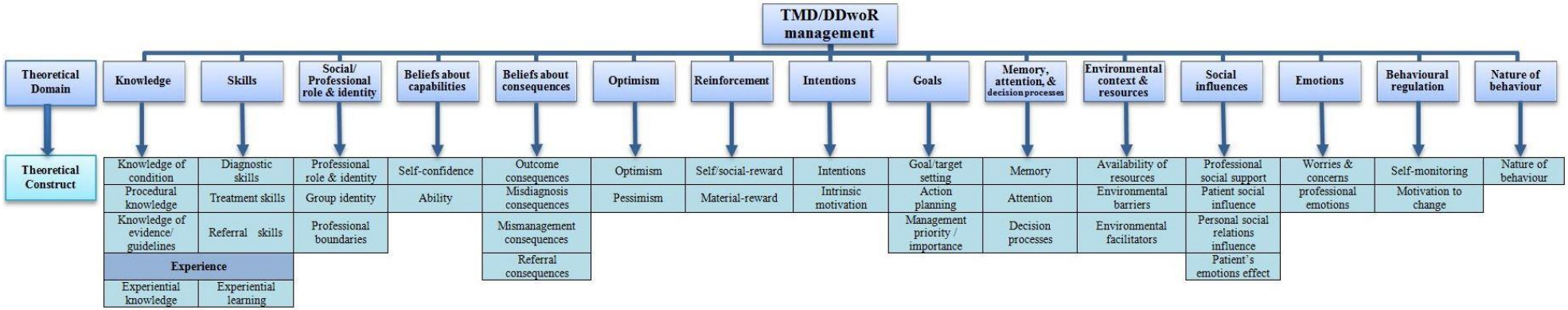


Figure 6.1: Study's theoretical domains and their relevant constructs.

Stage 5- Identifying relevant theoretical domains

The domains having greater clinical significance and reporting were considered likely to be relevant for changing the professionals' behaviour. The relevance of the domains were identified through consensus discussion between the student and one of the supervisors (JD), a topic expert, to interpret the importance of the domain from a clinical perspective and then confirmed by another supervisor (VA), a specialist in health psychology.

Stage 6- Mapping the clinical decision-making processes of participants

As a separate analysis, the pattern of clinical decision-making process for each practitioner was identified, analysed, and then depicted in a graphical map representing the management pathway of individual clinician.

This additional step of data analysis served three purposes: First, it enabled the researcher to understand more thoroughly the clinical decision-making process for each individual practitioner (a worked example for one clinician is available in Appendix L). Second, it allowed the researcher to identify the commonalities and differences between clinicians' decision-making processes and combining those processes that shared similar patterns in a singular assembled map representing each group of practitioners (Appendix M). Third, it helped the development process of a generic map of decision-making processes for all clinicians (Figure 6.6).

Stage 7- Data interpretation

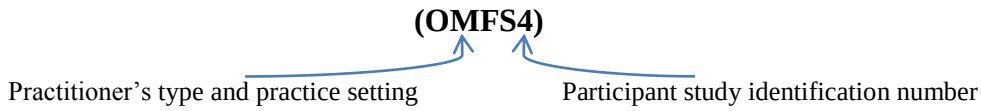
This is the final step in data analysis in which the data were summarised and the findings were reported. Representative data from the transcripts were used to support the discussed findings.

All the data in this chapter were independently examined by three of the supervisors (JD, VA, & RG) at various stages of data analysis and the analysis findings were reviewed, discussed, revised, and agreed.

6.4 Data and Discussion

6.4.1 Introduction

As is usual practice in qualitative research, the qualitative data are often presented and discussed simultaneously (Mays and Pope, 1995). Throughout this section, therefore, the findings from the qualitative analysis will be discussed jointly with presenting quotations to support the discussed data. The presented quotes are representative of the qualitative data. The quotes are edited sometimes by adding additional words in squared brackets to aid clarity and meaning but no substantial changes have been made to the original meaning by interviewee. At the end of each quotation, acronyms in parenthesis are used referring to practitioner's type and practice setting as well as participant's reference number as clarified in the below example. Table 6.3 gives further details regarding the meanings of acronyms used in this section.



The findings from the qualitative analysis will be discussed in four main subsections:

- Subsection 6.4.2: Generic and detailed section describing the professionals' clinical decision-making processes in TMD/DDwoR management.
- Subsection 6.4.3: Brief and focused section summarising the influences on the professionals' decisions in TMD/DDwoR management building upon data presented in Section 6.4.2.
- Subsection 6.4.4: Summary section of main findings from Sections 6.4.2 and 6.4.3.
- Subsection 6.4.5: Strengths and limitations section of the qualitative study.

6.4.2 Professionals' clinical decision-making process in the management of temporomandibular disorders

The clinical decision-making process is known to be a complex non-sequenced process influenced usually by numerous factors at different phases of process (Mezher *et al.*, 1998; Hajjaj *et al.*, 2010). For the purposes of discussing the qualitative data and clarity for the reader, however, this section will consider the following:

First, any similarities and differences in decision-making process between different groups of practitioners are highlighted wherever possible. As it will become clear later from the presented data in this section, the clinicians' processes were based mainly on their professionals' background (dentally- or medically-qualified) and practice setting (primary or secondary care, emergency or community non-specialist or specialist services). Therefore, the healthcare professionals are grouped as follows:

- Frontline clinicians: include GMPs, GDPs, and A&E clinicians.
- Primary care clinicians: include GMPs and GDPs.
- Secondary care clinicians: include A&E and OMFS clinicians.
- Dentally-qualified clinicians: include GDPs and OMFS clinicians[5].
- Medically-qualified clinicians: include GMPs and A&E clinicians.

Second, the factors, as informed by the TDF, that emerged from the data throughout this section that reportedly implicitly or explicitly influenced the clinicians' decisions are emboldened in brackets after each quotation and related back to Table 6.4 which explains the domains of the decision-making taxonomy used. The main findings from each of these emerging themes, however, will be summarised separately in Section 6.4.3 on factors influencing the clinicians' decisions.

Third, although in clinical practice multiple decisions are often made concurrently by the clinicians during the decision-making process and each decision made may provide feedback for others (Zeleny, 1982; Bornstein and Emler, 2001), for the purposes of this section, the clinicians' decision-making process is discussed in a chronological event

[5] Some interviewed clinicians are dually qualified (i.e., they hold a medical degree in addition to dental degree).

order. This is started from patients' presentation till their referral and clinicians' suggestions to avoid referral. This section, therefore, includes five separate, but sequential, steps as follows:

- Step 1: Patients' presentation to clinician's practice.
- Step 2: Clinicians' diagnostic decisions (patients' diagnosis).
- Step 3: Clinicians' treatment decisions (patients' treatment[6]).
- Step 4: Clinicians' referral decisions (patients' referral).
- Step 5: Clinicians' suggestions to support their own decisions.

Fourth, in each step, the data are reported sequentially. Firstly COFP and TMD in general are discussed, followed by the more specific diagnoses of DDwoR and TMJ dislocation.

Step 1: Presentation

The clinicians varied in their knowledge and experience of managing patients' presenting with the discussed clinical conditions (COFP, TMD, DDwoR, and TMJ dislocation). This seemed to be related, in addition to their qualification, to their clinical work context.

Work context influence on clinicians' knowledge and experience

The work context of clinicians seemed to determine the type and frequency of contact with patients having acute or chronic conditions. This, in turn, appeared to influence the clinicians' knowledge and experience about the discussed clinical conditions.

The literature suggests that patients suffering from painful conditions in the head and neck region can present to clinicians of any medical or dental speciality in primary or secondary care (Madland and Feinmann, 2001; Beecroft *et al.*, 2013; Israel and Davila, 2014). However, due to the structure of the UK National Health Service (NHS), patients with COFP often seek care first from their general medical or dental practitioners in

[6] Although the term 'management' may be more accurate than 'treatment' for a non-curable condition such as TMD (Mercuri, 2013), it was used in this chapter to differentiate it from the broad 'management' term (see Footnote 3).

primary care (community, often non-specialist, based care) (Newton-John *et al.*, 2001; Bell *et al.*, 2008; Durham *et al.*, 2011). The study sample confirmed this and offered reasons for it:

1. Primary care clinicians as gatekeepers to secondary care.
2. Patients' ease of access.

> *"I guess these people they've perhaps put up with such [chronic] pain…and so with the access to GPs [being] easier than specialists you're going to be seeing them a lot"* (GMP9) **(Environmental context and resources)**.

Some of the clinicians in primary care, however, seemed to have limited knowledge about the main conditions causing chronic pain in the orofacial region. The most frequently acknowledged or mentioned condition was TMD, perhaps as a result of the fact that they knew they were being interviewed about this, or possibly because it is the most common COFP condition that the clinicians frequently encounter with in their clinical practice (Wirz *et al.*, 2010; Yazdi *et al.*, 2012).

> *"Q[7]: What do you know about other [COFP] conditions apart from the TMD?*
> *R[8]: I suppose there's the salivary glands could cause problems. And, you know, there's [are] other things related like the ears and the head, ears related to it I suppose could be nothing to do with the teeth or the TMD"* (EGDP18) **(Knowledge)**.

In contrast, the secondary care clinicians working in hospital-based specialist services such as the oral surgery and maxillofacial surgery departments (OMFS) appeared more familiar with the diagnosis and treatment of patients presenting with conditions causing chronic pain in the head and neck region (Beecroft *et al.*, 2013) and, subsequently, seemed to have higher levels of knowledge and greater experience of COFP.

> *"I suppose immediately I'd think of a shortlist of things [COFP conditions] but the things that spring to mind would be temporomandibular joint pain disorder [dys]function, TMJPDS [previously used acronym for TMD] – atypical facial pain, trigeminal neuralgia, I'd also think about burning mouth syndrome. There are other causes of chronic pain…chronic neuropathic pain following cancer surgery, …chronic pain because…[of] bisphosphonate necrosis or osteomyelitis or osteoradionecrosis"* (OMFS11) **(Knowledge)**.

[7] Interviewer Question
[8] Interviewee Response

The clinicians working in hospital-based emergency (urgent care) services such as the accident and emergency departments (A&E) were *"not really exposed to this kind of thing [COFP] very often at all and especially in A&E"* (A&E6). The A&E clinicians appeared to have a very basic knowledge about COFP and the conditions that comprise it but they seemed to be more aware about the acute presentations of COFP conditions (Durham, 2012) they might encounter in A&E.

> *"We probably don't see very much of that [COFP] where I work. It tends to be more er the obviously trauma, acute infections and things like that...but I imagine the sort of the things you'll be getting [in A&E], er things like the neuralgias, so facial neuralgias and like I say disc disorders of the TMJ joint and bits and pieces like that but again it's not something that we see very much of"* (A&E16) **(Knowledge 'experience')**.

TMD is the most common non-odontogenic pain in the orofacial region. In the UK, it was suggested that approximately 3-4% of population suffering from TMD attend clinical practice for consultation and/or management (Gray *et al.*, 1994a). In primary care, the dental practitioners suggested TMD was quite a common problem and they probably saw such patients on a weekly to monthly basis: *"I probably see on average I would say 2, 3 [TMD] patients a week"* (EGDP12), whilst the medical practitioners explained that TMD patients presented less frequently to their surgeries, probably on a monthly or yearly basis: *"new patients [with TMD] I would think er probably one a month"* (A&E/GMP17). In secondary care, the OMFS clinicians reported seeing referred TMD patients *"probably, on a weekly basis"* (OMFS20). The A&E clinicians, however, reported being rarely confronted with any of the common TMD problems but they reported their experience of acute presentations: *"I've had someone come in with trigeminal neuralgia but I haven't had someone come in with temporomandibular joint dysfunction. I've had someone come in with a jaw dislocation…. It really isn't something [TMD] that we commonly see"* (A&E6). This suggests that the dentally-qualified clinicians in the study sample had generally more experience with TMD than the medically-qualified clinicians. In addition to their limited experience, the medically-qualified clinicians in the study sample (GMPs and A&E) acknowledged their insufficient knowledge about TMD topic because it was not covered sufficiently neither in their undergraduate educational courses: *"we weren't taught very much about it"* (A&E6) nor in their postgraduate training programmes.

"I think it's probably not something [TMD] that, you know, is done at undergraduate much. Obviously most GPs go through various rotations and, you know, the ones that you most do is something like paediatrics, gyne.., psychiatry. These are the kind of mandatory ones and obviously none of those really cover TMJ problems and then people may choose to do extra things like say ENT but then that's not a mandatory one so I think that people just pick it up from their GP training as opposed to having a special orthopaedic or erm ENT or, you know, any specific rotation or specific pathway" (GMP8) **(Knowledge; Skills)**.

The professionals' knowledge of the aetiological factors causing TMD varied widely among clinicians, which reflects the uncertainty in the literature (Luther, 2007), but it seemed to depend, to some extent, on their reported experiences with patients attending treatment to their practices. The literature suggests that general practitioners more commonly encounter simpler TMD cases whilst the specialists are more likely encountering more complex TMD cases (Steenks, 2007; De Boever *et al.*, 2008; Beecroft *et al.*, 2013). This seems to be reflected in the study data when aetiological factors were discussed. In primary care, most clinicians focused purely on the pivotal role of stress as the main aetiological factor in common TMD. This is in contrast to OMFS clinicians in secondary care who seemed to be more knowledgeable about the complex 'biopsychosocial' aetiology of TMD (Dougall *et al.*, 2012). This is probably related to their knowledge and experience of managing patients with the chronic refractory TMD who are often referred to secondary care.

"I think the majority [of TMD] I see are due to parafunction and er sort of bruxism and that kind of thing. Very rarely have I seen any associations with trauma but erm it's sort of mainly parafunction and I think stress has got a massive part to play in all of that and often you see patients where they have a very stressful life event going on and, you know, they're on top of everything else, now they've got this pain and they're not sleeping and they can't make sense of it" (EGDP12) **(Knowledge 'experience')**.

"I think there's clearly an exacerbation or a precipitation by psychosocial factors which interact very strongly with whatever mechanical and functional problems are going on and I think it's quite complex… I think you have to judge each case on its merits and I think you have to try and pick out for that patient how much of this is caused by sort of tissue damage or...and how much of it is related to the psychosocial components, and I think that varies from person to person, but I believe quite firmly that all the patients that we see have got a combination of all of these factors…" (OMFS11) **(Knowledge 'experience')**.

Given their experience in chronic refractory cases, some OMFS clinicians exemplified the interaction between the patient's biomechanical and psychosocial factors as a

'vicious cycle': *"it's the chicken and the egg situation is it, they've had the problem with the jaw, they've had the pain, they're sick of the pain, now they're depressed, the depression is making the jaw problem worse… it is a circle and everything's got one thing has an effect on the other"* (OMFS20) **(Knowledge 'experience')**.

Some of the clinicians in OMFS departments were also able to discuss the possible aetiological factors behind the genesis of disc displacement in patients with advanced disc derangement disorders they might encounter in specialist service, such as the disc could be displaced due to: *"acute trauma to the jaw…a whiplash to the jaw…crash intubation… [or] chronic causes of it [DDwoR] as well where just sort of click, click, click and eventually it just goes"* (OMFS21), or because *"the articular disc…attached… anteriorly by the superior head of the lateral pterygoids"* (OMFS4). The causes they discussed, however, are considered only as possible risk factors in the multifactorial aetiology of disc displacement (Manfredini, 2009).

These views differ from those in A&E departments who seemed to have a more limited knowledge regarding the aetiology of acute presentations of TMD they might encounter in emergency service.

> *"I know that certain patients are more prone to er to getting things like the dislocations because they have sort of a laxity of the ligaments or and it's sort of like a shallower angle between the articulating bits of the joint. Erm…sometimes it's almost a trauma to an area can make them more prone to it…"* (A&E16) **(Knowledge)**.

In general, the respondents reported diverse experiences with TMD but suggested that the TMD patients who seek treatment with them are often middle-aged or younger patients, mostly females, during periods of stress. This finding is in line with the majority of the TMD literature (de Kanter *et al.*, 1993; Wahlund, 2003). Although, in contrast, OPPERA studies suggested that the first-onset TMD is not predominantly a condition of females in early adulthood (Slade *et al.*, 2013a).

> *"In general practice it tends to be erm I'd see mainly women late thirties or forties they seem to have problems with TMD because they might be going through a lot of stress in their personal lives erm so that's something that, you know, can be picked up on"* (NGDP15) **(Knowledge 'experience'; Skills)**.

In primary care, the clinicians reported they most commonly saw patients with either asymptomatic clicking or mild TMD pain whilst they saw patients with severe TMD pain less commonly. This is again consistent with the incidence of TMD subgroups because the most common forms of TMD are low grade myofascial pain and disc displacement with reduction (DDwR) whilst acute TMD problems are, relatively, less common (Manfredini *et al.*, 2012).

> *"Usually the patients I come across come in with pain and clicking and I'd say 9 times out of 10 they do grind their teeth through the night and they're aware of that or their partner is, they wake up in the morning with pain… so I'd say that's the usual kind of patients we see"* (EGDP18) **(Knowledge 'experience')**.

> *"There will be certain conditions like the acute TMD cases which can be challenging because the patient is in extreme pain…but that's very low"* (EMGDP1) **(Knowledge 'experience'**; **Beliefs about capabilities)**.

Unsurprisingly, therefore, the primary care clinicians reported more experience with the more common TMD subtypes and considered these to be usually a mild, self-limiting but a chronic, recurrent problem: *"often it is a chronic condition and a recurring condition"* (EGDP13) and *"most cases are probably not so severe"* (NGDP5). This is as opposed to acute DDwoR (i.e., closed lock[9]) which the primary care clinicians apparently saw as a very different condition: acute, severe, uncommon problem that they do not encounter frequently in their daily general practice describing their experiences with such an acute DDwoR patient's presentation as *"the odd time"* (EMGDP3).

> *"I mean generally the TMD problems that you do see in practice is [are] due to grinding, stress, you know, the bog standard sort of things. You haven't got the locking jaws or with this lady [referring to a DDwoR patient] it was just I hadn't seen it before"* (EMGDP2) **(Knowledge 'experience')**.

The clinicians usually remember their personal experience with the conditions they have encountered in the past: "*we tend to remember patients we've seen and conditions we've treated"* (A&E/GMP17). This is especially true for recognition and recall of salient event/critical incident such as patients presenting with acute severe symptoms (Arkin

[9] During the interviews, the terms 'closed lock' and 'DDwoR' were used colloquially indistinguishably but the clinical condition was explained to the interviewee as the symptomatic acute DDwoR associated with TMJ pain and limited mouth opening.

and Duval, 1975; Light *et al.*, 1979; Cioffi, 2001). Patients with DDwoR, especially in early/acute phase, can be presented with quite severe complaints of TMJ pain and limited opening symptoms impacting their functional capabilities and quality of life (Anastassaki and Magnusson, 2004; Silva Machado *et al.*, 2012; Fotedar *et al.*, 2015), as demonstrated in this quote: *"she was clearly in acute pain and hadn't slept…she had quite severe trismus as well"* (EMGDP3). Some clinicians in primary care, therefore, could easily retrieve their previous experience with this type of patient's presentation: *"there was a gentleman, this is quite a long time ago, who had a very...limited opening and he erm just couldn't get any opening at all really, …it was one of the worst ones I've ever seen"* (EGDP12). The ease of retrieval of these particular DDwoR cases from the participants' memory is probably related to their salience and, therefore, they were intensively and dominantly held in participants' memory (Arkin and Duval, 1975). The clinicians, however, found it difficult to remember the characteristic signs and symptoms of DDwoR if they had not encountered such a case frequently in clinical practice.

> *"The anatomical malalignment as they [DDwoR patients] open their mouth erm would make me think this is significant, I need to do something about this. Now whether I would remember which side it [jaw] deviated to or not that I couldn't tell you"* (A&E/GMP17) **(Knowledge; Beliefs about consequences; Memory, attention, and decision processes)**.

Patients with DDwoR can be presented to any clinician at the frontline. In a survey-based study of patients' choices conducted in the UK, the majority of patients chose to consult first a medical (84%) rather than a dental (16%) practitioner if they would have a restricted mouth opening symptom (Bell *et al.*, 2008). In the data, however, the majority of clinicians at the frontline, whether dentally- or medically- qualified, seemed unfamiliar with this type of patient's presentation.

> *"I think genuinely it would strike me as being such an unusual presentation [DDwoR] that actually, you know, a differential list of things that it may or may not be would be even less and I fear to say would be beyond my understanding of the situation such that I'd be saying 'listen I don't know what it is, what's the plan to somebody in secondary care'. So it's less missing diagnosis, it's more not having any idea what it is"* (GMP7) **(Knowledge; Beliefs about capabilities)**.

Many of frontline clinicians (A&E, GMPs, & GDPs) in the study sample reported they had not been confronted with a patient having painful limited opening symptom of

'DDwoR' (12 out of 16 clinicians). That said, some clinicians might have seen such a patient but uncertain about the specific 'DDwoR' diagnosis.

> *"If it's either painful for them or they can't seem to open their mouth very wide then erm, and I have come across those patients which haven't given it that name [DDwoR], and I would erm, you know, I would refer those patients early"* (GMP8) **(Knowledge; Skills; Memory, attention, and decision processes; Nature of behaviour)**.

The low incidence of DDwoR amongst TMD patients (Manfredini *et al.*, 2011) is probably one of the main reasons for the lack of knowledge and experience with DDwoR disorder specifically amongst the majority of frontline clinicians in the sample: *"I'm not sure if I know much about that [DDwoR] at all"* (NGDP14). Perhaps not unexpectedly, the clinicians' experience with patients having DDwoR, as any other sudden-onset uncommon condition, did not depend on the number of years the practitioners worked in clinical practice: *"I haven't come across it in my how many years of practice and I did used to work full-time"* (EGDP10); it depended, however, on their previous exposure, probably by chance, to such acute DDwoR in the out-of-hours emergency service, as demonstrated in the below quote:

> *"…when I was on-call I had this poor lady [referring to a DDwoR patient] who'd come in…for this one-to-one system …, she'd been told to go to her GP. She'd gone to the walk-in centre and because we're right opposite the walk-in centre she'd stumbled across us erm so I managed just to see her"* (EMGDP2) **(Environmental context and resources)**.

In the data, the majority of frontline clinicians appeared 'unfamiliar' with the nature of DDwoR *"I'm not familiar with that at all"* (EGDP18). Therefore, they expressed several worries and concerns if confronted with patients displaying symptoms of DDwoR:

> *"Actually my first worry would be that they'll be [DDwoR patients] in a lot of discomfort and a lot of pain, affect their eating and, you know, general day to day things. So I guess that will be my first concern is that they'll be going through a lot of pain really"* (EGDP18) **(Beliefs about consequences; Emotions)**.

On the contrary, apart from one clinician unfamiliar with the condition: *"I've not encountered it myself"* (OMFS20), all OMFS clinicians, regardless of their working experience, reported that they had encountered patients having DDwoR in secondary

care and being familiar with this type of patient's presentation: *"that's a fairly frequent [presentation]"* (OMFS11). Therefore, they were relatively, *"not particularly [worried]"* (OMFS11) if confronted with an acute DDwoR.

The uncertainty over the DDwoR diagnosis in primary care and the early referral of the 'undiagnosed' patients from primary to secondary care for such a low incidence disorder could explain why the OMFS clinicians saw DDwoR patients more frequently in secondary care setting and, therefore, had more experience than the primary care clinicians. Another finding relating to the referral process was that of the referral waiting time was sometimes seen as being too long: *"it usually takes a few months...about 2 to 3 months"* (EGDP18), and by this time the DDwoR patients may have resolution of the acute symptoms (Yura, 2012). Therefore, if there is a delay in patient's presentation, the secondary care clinicians might be confronted more often with the chronic rather than the acute DDwoR; although this could not be verified in the data.

The low incidence of DDwoR, however, cannot be rationalised as the sole reason for the lack of knowledge about DDwoR among the frontline clinicians. The incidence of acute TMJ dislocation amongst TMD is not determined yet but it seems to be comparable to that of DDwoR (Luz and Oliveira, 1994; Dahlstrom, 1998). In the data, many frontline clinicians reported that they had also never been confronted with an acute TMJ dislocation (9 out of 15[10] clinicians) but despite that, many of them had seemingly sufficient knowledge about the condition presentation and its management.

> *"Q: If we talk about another condition which is the TMJ dislocation, have you been confronted with such a patient?*
> *R: No but I know about the management of it… you have to put your thumbs on the occlusal surface of the lower molars and then manipulate the mandible backwards into place"* (EMGDP3) **('procedural' Knowledge)**.

In summary, the clinicians' knowledge and experiences seemed to vary according to their work context which determines the type and frequency of patients' presentation to their practices. The GDPs appeared to have higher levels of knowledge and experience with TMD than the GMPs but, all the dental and medical primary care clinicians

[10] The first interviewee (EMGDP1) was not asked about TMJ dislocation.

seemed to be familiar with TMD patient's presentation and considered TMD as a mild self-limiting problem. The repetitive frequent exposure to more common TMD problems in primary care probably increases the professionals' knowledge and skills in diagnosing and treating such 'mild' conditions over the years. In contrast, given the low incidence and infrequent exposure to uncommon severe TMD problems, all the clinicians at the frontline, whether dentally- or medically- qualified, seemed unfamiliar with acute DDwoR patient's presentation and had limited knowledge and experience with DDwoR specifically. Clearly, these variations have impacts on the clinicians' diagnostic, treatment, and referral decisions.

Step 2: Diagnosis

The clinicians seemed to have differing levels of diagnostic uncertainty and ability to make a diagnosis for the discussed clinical conditions.

Value of terminology used for conditions' diagnosis

When the clinicians asked first about chronic orofacial pain (COFP), most, if not all, primary and secondary care clinicians considered it a vague generic terminology. The clinicians often described COFP as an *"umbrella"* (OMFS4), *"undifferentiated"* (GMP7), or *"very broad"* (OMFS11) term *"covering a wide umbrella of different problems"* (EGDP10), and *"could mean any number of things"* (EMGDP3). This supports the view that the term 'COFP' should not be used for diagnosis, instead it is necessary to sub-classify it in order to establish an accurate diagnosis (Benoliel and Sharav, 2010). The definition of the reference period for 'chronic' pain differed from clinician to clinician in secondary care as either *"longer than three months"* (OMFS19) or *"more than about 6 months"* (OMFS11). This reflects the debate around the definition of duration of 'chronic' pain in the literature (Von Korff *et al.*, 1992; Merskey and Bogduk, 1994; Palla, 2006; Dworkin *et al.*, 2011).

Similarly to the 'COFP' term, the term 'TMD' was also described by some clinicians as *"an umbrella term"* (EMGDP3) involving *"a wide variety of disorders"* (EGDP10). In the recently expanded TMD taxonomy, 56 different conditions were initially considered and 37 disorders were included (Peck *et al.*, 2014), which indicates that the use of TMD

as a diagnostic term is of limited value (Benoliel and Sharav, 2010). There is some evidence that the use of generic all-inclusive 'TMD' diagnosis in clinical practice and scientific research can be one of the reasons for the clinicians' lack of ability to differentiate between subtypes of temporomandibular disorders. Two recently published studies have shown that only a small percentage (10-24%) of referred TMD patients had a formal 'TMD' subgroup diagnosis defined (Beecroft *et al.*, 2013; Kraus, 2014). In the current study, many clinicians at the frontline (A&E, GMPs, & GDPs) found difficulty to remember the TMD subgroups or appeared uncertain about them: *"certainly I don't know the difference between erm the subgroups of TMD so maybe that would be something and maybe how to treat each one slightly differently"* (NGDP14). Furthermore, the data indicated that most frontline clinicians revealed vague knowledge about DDwoR/closed lock terms and confused these with other terms (e.g., DDwR and DDwoR; closed lock and open lock) or expressed lack of understanding of 'DDwoR' terminology: *"I don't understand what that term [DDwoR] is. I don't have insight into what that is and why that would be a subgroup of TMJ disorder"* (GMP7) **(Knowledge)**.

Clearly, labelling patients with different disorders as 'TMD' patients hinders the development of knowledge about different TMD subtypes' diagnoses and treatments. This has led some experts to suggest the use of TMD as a 'diagnostic label' should be discarded altogether (Laskin, 2008; Benoliel, 2010). However, this is a debatable issue with some experts arguing for simplicity by grouping all patients with common TMD problems together and treating them all using 'similar' conservative management approach in the first instance. They suggest this will be of benefit to frontline clinicians in that they will be more likely to easily remember the simple things to do in practice (Greene, 2010b). Others, however, argue for detailed management by differentiating between the different disorders of TMD and providing targeted treatments to each disorder specifically in order to avoid a "blunderbuss" type approach to treatment of all TMD patients (Okeson, 2007). There is, in fact, a need to understand both the specificity of each temporomandibular disorder's pathophysiology and the effectiveness of each associated specific treatment for each individual disorder (Okeson, 1997a). For example, the effectiveness of the 'unlock' mandibular manipulation when used as a treatment specifically for DDwoR management.

Diagnostic uncertainty

The general approach often reported by the clinicians when confronted with a clinical condition was trying to identify the source of the problem: *"very often we seek for the cause of the pain"* (A&E/GMP17). In biopsychosocial COFP conditions, however, there could be no obvious 'biomedical' cause to explain the chronic pain to make a diagnosis (Madland *et al.*, 2001). The clinicians in primary care, therefore, generally reflected upon COFP repeatedly as *"a long standing history of pain without an obvious cause or certainly one that's undiagnosed"* (GMP9) **(Knowledge)**.

In a national survey conducted in the UK, Aggarwal *et al.* (2012) explored GDPs' diagnosis, treatment and referral patterns of COFP conditions using 4 case-scenario questionnaires. The study found that most GDPs could correctly diagnose the TMD (87%) and burning mouth syndrome (92%) scenarios but they were less successful in diagnosing the other two 'atypical' orofacial pain conditions. In a national survey of the UK final year dental students, about 36% of respondents showed reduced confidence in the differentiation between pain of odontogenic and non-odontogenic origin (Macluskey *et al.*, 2012). Recently, a qualitative study conducted in the UK reported that all the sampled primary and secondary care medical and dental practitioners felt uncertain about diagnosing COFP patients (Peters *et al.*, 2015). Similarly, in this study, the majority of primary and secondary care clinicians generally acknowledged difficulty in diagnosing COFP conditions and often reported trying to 'pick-up' the diagnosis by *"a process of eliminating the causes"* (OMFS20). Many dental practitioners, however, indicated that they could recognise patients having a TMD problem: *"I pick it up quite straightaway when they [patients] start giving a history. Straightaway I'm thinking I don't think this is teeth, what it is: is TMD*" (EMGDP2). Nevertheless, most clinicians also pointed out that the TMD diagnostic process may not always be simple and *"can be very difficult"* (OMFS19) sometimes because it can be *"quite difficult to find the exact cause [of pain]"* (EGDP18) or to differentiate the TMD pain from other sources of pain.

> *"I think some cases are very plain and obvious that, you know, that is a temporomandibular disorder case, some I find tricky erm when the patient is coming in with a dental pain that I don't agree is of dental origin, you know. I find that those cases are a bit tricky to diagnose and is it this tooth that's maybe*

sort of causing the pain or is it a different condition to sort of a facial pain or a TMD" (NGDP5) **(Skills)**.

Misdiagnosis of TMD in general practice is not uncommon (Renton and McGurk, 1999). The clinicians' diagnostic uncertainty about TMD was highlighted in previous qualitative studies (Durham *et al.*, 2007; Durham *et al.*, 2010). In the data, the clinicians attributed their diagnostic uncertainty about TMD to several factors including: TMD being a clinical diagnosis without any definitive investigations available currently to identify its causes, non-specific TMD symptoms may overlap with other conditions or fluctuate over time, TMD symptoms are usually subjective and, therefore, the patients may find difficulty explaining their subjective 'pain' symptoms and clinicians may also find difficulty eliciting a meaningful response from the patient.

"I think it's not easy [to diagnose TMD] because of the potential for quite a lot of uncertainty and also my appreciation of it suggests that it's largely a sort of clinical diagnosis therefore there's always a degree of uncertainty and I think a lot of it is about, you know, excluding the possibility of mass lesion or whatever, depends on the age of the patient, is probably on my mind first and then I would always suggest it to the patient openly that it's a working diagnosis really and not that I have the necessarily all of the answers but this is something we're going to try and, you know, we do see this, let's give it a try with that level of certainty…[because] there's no absolute way of proving or disproving it, you know, …there's not a definitive investigation which proves it or disproves is a dangerous thing" (GMP7) **(Skills; Beliefs about capabilities; Beliefs about consequences)**.

Some clinicians reported that they "*offer a trial of treatment"* (GMP9) to the TMD patients and measure the patients' treatment response as a kind of diagnostic measure: *"I think it's often diagnosis by providing a splint and seeing if the problem goes away"* (EGDP10). This strategy clearly shows the clinicians' diagnostic uncertainty as well as unpredictability about the outcomes of the provided treatment.

When asked if a patient having TMJ pain and limited opening presented to their practices, the majority of clinicians at the frontline (A&E, GMPs, & GDPs) felt *"uncomfortable"* (EGDP10) and expressed high degree of diagnostic uncertainty.

"Well you want to rule out, I guess erm...well you want to check their [DDwoR patients] background, their systemic history, you want to make sure they've not got something like quinsy or something. If that's ruled out and it does seem like

TMJ and they can't open their mouth I'd be quite uncertain actually" (GMP9) **(Knowledge; Skills; Beliefs about capabilities; Beliefs about consequences)**.

In actual practice situations, some frontline clinicians recalled their past experiences of confronting patients with TMJ pain and limited opening symptoms which potentially are suggestive of a 'DDwoR' disorder. Most of them, however, were either uncertain about the specific 'DDwoR' diagnosis: *"the one patient I did see, I wasn't really sure if they had reduced or not. They [She] had quite bad trismus and restricted movement so I wasn't sure whether it was [disc displacement] without reduction or with reduction"* (EMGDP3), or concerned regarding a misdiagnosis: *"I've had one patient who couldn't open their mouth for some months and I'm worried about a dislocation of the TMJ"* (GMP9) **(Knowledge; Skills; Beliefs about capabilities; Beliefs about consequences)**.

This study indicates that diagnostic uncertainty about DDwoR among frontline clinicians is mostly attributed to their limited knowledge and experience with the type of acute DDwoR that presents as a severely painful sudden-onset condition with an 'extra' symptom of limited mouth opening. Consequently, most, if not all, clinicians at the frontline reported their lack of confidence in diagnosing the 'DDwoR'.

"I wouldn't feel very confident. Erm I'd probably sort of describe the situation and describe my examination finding to someone but reaching sort of the actual [DDwoR] diagnosis I think I would probably struggle with that because I don't see very much of it" (A&E16) **(Knowledge; Skills; Beliefs about capabilities)**.

The uncertainty in DDwoR diagnosis among the frontline clinicians could be also due to the fact that DDwoR may be 'lost' through the general, and colloquial, use of the catchall 'TMD' term (Laskin, 1998). As mentioned, this may result in lack of ability to differentiate DDwoR from other temporomandibular disorders as shown in the below quote:

"Q: When you try to diagnose such a [DDwoR] patient how confident do you feel?
R: Erm not 100 percent. I'm not sure what the subgroups are all called. I know that it all falls under the one umbrella of TMD but I'm not sure which subtype to put it under. So to diagnose TMD I'd be fairly confident erm but to put it into a subcategory I'd be less confident, yeah" (NGDP14) **(Knowledge; Beliefs about capabilities)**.

The last point is confirmed in recent studies which found that the majority of referred patients with TMD signs and symptoms have not been given a specific descriptive subtype diagnosis or given only a generic 'TMD' diagnosis (Beecroft *et al.*, 2013; Kraus, 2014). In this study, most frontline clinicians seemingly were able to just simply categorise a patient presented with painful/limited opening as a patient having a 'significant' problem and refer the 'undiagnosed' patient early rather than being able to specifically diagnose 'DDwoR'.

> *"I think a lot of general practices knowing what's normal and knowing what's not normal but I think if I was examining that patient I would think that okay this is not normal mouth opening, you know, there's something going on here that needs looking at more so, like I say, I wouldn't necessarily give it that [DDwoR] diagnosis but I would refer on for a diagnosis"* (GMP8) **(Knowledge; Skills; Beliefs about capabilities; Beliefs about consequences; Memory, attention, and decision processes)**.

Clearly, the high diagnostic uncertainty of frontline clinicians could have a negative impact on patients who might be referred without being given a specific diagnostic 'label' and subsequently not having any information, explanation, or reassurance about their condition at the first-point of contact (Durham *et al.*, 2010).

> *"I saw him [a potential DDwoR patient] on sort of an acute basis obviously but then it took a while for the referral to come through and that gentleman sadly always had, he never regained full movement of his joint after that, that occasion. Erm he was very accepting of it and, you know, it made it potentially quite difficult erm but, you know, for that gentleman it wasn't a positive outcome...there was a permanent problem and they never resolved…. We never really did get to the bottom of why that occurred"* (EGDP12) **(Skills; Beliefs about capabilities; Beliefs about consequences)**.

In contrast to frontline clinicians, all OMFS clinicians, apart from one: *"I wouldn't feel particularly confident"* (OMFS20), felt able to make at least the clinical diagnosis of DDwoR, but reported using magnetic resonance imaging (MRI) in order to investigate the disc position and increase their confidence through confirmation of their 'provisional' DDwoR clinical diagnosis.

> *"I tend to usually carry out an MRI before I feel really confident [in DDwoR diagnosis] but I feel erm yeah that there are significant amounts of patients that I think that's what's happening, or I'm pretty sure that's what's happening, yeah"* (OMFS19) **(Knowledge; Skills; Beliefs about capabilities; Environmental context and resources)**.

Diagnosis process

History and clinical examination

TMD diagnosis is based largely on a detailed patient history and thorough clinical examination (Greene, 2010b). In a recent survey-based study, most GDPs reported that they primarily diagnose TMD on the basis of history (37%) or examination (30%) (Aldrigue *et al.*, 2015). In this study, the majority of primary and secondary care clinicians paid specific attention to key findings in patient history, specifically social history, and/or clinical examination. The dentally-qualified clinicians, however, focused their attention more on characteristic signs and symptoms of TMD and, therefore, appeared more confidently able to diagnose TMD clinically than the medically-qualified clinicians.

> *"I find it quite easy [to diagnose TMD]. Erm often they've come to the practice a few times that I often notice, because I always do my full checks of everything, doing my extra-oral examinations, so I pick up on erm people that are quite stressed"* (NGDP15) **(Knowledge; Skills; Beliefs about capabilities)**.

> *"It's difficult so it might not be someone [TMD patient] who you automatically straightaway diagnose it"* (GMP8) **(Knowledge; Skills; Beliefs about capabilities)**.

The difference between dental and medical practitioners' ability to diagnose TMD could be attributed to limited knowledge, experience, and expertise in TMD among medical practitioners as one dental practitioner articulated: *"[The] general medical practitioners…very much feel, or seem to feel, that the mouth is a dentist's remit and don't have quite so much expertise"* (OMFS19). The medical practitioners confirmed this assertion by giving that as a reason to signpost their patients to GDPs: *"I have a healthy regard for my lack of understanding about what goes on in the mouth and er our dental colleagues are experts in that area"* (GMP7) **(Knowledge; Skills)**.

As previously stated, TMD is a group of different disorders and clinicians might, therefore, expectedly encounter various types of TMD problems in their clinical practice. This was seen to add difficulty with the diagnosis process as demonstrated in the below quote:

> *"It's [TMD] just so varied. That's part of the difficulty that it's trying to make a clear diagnosis about how serious the condition is based on their symptoms because it can be acute or they can become chronic"* (EGDP12) **(Skills; Beliefs about capabilities)**.

In the initial step of the TMD diagnosis process, therefore, some dental practitioners reported that they split-up the TMD into different subgroups, mainly muscular- and joint-related disorders.

> *"Well in my mind and from my training I tend to divide it [TMD] up into myofascial problems so muscular, joints, specifically joint related problems and then TMD as a manifestation of any chronic systemic disorder such as arthritis or things like that"* (EMGDP3) **(Knowledge; Skills)**.

The most reliable criteria that can help clinicians differentiate between subgroups of TMD are the research diagnostic criteria (RDC/TMD) (Dworkin and LeResche, 1992). The use of the RDC/TMD in clinical practice, however, has been shown to be hindered by lots of barriers: lack of clinicians' familiarity; clinicians' perceptions of the tool as overly complex, time-consuming, and designed specifically for research purposes; the similarity of conservative treatments utilised for most TMD patients regardless of their specific diagnosis; the presence of sub-clinical symptoms with respect to the RDC/TMD in some TMD patients (Durham *et al.*, 2007; Beecroft *et al.*, 2013). In this study, one GDP highlighted the difficulty of applying 'extensive' criteria to diagnose different subgroups of TMD due to time constraints in NHS primary care:

> *"I think clinicians just need to be taught better understanding of TMD conditions just generally and then a bit more specifically about…diagnosing the different conditions but I think the NHS contract doesn't allow time for clinicians to spend time doing all the different criteria that they do in a hospital"* (NGDP15) **(Knowledge; Skills; Environmental context and resources)**.

In fact, the 'original' RDC/TMD has been criticised for being only appropriate for research purposes (Dimitroulis, 2013). An adapted, more practical, shortened version has been established and disseminated (Hasanain *et al.*, 2009) but it seems to be not widely used in clinical practice. Hopefully, the newly developed diagnostic criteria (DC/TMD) (Schiffman *et al.*, 2014a) may overcome this problem but their claimed clinical utility and practicality seems doubtful and needs to be proven. To give an example, one of the criteria for DDwoR diagnosis in the 'original' RDC/TMD is the absence of clicking sound. Interestingly, most OMFS clinicians in the study sample

reported their reliance on this criterion to make the 'DDwoR' diagnosis: *"usually these patients have…a long standing history of a clicking jaw and then one day it doesn't click, it just locks"* (OMFS11). Unfortunately, to increase the sensitivity and specificity scores of DDwoR diagnosis, this criterion has been omitted from the newly 'recommended' DC/TMD (Table 2.6), perhaps because it cannot always be confirmatory for DDwoR diagnosis (Miller *et al.*, 1985; Widmalm *et al.*, 1992). This finding gives some indication that the new criteria for DDwoR may be impractical for use. This study shows that most of the clinicians sampled found difficulty recalling different TMD subtypes and specifically were unfamiliar with the diagnosis of DDwoR. The clinicians, it would seem, are in need of a user friendly tool focusing on particular pathognomonic signs and symptoms which will allow them to make better diagnostic decisions and, for DDwoR specifically, avoid the potentially serious consequences of misdiagnosis (Beddis *et al.*, 2014). At the moment, it is difficult to prove if the new DC/TMD has the claimed clinical utility (Vilanova *et al.*, 2015) and if it can aid the clinicians to differentiate the DDwoR from other conditions with similar 'trismus' symptom (Table 2.7).

The existence of numerous conditions which may present with symptoms mimic to DDwoR, such as limited opening, is one of the diagnostic difficulties that clinicians may encounter when diagnosing a DDwoR patient, making the differential diagnosis of DDwoR challenging. Nevertheless, there are specific key findings that should make the clinician able to distinguish the DDwoR disorder from other conditions causing 'trismus' and most OMFS clinicians were seemingly aware of these.

It has been suggested that the practice of decision-making improves the clinicians' performance over time (Benner, 1982; Botti and Reeve, 2003; Croskerry, 2005a) and, therefore, "experienced clinicians perform better than novices" (Croskerry, 2005a). This seems to be reflected in this study as it was noticed that there was an important disparity in the initial phase of diagnostic decision-making processes for DDwoR between clinicians at the frontline (A&E, GMPs, & GDPs) and those at the specialist (OMFS) service. Most OMFS clinicians focused their attention to pathognomonic signs and symptoms of DDwoR:

"Well there may be clues in what they tell you that they may have had problems for a number of years, they may have had a clicking joint initially and then it stopped clicking and then they started to have problems opening. They might have a completely closed down in the morning, they might get much more sort of stiff as the day goes on but yeah, generally kind of pain and mobility issues and I suppose on examination you might notice…they wouldn't have a click, they might have trismus, they might deviate to their abnormal site,… They might be very tender as well, the muscles of mastication" (OMFS19) **(Knowledge; Skills; Memory, attention, and decision processes)**.

In contrary, most frontline clinicians did not pay specific attention to such signs and symptoms. This is apparently related to lack of knowledge and experience with DDwoR disorder specifically among the frontline clinicians rather than forgetting to mention the details of the decision-making process pertaining diagnosis, as illustrated in the below quote:

"I try and do a physical examination first so I try and work out how the joint is actually working by literally just asking patients to open and close. Find out if the joint's rotating and translating properly, if there's a click present, erm if there's any deviation of the lower jaw whilst the patient's opening or closing and if there's any pain associated with any of those movements and then I would just record that. I'm not terribly confident in interpreting that and saying exactly what's going on within the joint but if there was something significant, erm particularly the patient couldn't translate to something like that that with the limited opening those would be the ones I would be most concerned about, the ones I would need to refer more quickly" (EGDP12) **(Knowledge; Skills; Beliefs about capabilities; Beliefs about consequences; Memory, attention, and decision processes; Nature of behaviour)**.

The two groups of clinicians seemingly utilised completely different approaches in decision-making. The 'experienced' OMFS clinicians seemingly could recognise the pattern of DDwoR early and target particular information to diagnose 'DDwoR' by the pattern recognition decision-making approach (Manias *et al.*, 2004; Banning, 2008). This is illustrated in the below quote:

"I suppose it's a matter of er if something that the patient might say might trigger you into thinking oh maybe it's this and I'll ask a few more questions about this erm, you know, some of them might say 'I initially had a click and now I don't have a click anymore' and so that might make you feel that, you know, they've got disc displacement without reduction now" (OMFS19) **(Knowledge; Skills; Memory, attention, and decision processes)**.

In contrast, given their high diagnostic uncertainty, the 'inexperienced' frontline clinicians faced with DDwoR might try to use all the available resources in order to ascertain a diagnosis by an exhaustive decision-making approach (Croskerry, 2002). This is demonstrated in the below quote:

> *"I think you'd think about getting x-rays erm because it will be a case of wanting to see if there is either er injury to the jaw, a dislocation so you think about your OPG and your mandible, again your OPG would show if there's something that's sort of a tooth abscess or something that could be causing infection so it would help with the diagnosis. Erm again you'd probably think about doing blood tests if you were thinking of it as something like an acute infection or to check things like erm sort of calcium levels and bits and pieces in case, rather than it being a jaw that was locked, it was like a trismus erm or anything and you don't really sort of see it or you only see it rarely with things like sort of tetanus"* (A&E16) **(Knowledge; Skills; Beliefs about consequences; Environmental context and resources)**.

Many clinicians, however, seemed to approach clinical decision-making by firstly ruling out the worst-case scenario (Croskerry, 2002) when they encountered patient with 'unusual' presentation, such as DDwoR. This approach not only reflects the clinicians' diagnostic uncertainty but also their concerns/worries about missing serious pathology.

> *"I think one thing that would be quite important to pick up with it and one reason why you may do an MRI scan is people who present with trismus, ...it can sometimes be caused by temporal fossa tumours so you do an MRI scan to investigate for that because often sort of women over 30 or 40 would start to get...you start to sort of think could it be something odd, you know, just some facial pain you can't quite understand that it doesn't fit with anything classic"* (OMFS4) **(Knowledge; Beliefs about consequences; Memory, attention, and decision processes; Environmental context and resources)**.

The clinicians' concerns/worries about misdiagnosis and the consequences of missing serious pathology 'in their mind' and their expectations of 'worst case scenarios' probably led the 'inexperienced' clinicians at the frontline to directly refer possible DDwoR patients to the specialists. This 'rule of thumb' approach of referring the undiagnosed potentially 'significant' condition early before establishing a definitive 'DDwoR' diagnosis is a simple heuristic decision-making but it might not be the best decision and often prone to bias in conditions of uncertainty (Gigerenzer *et al.*, 1999; Hutchinson and Gigerenzer, 2005).

In the data, some clinicians pointed out the importance they placed on identifying that *"there are no red flags that concern"* (A&E/GMP17; **Emotions**) them in the initial stage of the diagnostic process. The necessity to educate clinicians to enhance their knowledge about the red flags' signs and symptoms (Table 2.9) when diagnosing patients with painful conditions in order to avoid potential serious consequences of delayed diagnosis/treatment has been emphasised in the literature (Huntley and Wiesenfeld, 1994; Al-Jamali *et al.*, 2013; Beddis *et al.*, 2014). This point was also highlighted in this study by one OMFS clinician as a result of discussion with peers:

> *"I think that as a whole professionals maybe should be more aware of the worrying signs to look out for, like I went and had a chat with [surgeon name], …and said well you're forgetting a patient's kind of got this sudden boring type pain around the TMJ region and they're kind of over 50, you've got to be thinking about things like acoustic neuromas, also if you're getting bilateral pain up here thinking things of giant cell arteritis or be aware of the broader picture. Erm and it's something that doesn't always come to the forefront. I suppose if I saw an elderly patient and they were getting this pain for the first time, they've not had it before, I'd be more concerned just because of their age, erm but I don't think everybody's particularly aware of that"* (OMFS20) **(Knowledge; Beliefs about consequences; Memory, attention, and decision processes**; **Emotions; Social influences)**.

Radiographic investigations

In addition to patient history and clinical examination, many clinicians discussed the role of various diagnostic investigations, mostly TMJ radiographic investigations. In the literature, TMJ imaging such as orthopantomograph (OPG), computed tomography (CT) scan, or MRI have been found to be routinely and repeatedly used for patients with TMD (Beecroft *et al.*, 2013; Kraus, 2014). In a survey-based study, about half of the GDPs sampled reported their frequent use of radiological investigations to diagnose TMD (Wirz *et al.*, 2005). In this study, most primary care clinicians reported that panoramic radiographs are unnecessary for the majority of TMD patients but they might order OPG for DDwoR case scenario to rule-out other pathologies: *"I might take an OPG just to rule out any pathology around the joints"* (NGDP15). The absence of OPG machine in some primary care practices was, sometimes, given as an additional reason to refer patients to secondary care: *"we have no erm OPG machine erm so we have no availability to do that so that would be another reason why I would need to refer if I*

thought the joint did need to be looked at" (EGDP12) **(Knowledge; Memory, attention, and decision processes; Environmental context and resources)**.

The OMFS clinicians also reported that they might request an OPG or even a CT scan for joint-related disorders to rule-out pathologies and they might order a MRI for DDwoR to identify the disc position. The clinicians, however, differed in their perspectives regarding the necessity of imaging the joint: *"I'm not entirely convinced about the usefulness of the MR scan for imaging the jaw joint mechanism"* (OMFS11). They also expressed contradictory opinions about the usefulness of MRI findings for DDwoR treatment planning, for example with this clinician saying: *"sometimes you might confirm that there is a problem with the disc but you might still not do anything about it anyway"* (OMFS19), as opposed to this clinician who stated: *"it does influence my decision to actually be more aggressive in the treatment"* (OMFS21). These opposing views reflect the considerable debate in the literature around the role of imaging in TMJ disorders management in general and its appropriateness for DDwoR patients in particular. Many authors advocated minimising their use to avoid unnecessary risk of ionising radiation and waste resources without beneficial outcome (Kraus, 2014; Ekberg *et al.*, 2015), whilst others supported their use to aid diagnostic decision-making process and avoid risk of missing a serious pathology (White and Pullinger, 1995; Al-Jamali *et al.*, 2013; Beddis *et al.*, 2014).

In fact, with detailed history and thorough clinical examination, it is often possible to diagnose patients with 'acute' DDwoR with limited opening clinically without the need for any imaging to the joint (Manfredini and Guarda-Nardini, 2008). Nevertheless, this study indicated that most of the OMFS clinicians sampled might order MRI for DDwoR patients despite its controversial role and effect on management decision. The rationale given for ordering MRI varied between clinicians, but in summary the reasons given included:

1. Rule-out serious pathologies such as tumours and reassure the clinician's concerns:

   "Erm you may do an MRI scan just to reassure yourself that there's nothing abnormal there" (OMFS4) **(Beliefs about consequences)**.

2. Confirm DDwoR clinical diagnosis:

"I think that the only way you can absolutely confidently diagnose that [DDwoR] is to have an MRI which is actually being reported by an experienced radiologists or you have a look at it yourself" (OMFS21) **(Beliefs about capabilities)**.

3. Used to find a biomedical cause of the problem thereby increasing the professional's confidence about the diagnosis of the condition and explaining it to the patient. It is also used as a back-up for the clinician (potentially for medico-legal purposes):

   "I like to do it [MRI]. I think erm I don't know if that's the nature of someone that's involved in surgery. You just like to see a picture of something clearly. Because…sometimes it doesn't necessarily manage and it doesn't really necessarily change what you end up doing, but I suppose then you can more confidently explain to the patient, it's like a backup at the very least. So I like to do them" (OMFS19) **(Professional role and identity; Beliefs about capabilities; Beliefs about consequences)**.

4. Planning for joint surgery before intervening:

   "If it [DDwoR] comes to surgery a lot of the time I would arrange an MRI" (OMFS21) **(Beliefs about consequences)**.

In summary, the clinicians vary in their diagnostic decision-making processes and abilities to diagnose TMD and DDwoR. The dental practitioners appeared more confidently able to diagnose TMD clinically than the medical practitioners, but all the clinicians at the frontline, whether dentally- or medically- qualified, were uncertain about DDwoR disorder specifically to make a diagnosis. These variations clearly have impacts on their treatment/referral decisions.

Step 3: Treatment

The clinicians seemingly vary in their perceived role, abilities, and plans to treat the discussed clinical conditions.

Clinicians' perceptions of the conditions and their perceived role in treatment process

Several published reports emphasise the important role the general medical and dental practitioners should play in early diagnosis and treatment of COFP/TMD conditions in a primary care setting (Okeson and de Kanter, 1996; Dimitroulis, 1998; Newton-John *et al.*, 2001; Steenks, 2007; Durham *et al.*, 2011; Klasser and Gremillion, 2013). This is

primarily to avoid potential psychosocial consequences of delayed diagnosis and treatment (Gatchel *et al.*, 2006; Durham *et al.*, 2010). In the study data, however, the primary care clinicians often reported their negative perceptions about COFP patients' response to treatment and prognosis: *"I think that will be, without referring them [COFP patients], I think it will be a case of seeing them all the time and without moving forward"* (GMP9). The perceived role of the majority of primary care clinicians, therefore, was to try and identify the cause of the problem or source of pain, rule-out serious pathology and 'pick-up' a diagnosis, and then refer patients with chronic pain early to secondary care rather than treating them in primary care. In a recent qualitative study conducted in the UK, Peters *et al.* (2015) explored the experience and understanding of COFP by patients and primary and secondary care medical and dental practitioners. The study found that all participants share negative experience of COFP as difficult and frustrating to understand and manage (Peters *et al.*, 2015). Other studies also found that the primary care clinicians have difficulties in managing COFP patients and often prefer to refer early without initiating a treatment (Aggarwal *et al.*, 2012; Beecroft *et al.*, 2013). This could be interpreted as a type of disposal of 'deviant' patients as described by Jeffery (1979) and Freidson (1984).

> *"My role in chronic conditions would be, as a general practitioner in a primary care setting, would be to 1) exclude er easily treatable dental conditions, say dental caries, periodontal disease, pulpitic teeth, erm that sort of thing to er look for obvious occlusal problems, erm say loss of posterior support and treating that sort of thing. 2) I would erm be involved in simple treatment of TMJ dysfunction erm and referral for the other conditions like if I made a diagnosis of trigeminal neuralgia I would refer erm for treatment erm and more complex erm occlusal problems I would refer"* (EGDP13) **(Professional role and identity; Beliefs about capabilities; Memory, attention, and decision processes)**.

Some GMPs, however, felt that they have a role to treat chronic pain patients in primary care. This may be in part due to their broad medical background and experience in treating chronic conditions such as diabetes and rheumatoid arthritis (Weel, 1996) and in part due to differences in the nature and type of clinicians' practices; that is: the dental practitioners are usually more orientated to intervene 'physically' to treat the patients' dentoalveolar diseases rather than to wait and see (Brennan and Spencer, 2006) whilst the medical practitioners are generally more orientated to listen to patients' complaints and prescribe medications (Bell *et al.*, 2008) as one participant highlighted:

"I think that my role almost begins and ends with listening to the patient and certainly that's 99 percent of the job that I do day in day as a GP" (GMP7) **(Professional role and identity)**.

In secondary care, the difference in the nature of the services provided by A&E and OMFS clinicians and how patients access them for care seemed to be reflected in clinicians' perceived roles (Ismail *et al.*, 2013). The A&E clinicians seemed to feel that patient attendance with chronic problems to A&E is 'inappropriate'. They stated that in the context of urgent access services they cannot prescribe long-term medications, review or follow-up these patients, refer them to other services or receive feedback from these services. Therefore, they felt that they do not have a role to treat COFP patients and prefer to signpost those patients directly to a more 'appropriate' clinician: *"if people do come in with chronic problems your main role is to try and signpost them to someone more appropriate or unless there's something more serious going on"* (A&E6). The OMFS clinicians, however, are usually involved in treating referred COFP patients (Beecroft *et al.*, 2013). In the data, apart from one OMFS clinician: *"if it doesn't involve surgery, I don't think it's my role"* (OMFS21), all felt they have a role to treat the COFP patients.

> *"I think my first role is to rule out any serious pathology and then …try and pick out what is wrong with that patient, what is the major contributing factor to their symptoms and then try to work out what's going to benefit them most in terms of reducing their symptoms, and this is where it gets quite difficult"* (OMFS11) **(Professional role and identity; Beliefs about consequences; Beliefs about capabilities; Memory, attention, and decision processes)**.

Similarly to clinicians' negative perceptions about COFP patients, the primary and secondary care clinicians also reported negative perceptions about TMD patients: *"often when you talk to colleagues about patients everyone kind of gets that heart sink when there's a TMD patient"* (OMFS20). The so-called 'heart sink' feeling (O'Dowd, 1988; Bligh, 1999) about TMD patients among clinicians is probably related to their awareness about the complex biopsychosocial nature of TMD and the possible challenges when managing those patients which can potentially be attributed to multiple reasons.

One of the reasons for this may be a previously expressed view that the TMD patients can be 'needy' patients (Durham, 2007) because they *"take a lot more time"* (GMP8) and require longer successive appointments. In the data, most clinicians highlighted that they *"need [a] longer [appointment time]…with TMD patients"* (OMFS20) than other conditions to take history, examine, diagnose, and treat, or even to review them on regular follow-up appointments. In one study, an initial comprehensive consultation of about 45-60 minutes was suggested to be needed for complex COFP condition in order to achieve patient's satisfaction (Napenas *et al.*, 2011). Time constraints, therefore, were repeatedly mentioned by the primary and secondary care clinicians for TMD management: *"often you need a lot of time spent just listening to them and often a GP doesn't have that time"* (NGDP14) **(Beliefs about consequences; Environmental context and resources)**.

Another reason for the perceived difficulty is related to clinicians' perceptions of unpredictability of outcomes of provided treatments for TMD that achieves optimal outcomes: *"often it's a case of trying something and seeing how that particular individual responds to that"* (EGDP12). This is again attributed to the biopsychosocial nature of TMD which may require management at the individual level as emphasised by many participants: *"it's a case of managing the individual rather than the case itself"* (EMGDP1) because *"no two patients are the same"* (OMFS19), this is, *"because you might have [TMD] patient(s) with the same sort of symptoms and they respond differently to the same treatment"* (OMFS20) **(Knowledge; Beliefs about consequences)**.

The individualised management of the biopsychosocial TMD may require the need for a tailored intervention personalised to each individual TMD patient needs (Litt and Porto, 2013). This approach, however, can be problematic if we want to apply the evidence-based practice for 'optimum' TMD care. This is because the 'evidence-base' concept is based largely on findings from high-quality, methodologically robust, randomised controlled trials (RCTs) which form the basis for high-grade evidence from systematic reviews and meta-analyses (Rosner, 2012). Currently, however, the vast majority of RCTs about TMD management are conducted by recruiting, grouping, and randomising the patients based on their biomedical rather than their psychosocial factors. Although

the findings from such RCTs may provide some indications of evidence for TMD management, they may provide insufficient basis for tailoring effective interventions and can be difficult to generalise (Reissmann *et al.*, 2008). Subsequently, this may indicate that the current application of 'evidence-base' concept in TMD management is questionable. This is certainly true in 'non-mechanical' biopsychosocial disorders such as myofascial pain as opposed to more biomechanical disorders such as TMJ DDwoR or ankylosis. This coupled with the fact that the TMD is a group of heterogeneous disorders rather than a singular disorder (Peck *et al.*, 2014), which adds further difficulty to TMD management. Unfortunately, in addition, several published systematic reviews such as Cochrane reviews investigated the effects of a specific therapeutic intervention on general 'TMD' rather than on specific subtype of TMD (Shi *et al.*, 2003; Guo *et al.*, 2009; Luther *et al.*, 2010; Mujakperuo *et al.*, 2010; Rigon *et al.*, 2011), which adds further confusion to the field. All these points could explain why it is always difficult to find high-quality robust evidence and guidelines for TMD management despite the presence of numerous RCTs and systematic reviews about TMD management (Chapter 2, Section 2.2.7). Perhaps for future work, the axis 2 of DC/TMD (Dworkin *et al.*, 2002) should be used together with an adaptation of the template for behavioural change intervention description and replication criteria (TIDieR) (Hoffmann *et al.*, 2014) for conducting person-centred RCTs of tailored interventions for TMD management.

At the moment, the absence of high-quality robust evidence for TMD management and the presence of differing management ideologies and contradictory opinions among experts (Jenkins, 2014) can cause confusion for the clinicians managing the TMD patients, especially at the frontline.

> *"In terms of further education erm there's [are] so many courses on occlusion and different splints and this that and the other and a lot of them are really trying to help with TMJ [TMD]. It is quite confusing and it's difficult to know really which is one person saying a splint's rubbish, another person will say this splint's brilliant and this one won't work in that and then you'll hear somebody else saying something completely the opposite again and I'm just very sceptical about the whole thing"* (EGDP12) **(Knowledge)**.

There are, however, some published guidelines that could help the general practitioners to initially manage TMD/DDwoR patients such as: the National Institute for Health and

Care Excellence-Clinical Knowledge Summaries for TMJ disorders (NICE CKS, 2010), the European Academy of Craniomandibular Disorders (EACD) guidelines for GDPs (De Boever *et al.*, 2008), and the recent TMD management guidelines for primary care from the UK Specialist Interest Group in Orofacial pain and TMD (USOT) (Durham *et al.*, 2013). Studies, however, have shown that the clinicians often do not follow guidelines for COFP/TMD management and prefer to manage their patients by experiential-based practice (Durham *et al.*, 2007; Reissmann *et al.*, 2015). Similarly, most clinicians in this study reported that they do not use any specific guidelines in their practices neither for TMD management: *"no I wouldn't say I use any specific guidelines [for TMD management] at the moment"* (NGDP5), nor for DDwoR management: *"I haven't read anything for GDPs specifically on the sort of first line management of the closed lock"* (EMGDP3). The clinicians seemingly depended on their experiences about the treatments that *"seem to work"* (NGDP14), their clinical training, and the management ideologies of teaching staff which are often influenced by personal perspectives (Durham *et al.*, 2007; Klasser and Greene, 2007).

> *"I don't have any written guidelines [to use for TMD management]. What I've read, what I've done as a practitioner that seems to work. And what I know, what I've been taught"* (EGDP10) **(Knowledge; Skills)**.

In the absence of use of management guidelines, the professionals' clinical decision-making processes are, expectedly, subjective. In the data, there was some subjectivity and variability in decision-making processes among clinicians but it was clear that the decision processes for TMD management were relatively similar among each group of practitioners.

In primary care, the GMPs as 'generalists' who *"see everything of everybody's specialist area"* (GMP7) perceived the TMD as a more 'dental' topic: *"I guess it's a problem that sometimes people just associate it with seeing your dentist"* (GMP9). The GMPs reported that they had *"a role [in TMD management] but it's very early on because erm there's only so much we can do in primary care"* (GMP9). One of the reasons for this perceived minor role in TMD management is discussed in the literature (Okeson and de Kanter, 1996; Field *et al.*, 2013) and highlighted by one dental practitioner: *"a doctor can't be expected to take an impression to make a splint fit but they could suggest that they went to the dentist and had that"* (OMFS19). The GMPs

confirmed this statement: *"I've often signposted people to their community dentist because as I understand it they sometimes consider fitting them with certain devices to wear particularly overnight"* (GMP7) and reported that they could treat TMD patients by medications only. One GMP, however, reported the 'additional' prescription of over-the-counter mouth guards due to suggestion by a dentist who was a relative of theirs. These 'non-fitting' appliances, however, can cause serious adverse events including choking hazards, tissue damage, and irreversible occlusal changes (Wassell *et al.*, 2014).

The GDPs, on the other hand, perceived their role included the initial management of TMD: *"I think my role is to try and erm sort of diagnose, you know, try and do the simple things that I can do in a practice setting before I refer"* (EGDP18). They reported that they can largely treat the more common and usually mild pain TMD cases related to 'stress', by providing the 'simple or basic' conservative treatments including: education, reassurance, self-care instructions and advice, analgesic and/or anti-inflammatory medications, and jaw exercises, massages, and hot/cold packs; then the next step is the provision of soft splints and occasionally the hard splints. This initial conservative treatment, up to the stage of provision of splints, was described as *"the first-line of defence"* (EMGDP2) for the GDP, possibly due to clinician's perceived limits in providing further treatment options to TMD patients.

The GDPs seemingly perceived the provision of splints as the only physical action they could do to TMD patients in primary care: *"the only treatment you do would be kind of stage 2 as I would call it, so first stage would be conservative [self-management], stage 2 would be the splint, stage 3 would be referral to hospital"* (NGDP14). Some studies have shown that the most widely used splint type by GDPs for TMD was the hard (stabilisation) splint (35%-45%) whilst the soft splint was used less frequently (6%-26%) (Ommerborn *et al.*, 2010; Aldrigue *et al.*, 2015). In another study, however, the GDPs applied the soft splints more frequently to treat TMD (Gnauck *et al.*, 2012). In this study, all the GDPs reported their ability to provide soft splints but only a few reported they had additional training to provide the hard (stabilisation) splints. When compared with the hard splints, the soft splints seemed to be more preferred by GDPs because they are easier to make, relatively cheaper, and not require specific skills (e.g.,

restorative course training (Wassell *et al.*, 2004)); in addition, the evidence shows that both types seem to be effective (Pettengill *et al.*, 1998; Alencar and Becker, 2009).

> *"Probably early in my career I used hard acrylic splints quite often, bite raising appliances, I've used erm soft splints latterly erm which are effective in some cases but not in every case but easy to make and those have been inexpensive to make"* (EGDP13) **(Skills; Beliefs about capabilities; Environmental context and resources)**.

In NHS primary care, the provision of splints is the only financial incentive to GDPs for TMD management because they *"are very well remunerated for providing an occlusal splint"* (EGDP10; **Reinforcement**) according to price per units of dental activity (splint= 12 UDAs) in the current NHS dental contract (Milsom *et al.*, 2008; DOH, 2013). However, the expensive cost of splint, in primary dental care NHS specifically (band 3) (DOH, 2014), is a financial barrier to TMD patients because it makes the patients refuse this treatment modality to what they think it is just a 'gum shield' and the clinicians cannot guarantee its effectiveness.

> *"I'd offer them [TMD patients] the splint, soft splint. Erm but in general practice patients often don't want to pay so what we do in our practice is erm if they're exempt it don't matter, that's their problem but often patients don't want to pay for a splint so we often offer them privately so say to them 'look we can get the lab to make you one for £70 instead of paying £214 because that's how much it would be on the NHS'. So that's the way we – well at the time persuade them to have this but often patients don't want to pay £70 for what they think is a gum shield"* (NGDP14) **(Environmental context and resources)**.

This financial barrier for TMD patients and lack of remuneration for GDPs (Tickle *et al.*, 2011) to compensate for the time required to manage TMD was also highlighted in a previous qualitative study (Durham *et al.*, 2007) suggesting the need to revise the NHS dental contract in the UK. Recently, there is a prospect for 'reforming' the current 'UDA-based system' dental contract by introducing a new system of payment incorporating a combination of activity, capitation ("paying dentists related to the number of patients under their care rather than the numbers of courses of treatment they provide"), registration ("encouraging a partnership between patient and dentist to facilitate health improvement over time"), and quality payments (DOH, 2010a; DOH, 2015; Holmes *et al.*, 2015). If implemented in the future, the national dental contract reform programme (DOH, 2015) together with 'smart' NHS dental services

commissioning (NHS Commissioning Board, 2013) may have the potential to influence clinical practice and improve quality of primary care for TMD patients.

In secondary care, the A&E clinicians perceived their role to provide urgent treatments to patients attending with more acute nature of TMD problems. Consequently, they reported providing only simple pain medications and advice if encountered TMD patients in addition to signposting them to a more 'appropriate' clinician. The OMFS clinicians, on the other hand, felt they were responsible to treat the 'referred' TMD patients from primary care: *"I am in a position where people refer to me for advice about what to do"* (OMFS4; **Professional role and identity**), but they often started with similar conservative treatment that may have been provided initially in primary care; although they also reported that they can provide further treatment options to patients following initial conservative treatment such as providing: further explanations using diagrams, skulls, and/or TMJ imaging, long-term pain medications such as anti-depressants, and/or surgical management.

The OMFS clinicians, however, vary in their perceived responsibility to treat TMD. For example, this clinician stated: *"I'm not sure I want to see a patient, a clinic that was only TMJ patients because I think I'd find that quite difficult, but equally I think seeing patients with facial pain disorders is part of my practice and it provides balance to my practice and I don't have a problem with that"* (OMFS11), as opposed to this clinician who stated: *"as a surgeon I feel it's my role…to actually help those [TMD] patients that require the surgery rather than deal with the other people that don't"* (OMFS21) **(Professional role and identity; Beliefs about capabilities)**.

It is worth noting that the study sample did not include clinicians sampled from different specialties in secondary care such as restorative dentistry or oral medicine specialists who may have different management ideologies. Despite that, it becomes quite noticeable from the current data, as well as from previous published qualitative data (Durham *et al.*, 2007), that the management ideologies of TMD appear to depend largely on the professionals' background, qualifications, interests, and practice.

"I think that erm I'm well aware of the fact that probably I'm I would say more dismissive than maybe I should be of things like occlusal rehabilitation. Erm I suppose that if some people get referred to a restorative department with TM joint dysfunction they'll be treated in a far different way than if they go to an oral surgery department because the interests are different and it's interesting to see how the treatment would [be] different and I'm sure it does differ. You probably get fancy splints, a bit of occlusal grinding, all that sort of thing" (OMFS21) **(Knowledge; Skills; Professional role and identity)**.

When the clinicians were specifically asked about their possible treatment plan for a patient who presents with painful/limited opening, most clinicians at the frontline (A&E, GMPs, & GDPs) showed lack of confidence in their abilities to treat the DDwoR case scenario: *"I don't feel confident that I'd know what I'm doing"* (EGDP10), giving the reasons of limited knowledge and lack of prior experience and/or proper training to treat such an acute condition: *"quite difficult [to manage DDwoR] I would say, based on what training I have and knowledge"* (EMGDP3) **(Knowledge; Skills; Beliefs about capabilities)**.

The data demonstrated that most GDPs felt they have sufficient training to diagnose and treat mild TMD problems but they felt they have insufficient training to diagnose and treat acute TMD problems such as DDwoR: *"To manage…[TMD] due to teeth grinding…, I think we have enough training. I think the basics are there for that. It's when it starts becoming a bit more complicated…. So I think that's [DDwoR] where we can and do need a bit more training"* (EMGDP2). Consequently, some GDPs felt their current role to manage mild TMD rather than severe TMD such as DDwoR: *"The role I have in terms of making sure that they make, you know, the right choices on a daily basis about how to manage that [TMD] condition and to understand it. Erm exercises, pain relief, avoidance of habits, that kind of thing. Erm but there are certain things that I feel are kind of out of my remit and if things aren't responding or for example if a patient had a limited opening or severe pain or whatever then I think that's when I would choose to refer"* (EGDP12) **(Skills; Professional role and identity; Beliefs about capabilities; Memory, attention, and decision processes; Nature of behaviour)**.

The perceived difficulty in DDwoR treatment amongst frontline clinicians is attributed in part to clinicians' uncertainty in identifying the cause of pain and/or limited opening

and in part to the fact that those patients often presented with acute severe symptoms of pain and restricted opening hindering the clinicians' ability to manage the patient.

> *"I think it's difficult [to manage such a patient with painful limited mouth opening] if it's not an obvious cause such as an infection and then give it tooth relating if it is an infection then there's a cause and you could treat the cause erm but I think if it didn't, you know, if it wasn't any of those things and you've eliminated everything else then actually it's very difficult to treat"* (EGDP18) **(Knowledge; Skills; Beliefs about capabilities)**.

> *"I mean obviously if they've got painful mouth opening and like an affected ability to eat and erm make the pain worse...it would probably make me want to refer them earlier than just someone with TMJ pain but with normal mouth opening… Erm just because I feel that I can offer something to TMJ, you know, in terms of pain relief and so on whereas this is sort of pain as well as not being able to open their mouth so I just feel that I can't offer anything so, you know, then I would refer earlier"* (GMP8) **(Knowledge; Skills; Beliefs about capabilities; Memory, attention, and decision processes; Nature of behaviour)**.

In real practice situations, the frontline clinicians reported their inability to manage DDwoR patient: *"I was a bit lost on exactly what to do"* (EMGDP2) and felt helpless to intervene and help when encountered a DDwoR patient: *"I did feel a little bit helpless but there was very little I could actually do to physically help him [a possible DDwoR patient] at the time that that happened"* (EGDP12). This *"bad experience"* (EGDP12) caused an emotional impact on the clinicians who regretted not being able to relieve the acute patients' symptoms and could not perform any 'physical' act to stop the patients' suffering at the first-point of contact. Noticeably, this past experience was also a motivational factor for those clinicians to improve their clinical knowledge and develop additional skills to manage DDwoR in the future.

> *"It was just I was quite lost when she was locked. I was quite lost exactly what to do because she was in so much pain erm and I just felt, you know, that's why I rang up the SHO Maxfax because obviously it was a Sunday evening and it was just for any other dental pain that comes in, abscesses and stuff I can get you out of pain, you know, I can numb you up, I can do something, I can sort you and I kind of felt a little bit lost that she came in and then when she walked out in the same pain that she came in because I couldn't physically do anything for her. I obviously told her what she had to do, instructions what to follow, and I had an appointment for her for a couple of days time but I did feel a bit lost that I couldn't take her pain away"* (EMGDP2) **(Beliefs about capabilities; Beliefs about consequences; Emotions; Memory, attention, and decision processes)**.

In contrast, the majority of OMFS clinicians reported that they were able to treat DDwoR patients at least initially.

> *"Generally I don't tend to find them [DDwoR patients] difficult to manage because I do have a sort of a set erm, you know, set of measures that generally help people so I think when they first attend it's fairly straightforward to manage them because they often haven't tried all of these measures and once you've started them then things improve. It becomes more difficult later on when they're not improving"* (OMFS4) **(Knowledge; Skills; Beliefs about capabilities)**.

In the data, all OMFS clinicians reported that it is the responsibility of primary care clinicians, primarily GDPs and to a lesser extent GMPs, to provide the initial management for TMD patients: *"I think it's well within the scope of the general dental practitioner to manage these [TMD] cases. I think if a general medical practitioner wants to develop this they need to get some further training"* (OMFS11). This is consistent with the views in the literature (Okeson and de Kanter, 1996; Dworkin, 2001; Steenks, 2007; De Boever *et al.*, 2008) and broadly agreed with the primary care clinicians' perceived role and beliefs about their abilities to manage the TMD patients conservatively initially: *"surely we can do that [conservative TMD management] as general practitioners"* (NGDP14).

For DDwoR management, however, the OMFS clinicians had contradictory opinions regarding the primary care clinicians' responsibility to manage patients with DDwoR. Some reported that *"it should be managed at primary care"* (OMFS4) and it is appropriate for GDPs to manage the DDwoR patients initially in primary care prior to referral to secondary care and, therefore, *"in terms of closed lock…there's still a role for primary care"* (OMFS11). However, others felt that it is a specialised area and often requires knowledge, experience, and expertise to be treated and, therefore, *"that's a condition that's justifiable to, for sure, to come to secondary care"* (OMFS19). This disparity in specialists' opinions was also found in the literature (Gray *et al.*, 1994a; Durham *et al.*, 2013; Field *et al.*, 2013; DeAngelis *et al.*, 2014) and in the data reported by the frontline clinicians regarding their perceptions and opinions in their ability and responsibility to manage DDwoR. Most clinicians at the frontline felt that they do not have the ability to manage patients with DDwoR and *"wouldn't institute any treatment"* (EGDP13). They perceived their role as 'generalists' and as such felt comfortable to treat the general most common mild pain in TMD patients but stated that an acute

severe DDwoR "*seems a very specialist thing which perhaps is beyond the scope of the general practitioner"* (EGDP10) and *"it's a sort of specialist area which would need access to specialist investigations…and specialist treatments and so not the primary care"* (EGDP13). Therefore, the data indicate that those clinicians prefer to refer DDwoR to be treated in secondary care rather than treating it in primary care. Conversely, few frontline clinicians, might try to *"do all the conservative stuff"* (NGDP14) for the initial management of DDwoR to relieve the patients' acute symptoms prior to referral to secondary care despite also acknowledging that *"the management is difficult for a primary care dental practitioner"* (NGDP5). They perceived their role as 'first-line clinicians' to relieve the patients' acute symptoms firstly in primary care prior to referral to secondary care.

> *"Yes [it's important to manage DDwoR in primary care] because I think, even though I haven't seen it in my day to day job, you know, I think we are going to get people coming to us as their first port of call and I think we should be able to do something to them, be able to help them"* (EMGDP2) **(Professional role and identity; Beliefs about capabilities; Goals)**.

This 'first-line' professional identity led one GDP to suggest a guideline for early management of DDwoR patient in primary care prior to referral to secondary care: *"maybe… there should be a system where the patient has to have had some early intervention by a clinician and they can only be referred after so long"* (NGDP15) **(Professional role and identity)**.

Actually, the majority of primary and secondary care clinicians seemingly had the perspective that early management is better for DDwoR patients. The clinicians, however, expressed different opinions about the pathophysiology of DDwoR in relation to the necessity to intervene early, as these participants stated: *"[to avoid] any risk of it progressing to the chronic closed lock"* (EMGDP3), *"the earlier it is er receiving definitive treatment the less disability will be in the long-term"* (A&E/GMP17), *"if it's just recently happened it's probably easier to correct than if they wait for perhaps a few hours"* (OMFS20), *"the longer you leave the meniscus all bunched up at the front of the joint the more likely it is to become deformed or and it's more likely to not be successful [the treatment]"* (OMFS21), or *"[the patient may] benefit from an earlier surgical intervention"* (OMFS11) **(Knowledge; Beliefs about consequences; Goals)**.

Most of these beliefs, however, are not necessarily well supported in the literature (Chapter 2, Section 2.2.4).

Overall, the perspective of many clinicians in primary care is that, although it is perceived as being important, they do not feel, at present, it is possible to manage DDwoR patients in primary care without guidance from secondary care, or appropriate further training. In the data, many primary care clinicians appeared to favour a role of providing the continuation of care after resolution of acute DDwoR symptoms in secondary care.

> *"I think it's important that we then pick up the kind of [DDwoR] patient afterwards so obviously like with any area when you refer a patient they still come back to you on the practice isn't it, so we still need to understand it and reinforce whatever the specialist may say but as far as I'm aware I don't know anything specific that you could do in primary care but certainly like with any conditions we would then sort of review the patients afterwards and just see, you know, how they are managing"* (GMP8) **(Professional role and identity; Beliefs about capabilities)**.

In summary, it is important to diagnose/reassure the DDwoR patients' initially at the first-point of contact (Durham *et al.*, 2010). It is also not infeasible, with further education and training, to treat this type of patient, at least initially, in primary care. However, given the limited knowledge and skills of primary care clinicians at the moment, it may be more appropriate for them to just review the DDwoR patients after they discharged back from secondary care for continuity of care.

Treatment options

Various treatment options were discussed in the literature for DDwoR management most commonly, manipulation therapy, splint therapy, and TMJ surgery (Murakami *et al.*, 1995). Nevertheless, the majority of clinicians at the frontline (A&E, GMPs, & GDPs) either had no idea about possible therapeutic interventions or suggested/guessed some conservative or surgical interventions that could be used in secondary care for patients with DDwoR: *"I don't know what the treatment is"* (EGDP10), or *"I would be guessing"* (EGDP12). In secondary care, however, the OMFS clinicians reported that they manage DDwoR initially conservatively in a similar way to any other TMD conditions: *"it's managed in the same way as er disc displacement with reduction"*

(OMFS4), but some clinicians focused on certain treatment options for DDwoR disorder specifically such as: reassurance about DDwoR natural course, explanation the role of disc and mechanism of the condyle-disc complex to the patient, early jaw manipulation and exercises, topical analgesic/anti-inflammatory medications over the affected joint/muscle, in addition to provision of or - referral for - more invasive treatment options such as intra-articular joint injections and/or surgical management depending on the clinician's surgical skills.

One of the conservative treatment options suggested in the literature more than four decades ago to specifically manage patients with DDwoR initially is the 'unlock' mandibular manipulation (Farrar, 1971). The data demonstrate, however, that only a few of the surgeons reported having the skills *"I tried to learn it"* (OMFS19) and/or the procedural knowledge *"I've kind of read about it rather than having to do it in practice"* (OMFS20) about the technique. Furthermore, all the other participant groups in primary and secondary care lacked any procedural knowledge about it. Nevertheless, some A&E clinicians suggested the manipulation therapy as a possible treatment approach to increase mouth opening in patients with DDwoR, possibly due to their knowledge in TMJ anatomy or may be due to their preference to achieve quick remedy in A&E (Maull *et al.*, 2009).

> *"I think it is manipulation of the jaw is what needs to be done [for DDwoR]. I suspect it's done in a very similar way for an anterior [TMJ] dislocation but I would say it's more difficult because of the reduced mouth opening and but again that's speculation. Erm that's just from what I know of the condition and the anatomy"* (A&E16) **(Knowledge; Beliefs about capabilities)**.

In comparison with the manual manipulation for 'unlocking' a locked jaw in patients with DDwoR, most GDPs reported evidence of procedural knowledge about the manual manipulation for 'relocating' a dislocated jaw. This was despite the fact, as previously mentioned, that the majority of those GDPs' interviewed had never been confronted with a TMJ dislocation case. The GMP group, however, also lacked the procedural knowledge about the 'relocation' technique but some assumed it would be a manipulation therapy, perhaps by lay knowledge and 'common-sense' thinking (Popay and Williams, 1996).

The identified differences in professionals' knowledge about the manipulation techniques for TMJ dislocation and DDwoR management give some possible indications that the curriculum for the UK dental schools may involve more focused teaching for dental students about TMJ dislocation than DDwoR, as one participant highlighted: *"I don't think we have been taught well [about DDwoR] but I think…if you're talking about the jaw locking there's always a lot of focus on the fact that oh it's most likely if it's kind of a really wide open lock then it's most likely to have been a dislocation"* (OMFS20). The differences in knowledge regarding TMJ dislocation management between the dentally- and medically- qualified clinicians may also indicate that the curriculum for the UK medical schools may not involve teaching the medical students about TMJ dislocation.

Learning the 'unlock' manual manipulation technique is one of the required skills for the early management of DDwoR and could be a 'life-saving' manoeuvre in critical situations (Redick, 1987; Aiello and Metcalf, 1992; Akasapu *et al.*, 2015). Although the manipulation therapy is often regarded in the literature as a simple treatment approach and easy to apply (Mongini *et al.*, 1996; Spencer, 2005), some clinicians in this study felt the opposite. One OMFS clinician described this manipulation as *"quite technique sensitive"* (OMFS19) requiring highly skilled hands to 'recapture' the displaced disc. When suggested as a potential treatment option, most frontline clinicians also felt that this treatment approach requires a level of acquired skill and is challenging to apply by them to DDwoR patient due to pain and limited opening symptoms. Some of them expressed their fears from manipulation consequences if they would try to manage the patient but some clinicians also expressed their intentions to learn and implement it in the future.

> *"I have, you know, dislocated jaws before erm [while] extracting teeth and I have been able to re-manipulate them but to do that on a patient that was already in pain erm I don't know. I would be very worried about making something worse. But maybe more information and I would feel more confident, I don't know"* (EGDP12) **(Skills; Beliefs about capabilities; Beliefs about consequences; Emotions)**.

The discrepancy between the literature and clinicians' perceptions regarding the manual manipulation simplicity and applicability highlights the problem that sometimes a treatment seen to be easy to 'experienced' clinicians may not be so to 'inexperienced'

clinicians. This is discussed in the literature regarding TMJ dislocation management (Parker, 2012) and highlighted in the data by one participant regarding DDwoR management:

> *"It's [DDwoR management] probably easier than I would think but then that's the expert would say this was easy and I would say well I've no idea because I've never done it so it's not easy for me"* (A&E/GMP17) **(Beliefs about capabilities)**.

Another conservative treatment option suggested extensively in the literature for DDwoR management is the splint therapy (Chung and Kim, 1993; Stiesch-Scholz *et al.*, 2002b). In several quantitative studies, the splint therapy was found to be the most widely chosen/used treatment option by GDPs to routinely manage TMD patients (Pierce *et al.*, 1995; Tegelberg *et al.*, 2001; Ommerborn *et al.*, 2010; Kraus, 2014; Aldrigue *et al.*, 2015; Reissmann *et al.*, 2015). The GDPs in this study were broadly consistent with this aspect of the professionals practice's pattern identified in these quantitative studies. They shared the experience that the splints can help the majority of TMD patients and have relatively low risks and, therefore, all GDPs reported that they provide splints routinely to lots of TMD patients. For DDwoR management, however, most GDPs expressed uncertainty if occlusal splints can be used at all due to limited opening symptom.

> *"With a closed lock I don't know whether a splint would be advisable straightaway. I think they might find that it's erm a bit too restrictive to put a splint in there where there's not enough movement anyway"* (NGDP14) **(Knowledge; Skills; Beliefs about capabilities)**.

The 'extra' symptom of mouth opening limitation may make the routine decision to take impression to construct a full-coverage splint challenging and sometimes impossible for the GDPs; although making an emergency partial-coverage splint is still possible (Stapelmann and Turp, 2008). Some OMFS clinicians, on the other hand, were able to discuss the possible role of splint in recapturing the displaced disc.

Surgical interventions, mostly arthrocentesis, are also suggested widely in the literature for DDwoR management (Al-Belasy and Dolwick, 2007). However, apart from very small number of GDPs suggesting arthrocentesis as a possible treatment option for DDwoR, the majority of frontline clinicians seemingly had vague knowledge about the

role of TMJ surgery in TMD/DDwoR management. Although it is not their professional role to provide TMJ surgical management, it is imperative for them to be aware about the role of TMJ surgery to clarify and explain its risks and benefits to the TMD patients (Dimitroulis, 2011).

Unsurprisingly, the OMFS clinicians reported higher levels of knowledge about the TMJ surgical procedures, their mechanisms of actions, and their risks but they had differing opinions regarding their beneficial effects. This reflects the lack of evidence to support or refute the use of TMJ surgical interventions (Chapter 5). The OMFS clinicians also expressed their concerns about the consequences of TMJ surgical management and, therefore, often reported that they tried to avoid TMJ surgery, instead informing them about the possible intra- and post- operative surgical complications alongside the message that TMJ surgery cannot guarantee success.

> *"I think…you have to make people aware of the fact that it's erm not really an ultimate success having this sort of surgery. You have to make sure that they're very well aware of the pitfalls and the possible complications and they've got to go in with their eyes open"* (OMFS21) **(Knowledge; Beliefs about consequences)**.

In fact, several therapeutic options of various degrees of invasiveness are available for the clinicians for TMD/DDwoR management but the evidence from the literature suggests that the clinicians should try the minimal non-invasive conservative options first (Al-Baghdadi *et al.*, 2014a; Al-Baghdadi *et al.*, 2014b). Reassuringly, all the clinicians, including the surgeons, in the current study sample applied generally the same first principle to their management of TMD/DDwoR, that being: *"do the patient no harm and [do not] make the problem worse"* (OMFS20). In practice this meant starting ordinarily with the non-invasive reversible conservative treatment options: *"I still think that you should start simple. I always think that, and you should start non-surgical"* (OMFS21), and putting the invasive irreversible surgical treatment option *"at the end of the management scale"* (EMGDP3). The participants shared the common attitude that *"the absolute last resort is jaw surgery"* (NGDP14) because the majority of TMD patients would improve with the conservative therapy and only a minority may require surgery which also increases their confidence and optimism in TMD conservative management.

> *"I think I've always had the view that a majority of patients with TMJ disorders can be managed conservatively but there will always be a minority that may require some surgical treatment and I think that basic philosophy has always underpinned my attitude towards it"* (OMFS11) **(Knowledge; Beliefs about consequences)**.

In comparison with the other TMD, however, the biomechanical DDwoR disorder can be sometimes more resistant to conservative treatment (Yamaoka *et al.*, 1997) requiring frequent visits to complete treatment (Dahlstrom, 1998; Anastassaki and Magnusson, 2004) and may occasionally need surgery (Castro *et al.*, 2009). This is mirrored in the data as a few OMFS clinicians reported that in their experience the DDwoR patient might not always improve early with the conservative management and may end-up requiring surgery. These experiences seemingly lessened the clinicians' confidence and optimism in DDwoR conservative management.

> *"I think I will probably in the explanation make more reference to the disc and to what might be going on…and I would usually say that 'I think that we try this sort of conservative management first and we'll see it may be that we'll need to do some further treatment following it' whereas I think I'd try and be a bit more optimistic with the other [TMD] patients. I'm not sure if I'd do anything else at that initial stage of treatment planning but I guess I might have a lower expectation of improvement maybe myself… Just that [because] they've kind of got a definite physical problem [DDwoR] that can be difficult, very difficult to sort out"* (OMFS19) **(Knowledge; Skills; Beliefs about capabilities; Beliefs about consequences; Optimism)**.

Overall, the data in this study suggest that the participants' management pathway at different levels of TMD/DDwoR patients care pathway (primary, secondary, and tertiary care) can be *"a ladder"* (OMFS4) management *"beginning from advice going all the way up to TM joint replacement"* (OMFS21) as depicted in Figure 6.2.

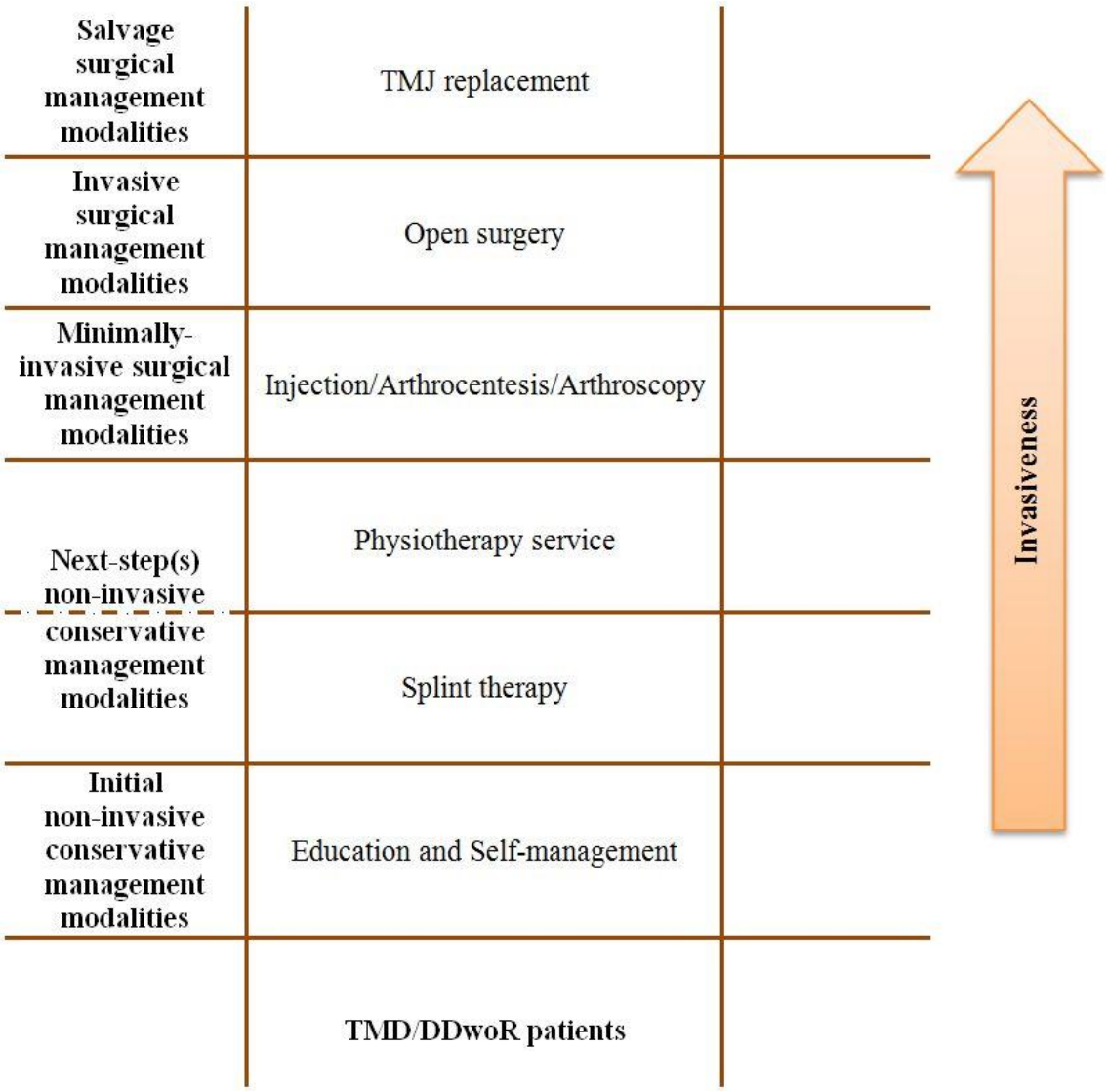


Figure 6.2: TMD/DDwoR Ladder Management.

Treatment plan time scale and rationale

In the data, all the clinicians, as mentioned, do not use any specific guidelines in their practices for TMD/DDwoR management. Interestingly, however, the majority of primary and secondary care clinicians seemed to have clear plan regarding the time-frame for the initial conservative step and for reviewing the patients before contemplating alternative treatment approach or referring them for further management.

> *"Well with any treatment plan the idea is to make sure that they're [patients] getting better so if they're not getting better within a certain time-frame then you might try a different type of treatment"* (GMP9) **(Goals; Memory, attention, and decision processes; Behavioural regulation)**.

The set ‘time-frame’, however, differed widely between clinicians in primary and secondary care from as early as couple of weeks to several months or even years. In primary care, most clinicians demonstrated a low threshold for reviewing TMD patients over and over again without progressing and they tended to refer their patients early, mostly within 1 month, if not responded to initial conservative treatment: *“I normally review them [TMD patients] after 2 weeks and then another 2 weeks and if things aren’t getting any better after 4 weeks I will refer”* (NGDP15); although few clinicians tended to review their patients for longer periods of times, mostly 2, 3 or even 6 months. In secondary care, however, the clinicians in OMFS departments tended to follow-up the referred TMD patients for longer periods of time, ranging from 6 months to 2 years or even longer: *“I would anticipate having the majority of TMJ patients under follow-up for maybe 1 to 2 years but I’d anticipate there would be a small percentage who go on to be, you know, almost on long-term follow-up”* (OMFS11). This difference is probably due to OMFS clinicians’ higher levels of knowledge about TMD chronicity plus their responsibility to provide the definitive management. Similarly, the OMFS clinicians seemingly had also a treatment plan for managing patients with DDwoR conservatively for several months before referring or escalating towards the surgical management.

> *“Q: For how long do you usually follow-up those [DDwoR] patients or wait for the conservative management before escalating to surg…?*
> *R: Probably not long. It very much depends. I’ll normally review them, as I say, after sort of two months then maybe four months and if things aren’t really getting much better maybe after sort of six months I’d probably say let’s do something else”* (OMFS21) **(Goals; Memory, attention, and decision processes; Behavioural regulation)**.

In general, the majority of primary and secondary care clinicians rationalised their plans of time-frame periods based on their expectations of patient’s response to treatment. The allocated time-frame by most primary care clinicians, however, was often too short: *“I think 4 weeks is adequate if somebody is wearing a soft splint, doing the exercises, soft diet and I think if things aren’t getting any improvement we should refer at that stage”* (NGDP15). The time-frame for ‘chronic’ pain of more than three months (Dworkin *et al.*, 2011) can probably be used to advise the primary care clinicians to follow-up/review the TMD patients before referral to secondary care unless there are ‘red flags’ (Table 2.9). This three-month review period probably avoids patient’s

disability and allows sufficient time to assess a clinically important change in TMD treatment outcomes (Moufti, 2007). However, the data suggest that such an advice can be challenging for a variety of reasons summarised in Table 6.5.

Reasons for TMD patients' follow-up difficulty by primary care clinicians
• Primary care clinicians need reassurance that the TMD patients have nothing else more serious **(Beliefs about consequences)**.
• Patients themselves need reassurance and may request further treatment by secondary care clinicians **(Social influences)**.
• Increase in patients suffering time if they do not respond to treatment provided in primary care **(Beliefs about consequences; Emotions)**.
• Lengthy referral waiting time (sometimes 2-3 months or longer) which can further increase patient suffering **(Beliefs about consequences)**.
• Lack of primary care clinicians' incentives/remuneration to manage those patients plus time constraints for TMD management and follow-up reviews in NHS primary care (financial and time restraints barriers) **(Reinforcement; Environmental context and resources)**.
• Lack of interest in TMD **(Knowledge; Professional role and identity)**.

Table 6.5: Reasons for TMD patients' follow-up difficulty in primary care.

Treatment outcomes, goals, and success

When managing TMD patients, the clinicians should have three basic goals to achieve from the provision of the treatments: reducing pain, restoring function, and optimising patients' quality of life (de Leeuw and Klasser, 2013). The majority of primary and secondary care clinicians, however, reported that they do not set 'formal' goals for TMD management, but a common goal of symptoms management was mentioned repeatedly throughout the interviews: *"to get the patient out of pain is my kind of goal"* (EMGDP2) **(Goals)**.

One of the important reasons for not setting 'formal' goals for TMD management can be attributed to unpredictable outcomes of treatments provided. The uncertainty over the TMD management outcomes seemingly led the clinicians to avoid setting goals due to the fear of not meeting these goals causing disappointment to both patient and clinician, as articulated by one participant:

> *"I don't [set goals], no, because I think it's difficult. I think if you then set goals then it's – I think it's probably out of fear of maybe failing to meet those goals…,*

but I don't think it will be unreasonable for there to be some goals, but I think if you set a goal it's whether you keep that goal to yourself or you shout it at the patient. I think if you shout at the patient the risk then of causing disappointment and I don't think you can say by then I would hope that you have less clicking and improved jaw movement and less pain" (OMFS20) **(Beliefs about consequences; Emotions)**.

In order to determine the 'clinical success', some clinicians reported depending mainly on subjective questioning relating to patients satisfaction with their level of improvement.

"Well I don't actually have a sort of any scales [to measure clinical success]. It's usually on direct questioning with the patients and if they've come along with pain, trismus, click they're the specific things that I ask them about, and if some people come along and say yeah that's fine,… So I don't really get too bothered if they've got reasonable function without absolutely wide opening as long as they're pain free and they're click free. So they're the three things that I ask and I would look upon, I suppose, absolute success if I've got somebody who is free of pain, erm can eat what they like, can open as wide as they want and don't have a click. I suppose that's it in simplistic terms" (OMFS21) **(Goals)**.

Patients' satisfaction as an outcome measure is clearly subjective and varies inter-individually and may not reflect the patients' needs (Durham *et al.*, 2007). For future research, there is a need for standardised criteria for measuring clinical success and treatment outcomes (not just relying on satisfaction) in TMD/DDwoR management which are currently lacking (Durham *et al.*, 2007; Schiffman *et al.*, 2014b).

In summary, the clinicians varied in their perceived roles, abilities, and plans to treat TMD and DDwoR. The primary care dental practitioners appeared more able to treat TMD initially when compared to the primary care medical practitioners, but all the clinicians at the frontline, whether dentally- or medically- qualified, seemed unable to treat DDwoR. These variations clearly have impacts on their referral decisions.

Step 4: Referral

The clinicians seemingly varied in their perceived limitations to manage the discussed clinical conditions and, therefore, their referral decisions and pattern were varied.

Referral decisions and reasons

Referral of TMD patients from primary to secondary care are often reported to be of a high rate in the literature (Beecroft *et al.*, 2013; Villa *et al.*, 2015). In a recent survey-based study, the frequency of clinicians' referrals of TMD patients to specialists was about 22.5% (Reissmann *et al.*, 2015). Studies indicate that most TMD patients referred to secondary care are from dental practitioners (56%-85%) and to a lesser degree from medical practitioners (15%-28%) (Anastassaki and Magnusson, 2004; Vallon and Nilner, 2009). In this study, the GMPs reported that they often signposted the TMD patients to primary care dental practitioners or sometimes referred them to secondary care setting. This referral decision was mostly made because of their perceived limits in providing further treatment options other than the medical management.

> *"I think we should be able to diagnose classic temporomandibular joint disorder and erm initiate basic treatment which what we can do in primary care… I don't think we should be thinking about how to fit erm mouth guards to the patients erm or whether we should decide if they should have an x-ray or CT or an MRI or whatever"* (GMP9) **(Skills; Professional role and identity; Beliefs about capabilities)**.

The GDPs, on the other hand, reported that they often referred the non-responding TMD patients to secondary dental care, specifically to local dental hospitals and, mostly to restorative departments. This referral decision was mostly made when the TMD patients failed initial conservative treatment and related to the GDPs' beliefs about their own limits in providing further treatment options.

> *"We've got the basic facilities in primary care that we can provide on the education side of things. Erm certain stabilisation splints can be provided erm but following on from that er I wouldn't be prescribing any long-term medications or anything along those lines so that would be sort of probably the limitation there is I would say we've got that basic management that we can try but if it's persisting longer than that or if the symptoms are severe then I think that's quite a difficult case to manage in primary care. I think that would be the sort of stage where I*

would be referring onwards" (NGDP5) **(Skills; Professional role and identity; Beliefs about capabilities; Memory, attention, and decision processes)**.

Within the interviews of those working in primary care, there were sporadic references to unrealistic expectations for the outcome of the referral and management by secondary care: *"positive [side of patient's referral] I think...I'm going to get this solved, you know. [The] dental hospital are [is] going to wave a magic wand and be able to cure this and sort this out"* (EMGDP2; **Optimism**). This unrealistic optimistic view about the specialists' ability to 'cure' chronic pain patients was also expressed by a few GDPs in a previous quantitative study (Dahlstrom *et al.*, 1997). Despite the fact that these references presented sporadically in our data, they could potentially have a significant impact, not only on the referred patients' expectations, but also on the clinicians' referral patterns. Nevertheless, there is also a constant pressure on clinicians in NHS primary care to undertake management themselves and reduce referrals to secondary care (Faulkner *et al.*, 2003; Akbari *et al.*, 2008). In the data, some primary care clinicians highlighted different kinds of pressure to decrease referrals such as: referral rates monitoring, referral costs, and referral back from secondary care.

"We also have constant downward pressure on our external referrals to secondary care so and this might be an area where erm if we do things better, if we know more we might reduce some referrals into secondary care which then our CCG [Clinical Commissioning Group[11]] would be happy about" (GMP7) **(Professional role and identity; Environmental context and resources; Social influences)**.

All the clinicians also highlighted the necessity of receiving feedback about their referred patients: *"Yes [I think it's important to receive a feedback] …Because they're ultimately our patients, they're going to be coming back to us for management and we need to know clearly what is expected in terms of monitoring that patient. Also we could learn…for the future"* (EGDP10). This 'ownership feeling' about their patients is one of the several reasons given for feedback importance. The most common reported reason, however, was attributed to professionals' future own-learning or self-education about the patient they were confronted with but diagnosed and/or treated by someone else in order to continue patients' care afterwards or avoid these referrals in the future. At the

[11] Clinical commissioning groups (CCGs) are NHS organisations recently developed by the Health and Social Care Act 2012 in order to organise the delivery of NHS services in England instead of the Primary Care Trusts (PCTs) (UK legislation, 2012).

moment, however, many clinicians at the frontline reported that they did not get 'formal' feedback letters which may not always be possible especially if the clinicians are working in emergency single-point access services. Therefore, enhancing the feedback process between the healthcare services can be beneficial.

> *"I think if it's possible [to get the feedback] yeah [it's important]. Both for my own education so I can remember next time to refer earlier, later, try something else first, but also just in terms of continuity of care, to know what the patient's being told and those sorts of things*" (A&E/GMP17) **(Behavioural regulation)**.

In secondary care, as previously mentioned, the A&E clinicians reported that they preferred to signpost the TMD patients to a more 'appropriate' clinician or service due to their perception that their role did not include treating patients with chronic conditions. On the contrary, the OMFS clinicians reported a responsibility to treat the referred TMD patients but they too reported limits, suggesting that they refer the refractory TMD patients to physiotherapy or other departments in the hospital including chronic pain management clinics (tertiary care). Some OMFS clinicians, however, reported problems with such referrals, including: poor communication with the physiotherapy team: *"I've never really been able to find an actual physiotherapist to speak to about their management, directly one on one"* (OMFS19); limited *"access to support services"* (OMFS20); and lack of psychological support service linked to their departments: *"we don't have a psychologist whose time is devoted to helping with facial pain issues"* (OMFS11) **(Environmental context and resources; Social influences)**.

Different reasons for TMD patients' referral to secondary or tertiary care services have been discussed in the literature (Vallon and Nilner, 2009; Kraus, 2014). In the data, the explicit reason for professionals' referral decisions for TMD patients was generally the patients' non-response to treatment provided. There were, however, other inferred 'implicit' reasons for clinicians' referral decisions for TMD patients which are summarised in Table 6.6.

TMD referral decision reasons
- Limited knowledge and experience for primary care clinicians especially the medical practitioners **(Knowledge; Skills)**.
- Acute TMD with severe signs and symptoms: early referral for difficult cases out of the remit of primary care clinician such as severe joint-related disorders or acute pain conditions and trauma-related disorders **(Professional role and identity; Beliefs about capabilities; Beliefs about consequences)**.
- Signpost TMD patients to a more appropriate clinician (e.g., referral to restorative dentists if suspecting an occlusal problem) **(Professional role and identity)**.
- For a diagnosis or to confirm diagnosis **(Skills)**.
- For extra- or alternative- therapy by other clinicians **(Skills)**.
- To avoid misdiagnosis and to make sure not missing something else (rule-out other pathologies, reassuring the patient that there is nothing more serious) **(Beliefs about consequences)**.
- To avoid patient suffering and go untreated **(Beliefs about consequences)**.
- For a second opinion: more reassurance for both clinician as well as the patient by having the advice from two clinicians: generalist and specialist **(Beliefs about capabilities; Beliefs about consequences)**.
- Anxious/distressed/emotional patient wants early referral for specialist opinion and may not listen to generalist or may not want to try the treatment options suggested by the primary care clinician perceiving them as too simple and not effective **(Emotions; Social influences)**.
- The clinician's own emotion and work stress/load/pressure may make the clinicians refer a patient not usually referred in normal circumstances **(Emotions; Environmental context and resources)**.
- Therapy cost (e.g., splint cost) **(Environmental context and resources)**.
- For further assessments and investigations such as joint imaging **(Environmental context and resources)**.
- Patients need more time to treat and review **(Environmental context and resources)**.
- To avoid patient spending a lot of money to get treated in primary dental care private practice **(Beliefs about consequences; Environmental context and resources)**.
- Lack of financial incentives/remuneration **(Reinforcement)**.
- Before a surgical intervention to the TMJ being considered **(Beliefs about consequences)**.

Table 6.6: Clinicians' referral reasons for TMD patients.

When discussing approaching management of the DDwoR case scenario, all the clinicians at the frontline (A&E, GMPs, & GDPs) reported that they preferred to seek advice/support directly over the phone from an experienced clinician in secondary care and/or make an early referral decision to secondary care setting, usually to oral and maxillofacial surgery and occasionally to restorative dentistry departments.

In real decision-making situations, the frontline clinicians reported seeking phone advice and referring early when encountered DDwoR patient for the first time.

> *"I managed just to see her [a DDwoR patient] and with her I had to actually ring up the SHO on-call for Maxfax to ask their advice because I was a bit lost on exactly what to do. But again they would just say, you know, quite reinforce, reassure her the soft diet, the ibuprofen, the hot-cold erm compresses and they actually booked her in for a consultant clinic about two days later to be reviewed"* (EMGDP2) **(Skills; Beliefs about capabilities; Memory, attention, and decision processes; Social influences; Nature of behaviour)**.

The advice over the phone should come normally from either the on-call senior house officers (SHO) in OMFS or ENT services in general hospitals or from the specialists in local dental hospitals: *"if it's during the day I'd ring the dental hospital. Obviously when it's out of hours I just ring the SHO on-call for Maxfax and find that"* (EMGDP2). The given advice and referral priority, however, may vary depending largely on call-handler experience and qualification, as highlighted by one participant:

> *"I think the problems are, at the outset, who answers the phone in the first place if it's somebody who is a dentist whose qualified they may be more likely to say yeah send them [DDwoR patients] over, we'll have a look to see what's going on and see what we can do. Erm if they get a receptionist or a nurse might say oh well you'll just have to fax the referral over and we'll prioritise it, so they may not highlight that it's something that maybe needed to be seen urgently"* (OMFS20) **(Environmental context and resources; Social influences)**.

The phone advice was described as easy, quick, and accessible to frontline clinicians: *"it's reasonably easy to get advice from the hospital. I found it very easy"* (EGDP10). The advice over the phone seems to be a very useful tool to reduce clinicians' uncertainty and increase their confidence in DDwoR management. This is because some frontline clinicians reported that they feel more confident to diagnose the DDwoR patient under guidance from experienced clinicians and were also more willing to commit to the advice given over the phone regarding the treatment plan and/or treatment/referral options.

> *"[I] need to be confident on the [DDwoR] diagnosis and that again can be discussed on the telephone…[and] if I'm given clear instructions I will do what I'm told to do and if it works that's great and if it doesn't then I'll send them in"* (A&E/GMP17) **(Beliefs about capabilities; Memory, attention, and decision processes; Intentions; Social influences)**.

In the literature, studies have reported a proportionally large number of DDwoR patients' referrals (11%-22%) among all the referred TMD patients, which is mostly related to the fact that patients with DDwoR are more often complain of severe symptoms (Dahlstrom, 1998; Anastassaki and Magnusson, 2004; Vallon and Nilner, 2009; Kraus, 2014). The severity of acute DDwoR symptoms may be what is leading the frontline clinicians in the study sample to seek advice and refer DDwoR early in comparison with the other temporomandibular disorders, *"because the other [TMD] conditions people are in pain but they're not in as much pain. Generally on a scale they're on a scale of about five out of ten as a kind of pain, the ones we see in practice but this lady [referring to a DDwoR patient] she was ten out of ten, she was an absolute agony"* (EMGDP2; **Nature of behaviour**). In addition to symptoms' severity, however, there were other inter-related reasons for frontline clinicians' early referral decision to DDwoR patients which are summarised in Table 6.7.

DDwoR early referral decision reasons:
- Professionals' lack of knowledge, training, and experience with DDwoR **(Knowledge; Skills)**.
- Professionals' beliefs that the DDwoR is a specific area require specialist investigations and treatments **(Professional role and identity)**.
- For definitive diagnosis **(Skills; Beliefs about capabilities)**.
- To avoid misdiagnosis **(Beliefs about consequences)**.
- For further investigations such as joint imaging **(Environmental context and resources)**.
- To avoid inappropriate treatment, mismanagement, or making the problem worse, or not providing the proper treatment at the appropriate time **(Beliefs about consequences)**.
- For patient's reassurance via inter-disciplinary care in secondary care **(Beliefs about consequences)**.
- To avoid patients' suffering from severe symptoms and their impact on patients' quality of life **(Beliefs about consequences; Emotions)**.
- To avoid chronic patients' disability due to lengthy referral process **(Beliefs about consequences; Emotions)**.

Table 6.7: Frontline clinicians' early referral decision inter-related reasons for DDwoR patients.

Although DDwoR is not a life-threating condition, all the frontline clinicians highlighted the need for referral 'urgency' for patients with acute DDwoR to be seen and treated 'quicker'. This urgent referral perception is probably related to clinicians' worries and concerns over the severity of acute DDwoR symptoms, patient suffering,

and the negative impact on patient's functional capability and quality of life. This perception is probably intensified by the clinicians' awareness about the potential negative consequences their referral decision could cause in patients in terms of patients' inconvenience and their continued worries and suffering due to lengthy referral process. This process may prolong due to environmental circumstances as demonstrated in this quote: *"she [a possible DDwoR patient] was already on referral to secondary care erm but she couldn't be seen at the hospital…at that time because it was the summer holidays"* (EMGDP3). The clinicians, therefore, often warned patients about the referral waiting time: *"I normally warn patients it could be 2 to 3 months and I would hope that during that time that they would at least see an appointment but I know sometimes it has been longer"* (EGDP12). The clinicians in secondary care also felt this long waiting time is an issue: *"I think waiting times for patients to get here to start with [is a problem]"* (OMFS20) **(Beliefs about consequences; Emotions; Environmental context and resources)**.

Overall, the frontline clinicians expressed several worries and concerns if confronted with the acute DDwoR patient's 'unusual' presentation, and this was seen to be related mainly to clinicians' limited knowledge and experience with it. The expressed worries and concerns led the frontline clinicians to make an early or urgent referral decision for DDwoR to secondary care as depicted in Figure 6.3.

In secondary care, however, the OMFS clinicians reported that they also make the decision to refer the DDwoR patients if they not respond to their initial conservative measures. The clinicians reported that they refer DDwoR patients firstly to physiotherapy service. If the patient fails to improve following physiotherapy, the OMFS clinicians suggested they refer to colleagues with a sub-specialist interest in the surgical management of TMD (tertiary care). They preferred to leave the decision on appropriateness of surgery to the sub-specialist because of their perceived 'difficulty' of making this surgical decision.

> *"I think once you're getting down to the delivery of erm surgical therapy, be that minimally invasive in the form of arthroscopy or arthrocentesis or even joint replacement, I think it needs to be sort of 1 or 2 er individuals who have developed that as a special interest within their practice who manage it and it's for them to make the ultimate decisions if they think that's appropriate and erm to*

> *deliver that treatment. I think it's better that it's someone with a sub-specialist interest that does that"* (OMFS11) **(Skills; Professional role and identity; Beliefs about capabilities; Memory, attention, and decision processes)**.

The surgical decision for TMD/DDwoR patients is usually a difficult decision to make (Moore, 2006) but its difficulty could be increased further by patients' requesting surgery; although it was accepted that this only really occurs in those with severe persistent symptoms: *"most of the time people are pushing me to have something more done because they're fed up of it"* (OMFS21).

> *"A lot of people though will find that with really particularly bad TM joints symptoms they can't go out for a meal, they can't, you know, their social interactions are affected and all those things and often people, by the time they come to having more major things done, they're really at their wits end and those would almost said that they'll have anything done if it will help"* (OMFS21) **(Social influences)**.

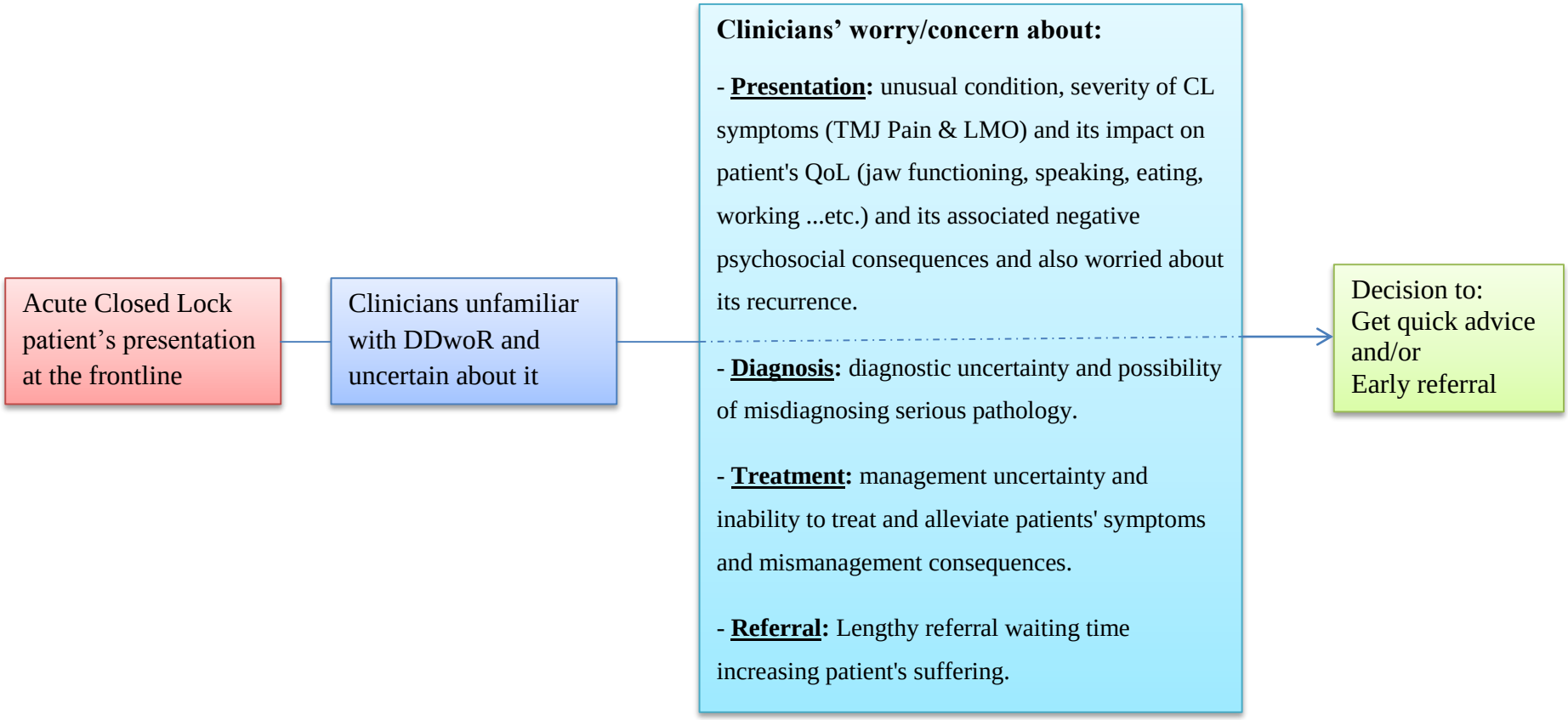


Figure 6.3: Map representing the frontline clinicians' early referral decision process and its reasons.

Referral pathway

The referral pathway for patients should progress logically from primary through to secondary to tertiary care services; although from the perspective of those interviewed, there is no obvious and 'straightforward' current referral pathway for the TMD patients. The lack of formal referral path for COFP/TMD patients was also highlighted in previous studies (Durham *et al.*, 2011; Peters *et al.*, 2015). In the study data, TMD patients' referral path could depend on multiple factors, one of which is the availability of a practitioner with a special interest in TMD in a particular region. This preference to refer TMD patients to TMD specialists was also expressed by the majority of GDPs in previous quantitative studies (Tegelberg *et al.*, 2001; Aggarwal *et al.*, 2012).

> *"There's not a clean cut kind of pathway for it [TMD] so depending on what area you are or you might know colleagues that are quite good or sensitive in treating that condition"* (GMP8) **(Environmental context and resources; Social influences)**.

Some GMPs, however, expressed 'referral uncertainty' about where to refer their TMD patients: *"it tends to be a referral which can be quite hard because you don't know often is it maxfax, is it dental, is it ENT, is it chronic pain clinic as it's quite hard to sometimes get these [TMD] patients to the right place"* (GMP8). This is perhaps due to lack of TMD speciality in the UK and the *"huge overlap between other specialties and…overlap of conditions it can be"* (GMP8) **(Knowledge)**.

There is also a possibility for multiplicity of referrals for patients having chronic refractory TMD pain. Such 'chronic' patients can see multiple clinicians and receive various diagnoses/treatments in different services in their care pathways (Durham *et al.*, 2011; Beecroft *et al.*, 2013; Kraus, 2014). In this study, a few clinicians mentioned some chronic patients not-responding to treatments with this participant stating: "*they've seen numerous dentists and they've been referred to numerous people and nobody can quite figure out what's going on"* (NGDP14). Evidently, such multiple 'cyclic' re-referrals of TMD patients can have negative psychosocial impacts on the patients (Durham *et al.*, 2011). The possible referral pathways reported in the data for TMD patients are depicted in Figure 6.4.

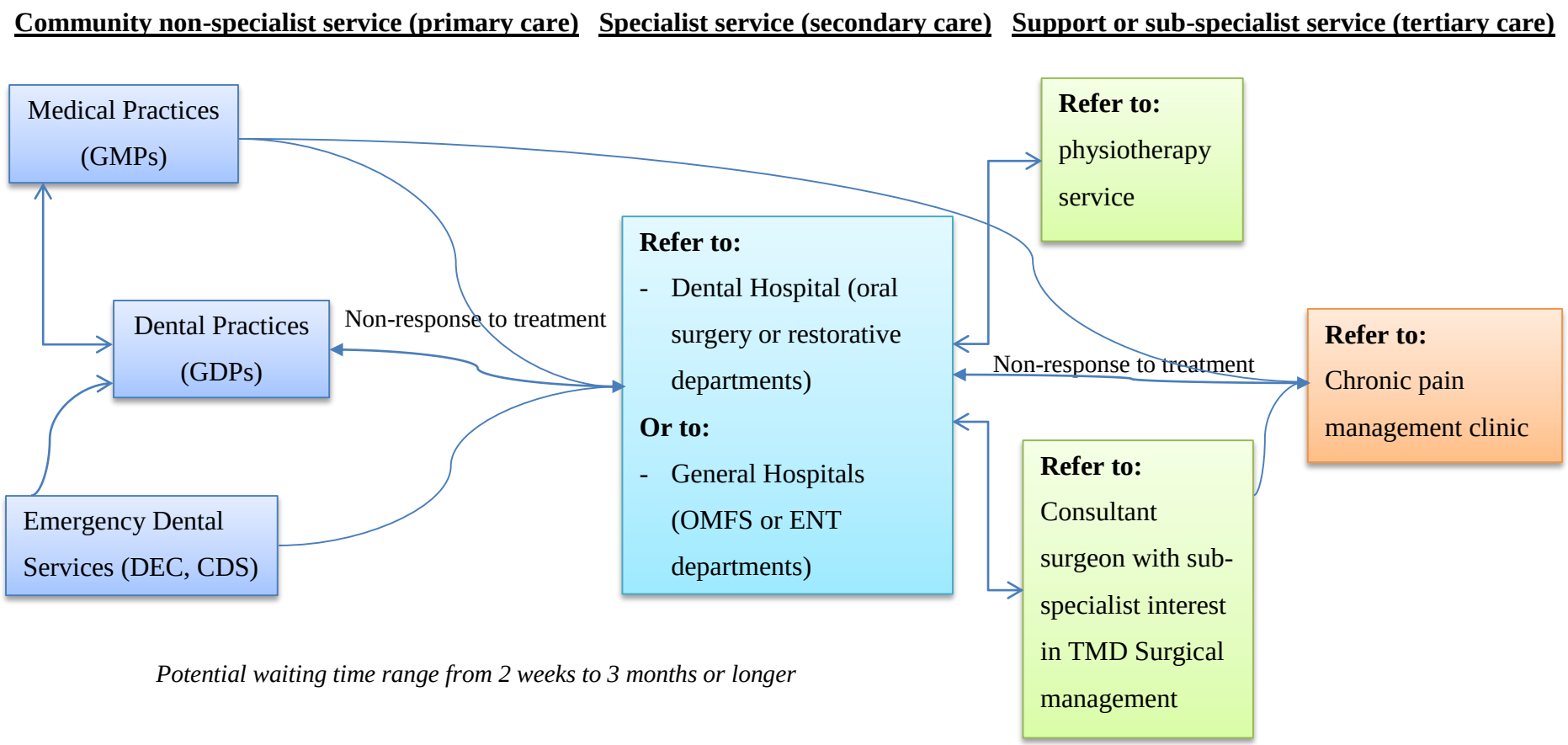


Figure 6.4: TMD patients' possible referral pathway.

In comparison with the TMD patients' referral pathways, the referral pathways for DDwoR patients in the reported data seemed to be less complicated. On the contrary to routine 'ordinary' TMD cases, none of the GMPs in the study sample preferred to signpost the DDwoR patients to their GDPs. This is possibly due to the nature of DDwoR patient's presentation and their perceptions for the necessity of 'urgent' management and their preference to get advice from a more experienced practitioner if confronted with such an acute condition.

> *"I'd probably have a very low threshold about phoning for some advice on somebody with that situation [DDwoR] which is clearly quite different from erm perhaps the kind of patients I had in mind when we were talking before [TMD] so and I think probably my port of call in that situation would be somebody from the maxillofacial team on the phone saying what do I do with this"* (GMP7) **(Beliefs about consequences; Memory, attention, and decision processes; Nature of behaviour)**.

The on-call senior house officers in general hospitals or the specialists in local dental hospitals were often the first point in DDwoR referral pathway (secondary care) whilst the surgeons with special interest in TMJ surgical management were seemingly the final step in the DDwoR management/referral pathway (tertiary care): *"I find that most of them are coming from almost tertiary referrals,…they've probably been seen by the general practitioner in the first instance then somebody else, then me"* (OMFS21). DDwoR patients with failed surgical management, however, may be referred further to chronic pain management clinics (Moody and Clark, 1995; Edwards *et al.*, 2014); although this is not explicitly revealed in the data. The potential referral pattern and multi-level care pathway for patients with DDwoR is demonstrated in Figure 6.5.

In summary, the clinicians varied in their perceived limitations to manage TMD/DDwoR. The primary dental and medical care clinicians appeared to refer TMD after providing, at least initially, some conservative treatments, but all the clinicians at the frontline, whether dentally- or medically- qualified, preferred to seek advice directly and/or refer DDwoR early. The participants, therefore, suggested various factors that can help them to change and improve their current clinical practice and avoid referrals.

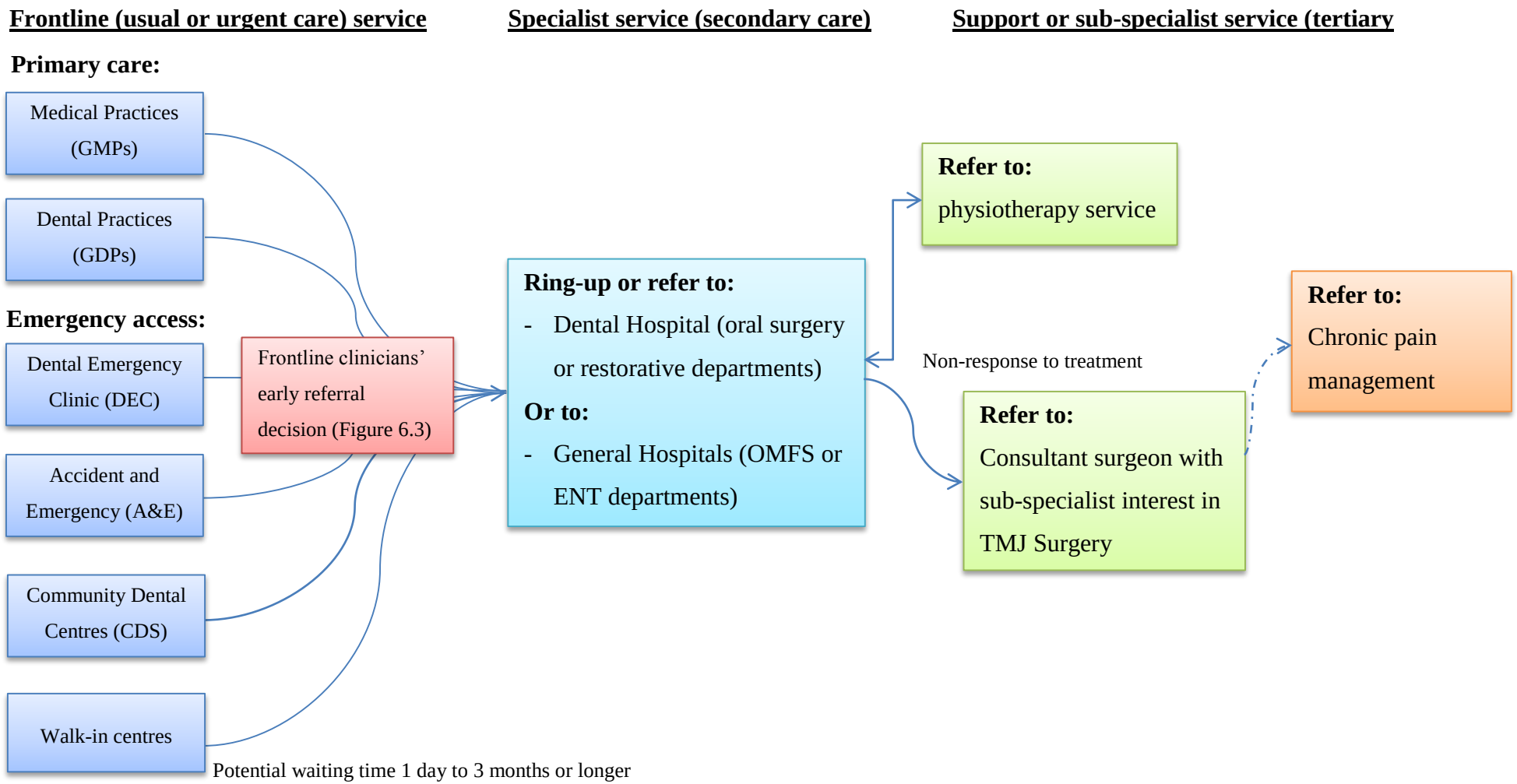


Figure 6.5: DDwoR patients' possible referral pathway.

Step 5: Clinicians' suggestions to support their own decisions

During the interviews, the participants suggested different future strategies to improve their current clinical practice, mostly related to enhancing their clinical knowledge and skills. One of the most frequently mentioned strategies given by the majority of primary and secondary care clinicians was the availability of evidence-based guidelines for TMD management: *"well as usual I suppose any evidence-based erm findings erm is always the best way to change a practice"* (OMFS19) **(Behavioural regulation)**.

There is, clearly, a need for all practitioners to have access to high-quality evidence-based guidelines detailing: when to treat, when to review, and when to refer the TMD/DDwoR patients which is currently lacking. However, the literature suggests that even if such guidelines did exist, there could be numerous barriers for dissemination and implementation of guidelines (Cabana *et al.*, 1999; Miller and Kearney, 2004; Stone *et al.*, 2014). In this study, several barriers to accessing and using guidelines were identified by some participants such as: their preference to read 'simple' rather than 'complicated' journals; their clinical experience can contradict and overrule the available evidence; they may not frequently examine the large number of available guidelines and may find difficulty to recall them in general practice. The last point can be specifically true for uncommon conditions such as DDwoR. This is because recalling a specific guideline among the numerous available guidelines in general practice can be challenging for the general practitioners and they seem to remember only the guidelines for the most commonly encountered cases. Therefore, even if guidelines about uncommon conditions such as DDwoR exist, the clinicians may not be aware of them or not remember to use them because they do not encounter such patients frequently.

> *"I think its possible new guidelines might [change my current practice] but guidelines for conditions which we don't see that often are often sort of filed in the cupboard really rather than online somewhere and they're not looked at again"* (GMP7) **(Memory, attention, and decision processes; Behavioural regulation)**.

One of the possible ways to overcome this problem and to support the clinicians' decision-making in relation to management of their patients is the use of electronic tools (e-tools) (Johnston *et al.*, 2004; Vikram and Karjodkar, 2009). In a cross-over randomised trial comparing internet-based TMJ tutorial with traditional seminars, the e-learning was perceived well by the dental student participants and no differences were found between the e-learning and usual teaching modes at delivering information to

students (Al-Riyami *et al.*, 2010). In the data, the e-tools were described as *"easily accessible mediums of education"* (OMFS19) and the majority of primary and secondary care clinicians thought that such an e-tool for DDwoR management can be useful because the clinicians are usually familiar with the e-learning, online induction, and continuing professional development (CPD) online learning (Leggate and Russell, 2002; Bullock *et al.*, 2003; Browne *et al.*, 2004; Stone *et al.*, 2014).

> *"Yeah definitely [a virtually delivered tool or intervention can help to manage DDwoR]. I think internet, if there's something online I mean that's the most useful easiest way of accessing even more than a study day really because I mean I do a lot of my CPD online so I think that's the best way really"* (EGDP18) **(Environmental context and resources)**.

Useful suggestions for the electronic intervention were given by the clinicians including the incorporation of patient educational leaflets and appropriate self-care videos to educate and teach the patients how to care themselves for their 'own' condition. Similarly, the e-tool was suggested to be eye catching, easily accessible, and attractive to use by rewarding the clinicians with CPD hours/points. It was suggested also to be simple and practical that can to be used easily within a short time and containing brief e-learning videos that can be easier to recall by the general practitioners.

> *"In GP we're bombarded with all sorts of stuff all the time and trying to work out what's useful and what's not can be very difficult. So, you know, if you can provide an eye catching simple and very brief erm information bite, sound bite, or something to general practitioners to say you can do this by doing this then that will be helpful"* (A&E/GMP17) **(Environmental context and resources; Behavioural regulation)**.

There are still, however, some barriers for using such an e-tool by frontline clinicians. Some clinicians expressed their concerns about the possibility of DDwoR misdiagnosis and mismanagement without hands-on 'formal' training courses.

> *"I think if there was a tool to help recognise the [DDwoR] condition that would help. If the treatment is manipulation then I'm not sure...that I would be able to do that without proper formal training. I think it would be quite difficult"* (GMP9) **(Beliefs about capabilities; Beliefs about consequences)**.

> *"The only concern I would have is that if I had misdiagnosed that patient and then I tried to manipulate the joint that I could make things worse and that's only the experience of hands-on actually achieving that and achieving a result with that"* (EGDP12) **(Beliefs about consequences)**.

The mode of intervention delivery could be via electronic health (eHealth) or mobile health (mHealth) media (Eysenbach and Group, 2011; Free *et al.*, 2013). In this study, some clinicians stated that they would prefer an intervention to be on desktop computer screen (eHealth) because these are better visualised by both patient and clinician in comparison with the smart phone (mHealth). However, although the latter might be more difficult to visualise and it is often regarded as a personal tool, phone applications (smartphone Apps) are easier and quicker to access (Akter and Ray, 2010).

> *"You don't need to do it on a phone because people like that are going to present to the surgery and you can look at YouTube like that. Looking on a phone, you know, it's a bit more difficult"* (A&E/GMP17) **(Environmental context and resources)**.

In relation to the content of the proposed virtual intervention, participants put forward, explicitly, several ideas they felt should be included in a proposed virtual intervention to help them diagnose and treat DDwoR. There were, however, some other components that emerged 'implicitly' from the interviews in terms of theoretical domains that could be also a part of an intervention tool. All these components are summarised in Table 6.8.

Suggested intervention's components:
An electronic tool (App) involves the following: - Simple diagnostic guide (easy, clear, concise, quick and practical) to help recognise closed lock condition and diagnose DDwoR **(Knowledge; Skills; Environmental context and resources)**. - Patient information leaflet include self-care instructions that can be printed out and provided to patients **(Knowledge; Skills; Environmental context and resources)**. - Virtual online videos attached for e-learning/training demonstration (certified videos rather than usual YouTube videos) about **(Knowledge; Skills)**: 1) How to examine the closed lock patient and make the DDwoR diagnosis. 2) Simple explanation about TMJ anatomy, mechanism of the disc, and DDwoR condition to both patients and professionals in addition to self-care instructions to patients. 3) How to perform the practical manoeuvre of 'unlock' manual mandibular manipulation technique for acute DDwoR and also probably the relocation manipulation technique for acute TMJ dislocation.
Educational lectures: - A brief bulletin or brief lecture series that can be delivered to all general practices or professionals' organisations or departments **(Knowledge)**.
Training courses: - Hands-on formal training courses or study days about TMD/DDwoR diagnosis and treatment **(Knowledge; Skills)**.
- All the above need to be attractive to use/attend by rewarding the professionals with CPD hours/points **(Reinforcement 'reward')**.
Emerged intervention's components:
In terms of theoretical domains: - **Knowledge:** Tutorials about normal/abnormal TMJ and condyle-disc complex mechanism. - **Skills 'experience':** Simulation web-based or 'real' practical courses. - **Social/Professional role and identity:** Increase responsibility perception of first-line clinicians. Emphasise the importance of early diagnosis/treatment and negative sequelae of delayed diagnosis/treatment. - **Beliefs about capabilities:** Increase self-efficacy. Set graded practice/tasks under supervised/supported conditions. Use modelling (brief videos). Increase awareness about the disorder natural course and good response to conservative treatments. - **Beliefs about consequences:** Dealing with outcome expectations on consequences of misdiagnosis, mismanagement and referral. Increase awareness about the disorder natural course and the red flags signs and symptoms. - **Memory, attention, and decision processes:** Electronic easily accessible tool to resolve memory and attention problems and to assist clinicians in their decision processes. - **Emotions:** Dealing with patients' emotions and with own emotions. Increase awareness about the acute TMD conditions and the red flags signs and symptoms. - **Social influences:** Advice over the phone from secondary care. - **Behavioural regulation:** Feedback about professionals' performance. It may also involve a questionnaire for evaluation of the e-tool.

Table 6.8: Components for a proposed intervention for DDwoR management.

Summary of professionals' decision-making processes

It becomes clear from the presented data in this section that the clinical decision-making processes of healthcare professionals for managing TMD generally and DDwoR particularly were varied between the clinicians but based mainly on professionals' background and their practice setting. These processes have been depicted in maps (diagrams) representing the management pathways for each group of practitioners (GDPs, GMPs, A&E, & OMFS) and are available, with their representative quotations, in Appendix M. A generic map summarising the TMD and DDwoR management pathways for all clinicians is shown in Figure 6.6.

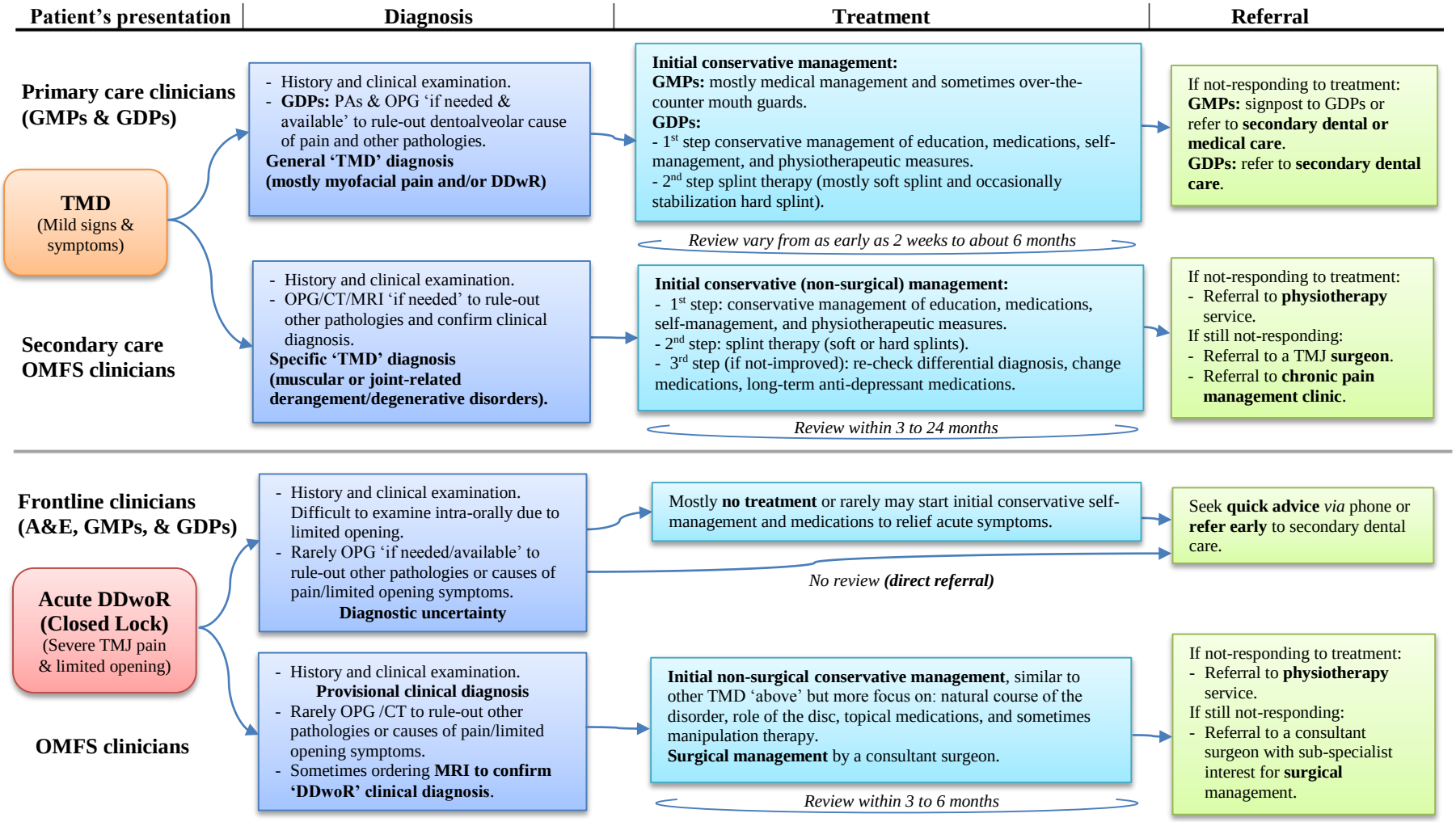


Figure 6.6: Generic map summarising the clinicians' decision-making processes for TMD and DDwoR management.

6.4.3 Factors influencing the professionals' clinical decision-making process: A summary of TDF-informed analysis

In the previous section (Section 6.4.2), the influences on clinicians' decision-making processes were presented under the generic recurrent themes, as informed by the TDF, which emerged from the interviews. These were represented by including emboldened references to the theoretical domains in parentheses following relevant data. This section (Section 6.4.3), therefore, is going to briefly outline and summarise the main findings of data relevant to each domain.

The possible factors from the TDF that influence the frontline clinicians' decision-making process in DDwoR management are summarised domain by domain in the text below and their relevant data are tabulated in Table 6.9. This table is a matrix representing the fifteen theoretical domains' representative data (vertical) against the three phases of clinical decision-making process: diagnosis, treatment, and referral decisions (horizontal).

Theoretical Domains	Quotes representing the influences (theoretical domains) on clinicians' decisions in DDwoR management		
	Clinical decision-making process		
	Diagnosis decisions	**Treatment decisions**	**Referral decisions**
1. Knowledge	*"I feel quite vague on it. I don't feel very knowledgeable on closed lock specifically"* (EMGDP3).	*"I think again it's just the knowledge of it [DDwoR]. Erm I think the main difficulties clinicians face is just they don't really know what treatment to provide for the different [TMD] conditions"* (NGDP15).	*"I really don't know about this condition"* (GMP9).
2. Skills	*"I don't know if it's happening because of muscle spasm or because there is an internal derangement. That's where I'm not sure"* (EGDP12).	*"I just feel we haven't really – I haven't been to any training that would, you know, that instantly tells me what to do if a patient had that [DDwoR]"* (EGDP18).	*"This is [DDwoR] out of my area of expertise. I would refer them"* (A&E/GMP17).
• **Experience**	*"I've worked here [general practice] for 10 years and we haven't come across anyone with that problem [DDwoR]"* (EGDP18).	*"It's probably one of those ones like say I haven't come across a case like that [DDwoR] so erm my experience of it is limited and I would imagine even if you have come across a case like that in your career it's going to be one or two sort of cases as extreme as you've described there so there's probably not going to be a whole lot of experience in it [to manage]"* (NGDP5).	*"From my point of view I've never seen it [DDwoR] so it's, you know, it's difficult to then say oh this is what we do and rather than to start with we can box it sometimes speaking to an experienced practitioner or maxillo..and either send them in"* (EMGDP1).
3. Professional role and identity	*"Well because you're the first, because you're in primary care, I think it is important that the [DDwoR] patient is aware of what's going on, that you're reassuring them that there's nothing serious wrong…. So yeah I do think it's important to get that knowledge to the patient first of all"* (NGDP14). *"I think for that patient who walks in with the limited opening or worse still the dislocated jaw it would be wrong not to be able to provide them with something, some advice"* (EGDP10).	*"I think if the [DDwoR] patient has been seen in secondary care and has been diagnosed and then needs further management, depending on what that would be, you know, if it's just a case of knowing that the patient has somewhere to go, just to free up the secondary care if nothing else, then that's the role of somebody in primary care I think"* (EGDP12).	*"I think it [DDwoR] is a specialised area and we don't see it often so we need to send on, to someone who treat to ultimate, maybe even, you know, someone who's seen a lot of it so they can manage it and understand it"* (GMP8).

Theoretical Domains	Quotes representing the influences (theoretical domains) on clinicians' decisions in DDwoR management		
	Clinical decision-making process		
	Diagnosis decisions	**Treatment decisions**	**Referral decisions**
4. Beliefs about capabilities	*"Maybe [I'll] not be able to just sort of diagnose the specific condition [DDwoR]"* (NGDP5).	*"A majority of [TMD] patients that I have managed I would term that, you know, for me as successful. Erm it's only been the difficult patients [DDwoR] that I feel that I've been unable to manage in practice so it's the only ones I'm least confident with that I've not really done enough maybe about improving my skills"* (EGDP12).	*"Q: Why do you think you start earlier referral for such a [DDwoR] condition while you may try to manage other [TMD] conditions before referral? R: I think it's because we don't know much about it, erm and it's a limited experience in treating it. Erm so I guess it's the lack of confidence treating it really"* (EGDP18).
5. Beliefs about consequences	*"I was concerned that there was something seriously deranged in the joints, that was my biggest fear and that's why I wanted him [a possible DDwoR patient] to be seen erm because his joint was not moving, you know, as it should have been"* (EGDP12).	*"The amount of pain killer I gave I would be very wary about. Again like I said with the patient with the jaw dislocation that had a reaction to the morphine… I'd be very worried about doing something like that with the patient with reduced mouth opening because of the difficulty there with intervention erm if they had issues"* (A&E16).	*"I think it's probably important [to manage DDwoR in primary care]… because if they're going to be in an acute situation coming to me with limitation of opening and I'm going to be sending them away saying 'I'm not really sure what's going on here' and then they're going to have that huge 3-month wait to be seen, 2 to 3 month it is"* (EGDP10).
6. Optimism		*"Obviously if somebody comes in with a locked jaw or erm, you know, really acute pain and sever trismus it can be very difficult. There's no magic quick fix that you can suddenly give them to improve that"* (EGDP12).	
7. Reinforcement	*"If I was working in a general practice I certainly want to be paid for it. Not that money's the be all and end all but when you've got UDA [Units of Dental Activity] targets to meet I think a lot of GPs are very guilty of 'I've only got 10 minutes to talk about this at the end', or not even, at the end of an examination because they're not going to really bring that – I mean…realistically a general practitioner isn't going to bring that patient back for a review"* (NGDP14).	*"If you were a practitioner working in the NHS there is no funding, you will be doing charity work if you got involved in these cases. It will be of no benefit. In fact it would be detrimental financially to a practitioner to treat such cases"* (EGDP13).	*"There's no particular incentive. It's just I would want to treat them as I would any other patient. The incentive, I mean I do prefer not having to refer a patient so and obviously it's much better for the patient as well if we can manage them here [at the general practice] and they don't have to, you know, go through a long waiting list, so yeah I mean there's a lot of incentives, you know, that you don't have to refer a patient and you can treat them at the practice"* (EGDP18).

Theoretical Domains	Quotes representing the influences (theoretical domains) on clinicians' decisions in DDwoR management		
	Clinical decision-making process		
	Diagnosis decisions	**Treatment decisions**	**Referral decisions**
8. Intentions	*"I think if I had a patient with the condition you mentioned earlier, disc displacement without reduction, I think if I saw more patients like that then that would influence me to increase my knowledge myself and try to manage them better"* (NGDP15).	*"I like doing practical manoeuvres. If it works for the patient the patient thinks it's wonderful, the doctor's a magician, he just did this and I was better, you know, and so learning practical manoeuvres that could help are very helpful"* (A&E/GMP17).	*"I mean I would quite prefer a bit more experience… I guess we should be trained on it a bit more and it would prevent needing that referral if I guess if we did think, if there isn't more we can do in our practice setting"* (EGDP18).
9. Goals	*"To relieve them of their pain and monitor them for progression or not"* (EMGDP3).	*"To get the patient sort of symptom free and to manage the condition"* (GMP8).	*"Obviously we want to get the patient out of pain and…resolve that pain as quickly and effectively as possible erm so that would probably be the goal"* (NGDP5).
10. Memory, attention, and decision processes	*"There's [are] probably…different [TMD] conditions so there's with reduction and there's the one disc displacement without reduction. Erm gosh I'm trying to think of the name now, I'm trying to think of the sheet. Erm there's with and without limited opening so there's 2 different types and then there's obviously all the arthritic problems as well"* (NGDP15).	*"I have heard things [about DDwoR evidence-based management] but you've getting a very honest interview here because I haven't done any special additional reading prior to it. Yes there is some evidence. I can't tell you what it is and I'd have to look it up again and I should know"* (OMFS11).	*"I would need to ask advice [about DDwoR] and if I'm told to do something I will do it then I will remember it for next time. So if that were the case then if it were possible I could remember it and do it next time"* (A&E/GMP17).
11. Environmental context and resources	*"I think the only thing might be that quite often when we first present a time that you have to take the full history, do the full examination and explain the management can be quite tight, and document it properly"* (EMGDP3).	*"I think it just depends if they [patients] pay… because if they don't want to pay for a soft splint then it's difficult to manage them to your full potential"* (EGDP18).	
12. Social influences	*"I'd probably have a go at making a [DDwoR] diagnosis given that I'd been guided by the dental hospital… I would have a go at the diagnosis but erm under guidance"* (EGDP10). *"If there was something erm out of the ordinary that I was concerned about yeah I would [discuss it with colleagues], especially with the people erm that work within the practice"* (EGDP12).	*"It's more getting advice [from secondary care on a DDwoR patient]. Erm, you know I'm very willing to give anything a go if the advice on the phone is right I want you to do this or do this or do this"* (EMGDP2).	*"We have a forum here where we discuss patients we wish to refer and that inevitably triggers a bit of discussion about whether you've done everything before referring for a second opinion"* (GMP7).

Theoretical Domains	Quotes representing the influences (theoretical domains) on clinicians' decisions in DDwoR management		
	Clinical decision-making process		
	Diagnosis decisions	**Treatment decisions**	**Referral decisions**
13. Emotions	*"I would be worry in the fact that I was uncertain of the [DDwoR] diagnosis and I would never sort of want to be sending somebody away with something like that if I didn't know what was going on"* (A&E16).		*"I think if...they're [patients] quite distressed about the condition, very worried erm that might push me a little bit more to refer…a bit sooner"* (EMGDP2).
14. Behavioural regulation	*"It's helpful [to receive a feedback from secondary care] to know if a diagnosis has been made erm and I need so that from my learning experience that, you know, matching the symptoms to what the final diagnosis was"* (EGDP12).	*"Definitely, yeah [I think it's important to receive a feedback from secondary care]…to know the treatment that they are providing, so that might help in the future to manage the patient who is having the treatment there, so it would be helpful to know what to do in a primary care setting in terms of long-term management of that patient or just to know what to do if it happened again or you came across someone else that it happened to"* (EGDP18).	*"I'd find that [receiving a feedback] really, really useful. Erm definitely so we can see what diagnosis was concluded upon and see what treatment was provided and how the patient's faring, yeah definitely I think that's important I like to see what the outcome at the dental hospital was and then what the patient believes it to be as well and they come in and compare the two erm so I find that quite interesting"* (NGDP5).
15. Nature of behaviour	*"I think in my head it seems a more serious condition [DDwoR]. Erm I think it's affecting the patient's day to day life a lot more rather than the former [TMD]"* (NGDP14).		*"[I am] not as confident [to manage DDwoR] as other forms of TMD…with normal opening just with pain… Erm if there's somebody with a closed lock it's almost like the condition has gone just that one step further erm so I think I would be more inclined to refer those patients sooner rather than later into hospitals, into secondary care"* (NGDP14).

Table 6.9: Summary influences and their representative quotes on frontline clinicians' decisions in DDwoR management.

1. Knowledge

The main finding from this domain was that the clinicians at the frontline considered TMD as a mild self-limiting problem but they lacked clinical knowledge about DDwoR to diagnose and treat. This exerts a major negative influence on their decision-making process in DDwoR management.

2. Skills

The main finding from this domain was that the dental practitioners seemingly had more skills to diagnose and treat TMD than the medical practitioners but that all the clinicians at the frontline lacked the three essential skills (diagnostic, treatment, and referral skills) required for DDwoR management (Table 6.10). This exerts a major negative influence on their decision-making process in DDwoR management.

Skills identified	Details
1. Diagnostic skills	a) History taking skills. b) Clinical examination skills (intra- and extra- oral examination). c) Differential diagnosis skills (symptoms-mimic conditions and red flags).
2. Treatment skills	a) Conservative treatment skills (including manual manipulation). b) Follow-up/review skills.
3. Referral skills	a) Appropriate referral skills. b) Urgent referral skills (identify red flag signs and symptoms for referral urgency).

Table 6.10: Skills required for TMD/DDwoR management.

3. Social/Professional role and identity

The main finding from this domain was that the clinicians at the frontline, apart from those in A&E, perceived having the responsibility, at least initially, to diagnose and treat mild common TMD, but the frontline clinicians had differing perceptions regarding their role and responsibility to manage acute uncommon TMD conditions such as DDwoR. This interesting disparity indicates that this domain, in reality, can exert a positive or negative influence on the frontline clinicians' decision-making process in DDwoR management.

4. Beliefs about capabilities

The main finding from this domain was that the dental practitioners had greater beliefs in their ability to diagnose and treat TMD than the medical practitioners but all seemed able to treat, at least initially, the mild common TMD, whilst all the clinicians at the frontline lacked ability and confidence to diagnose and treat acute DDwoR. This exerts a major negative influence on their decision-making process in DDwoR management.

5. Beliefs about consequences

The main finding from this domain was that the frontline clinicians' beliefs about consequences of DDwoR prognosis and their beliefs about consequences of misdiagnosis, mistreatment, and/or referral decisions can exert a major negative or positive influence on their decision-making process in DDwoR management.

6. Optimism

The main finding from this domain was that most clinicians were optimistic regarding TMD patients' response to conservative management but some clinicians seemed less optimistic regarding DDwoR patients' response to conservative management. This exerts a negative influence on their decision-making process in DDwoR management. That said, this domain seems unlikely to change the frontline clinicians' decisions to manage DDwoR because the majority had limited, if any, experience with it.

7. Reinforcement

The main finding from this domain was that the clinicians in NHS primary dental care lacked financial incentives to manage patients with TMD or DDwoR. This exerts a negative influence on their decision-making process in DDwoR management.

8. Intentions

The main finding from this domain was that many clinicians had the intentions and intrinsic motivation to manage TMD and DDwoR at the frontline and avoid referrals. This exerts a positive influence on their decision-making process in DDwoR management. That said, this domain, seems unlikely to change the frontline clinicians' decisions to manage DDwoR because the majority already motivated to manage the patients but their limited knowledge and skills were the main barriers.

9. Goals

The main finding from this domain was that many clinicians set a goal of improving patients' symptoms within a specific time-frame and the majority prioritise the importance of early management for patients with DDwoR at the first-point of contact. This exerts a positive influence on their decision-making process in DDwoR management. That said, this domain seems unlikely to change the frontline clinicians' decisions to manage DDwoR because the majority already aimed to manage DDwoR early at the frontline but their limited knowledge and skills hinder them from achieving this goal.

10. Memory, attention, and decision processes

The main finding from this domain was that the dental practitioners paid greater attention to TMD characteristic signs and symptoms than the medical practitioners but all the clinicians at the frontline had difficulty memorising and identifying the pathognomonic signs and symptoms of DDwoR, which was reflected in their decision processes. This exerts a major negative influence on their decision-making process in DDwoR management.

11. Environmental context and resources

The main finding from this domain was that the time and funding are the main environmental barriers of primary care for TMD and to a lesser extent DDwoR. This exerts a negative influence on clinicians' decision-making process in DDwoR management.

12. Social influences

The main finding from this domain was that the professionals and patients' social influences and interactions can exert a positive or negative influence on the frontline clinicians' decision-making process in DDwoR management.

13. Emotions

The main finding from this domain was that the own emotions of clinicians at the frontline appeared to be less affected when they were confronted with common mild TMD causing limited influence on their decisions, but the frontline clinicians' emotions

seemed to be affected when they encountered uncommon acute severe DDwoR. This exerts a major negative influence on their decision-making process in DDwoR management.

14. Behavioural regulation

The main finding from this domain was that most clinicians had increased knowledge and experience over the years in TMD's self-limiting nature and its chronicity but those at the frontline lacked growing knowledge and experience in DDwoR due to the relative rarity of the condition. All the clinicians at the frontline, however, had the motivation to receive feedback about their referred patients and the majority had also intrinsic motivation to change and improve their practice. This can exert a positive or negative influence on their decision-making process in DDwoR management.

15. Nature of behaviour

The main finding from this domain was that the nature of clinicians' behaviour seemed to differ considerably depending on clinicians' familiarity with the type and severity of clinical situation which had an impact on their decision-making processes. The majority of clinicians at the frontline seemed to try to diagnose and treat, at least initially, a patient who presented with 'chronic' mild TMD before making a referral decision, but all appeared to experience a high degree of uncertainty if they encountered a patient with acute severe DDwoR. For these patients they were more likely to seek an urgent advice and/or make an early referral decision.

In summary, the TDF-based analysis suggests that all the 15 theoretical domains influenced the clinicians' decisions in managing patients with TMD or DDwoR. The domains, however, vary in their likely influence, and strength, to change healthcare professionals' clinical behaviour. The domains that appeared most likely to change clinicians' decision-making behaviour when managing patients with DDwoR were: knowledge; skills; professional role and identity; beliefs about capabilities; beliefs about consequences; memory, attention, and decision processes; environmental context and resources; social influences; emotions; behavioural regulation; nature of behaviour, whilst the domains that appeared least likely to change clinicians' behaviour to manage patients with DDwoR were: optimism; intentions; goals. In comparison, the domains likely to change clinicians' behaviour when managing patients with TMD seem to be

relatively similar to DDwoR management but they differ in their influential strengths to change clinicians' behaviour. Specifically, the behavioural regulation and environmental context and resources domains are more likely to change clinicians' behaviour in TMD than DDwoR management whilst the emotions and nature of behaviour domains are less likely to change clinicians' behaviour in TMD management.

6.4.4 Summary of main findings

This study, to the research team's knowledge, is the first study that has used the TDF to explore the healthcare professionals' clinical decision-making process in temporomandibular disorders management in order to identify influences on clinicians' decisions regarding a particular subtype of temporomandibular disorders 'DDwoR'. The TDF-based analysis has highlighted the complexity of clinicians' decision-making processes. Data analysis has demonstrated that all theoretical domains emerged influencing clinical practice. In addition, it has demonstrated that the decision-making process varies among clinicians, but is mainly based on their professional qualifications and practice setting. Furthermore, the decision-making processes appeared to be related to, and differed according to, the individual clinician's familiarity with the type and severity of clinical condition.

For TMD, apparent differences in decision-making processes were identified between medically- and dentally-qualified practitioners. These were clearly related to insufficient education and training about the oral and maxillofacial related disorders in the UK undergraduate and postgraduate medical courses as compared to their dental counterparts (McCann *et al.*, 2005; Goodson *et al.*, 2013; Mahalingam *et al.*, 2015). Given the fact that many patients in the UK may consult a medical practitioner rather than a dental practitioner for a non-odontogenic oral and maxillofacial problem (Bell *et al.*, 2008), it seems pertinent to ensure that teaching related to TMD is included in the medical undergraduate curriculum and postgraduate training courses in order to ensure that medical practitioners possess the necessary knowledge and skills for TMD management. Recently, a syllabus of a brief educational course in maxillofacial emergencies for staff in the UK A&E departments is planned to be piloted in the future (Elledge and McAleer, 2015).

The identified influences on clinicians' decisions for TMD management were numerous, but the most influential factors seemed to be related primarily to 'non-

clinical' environmental barriers of primary TMD care, namely time constraints, and financial barriers, in addition to lack of robust evidence-based guidelines. Most of the identified barriers of TMD care replicate the main findings of a previous qualitative study (Durham *et al.*, 2007) and can be extrapolated to many other common chronic 'biopsychosocial' conditions (Wagner *et al.*, 2001; Ostbye *et al.*, 2005).

For DDwoR, important disparities were identified in decision-making processes between clinicians at the frontline (A&E, GMPs, & GDPs) and those providing a specialist (OMFS) service. These disparities appear to be directly linked to differences in knowledge and experience among clinicians. From the analysed data, it becomes quite clear that the main influencing factors on clinicians' decisions at the first point of contact were related primarily to frontline clinicians' lack of knowledge and experience in this 'rarer' disorder specifically. Again these findings can be extrapolated to many other uncommon acute conditions (Atherton *et al.*, 1999; Girdler and Smith, 1999; Greenwood, 2008; Muller *et al.*, 2008; Arsati *et al.*, 2010; Skapetis *et al.*, 2011).

The literature suggests that clinical knowledge is one of the key determinants of clinical decision-making process (Maudsley and Strivens, 2000; Botti and Reeve, 2003). The lack of knowledge about DDwoR specifically among the majority of the clinicians at the frontline, including the GDPs in the study sample, can be attributed to the following multiple reasons.

One of the main reasons is undoubtedly the low incidence of DDwoR. This, however, cannot be rationalised as the sole reason because, as mentioned, TMJ dislocation disorder has probably a comparable incidence and many clinicians at the frontline reported limited experience with this disorder too, but despite that most of them reported sufficient knowledge about TMJ dislocation and its management.

Another potential reason is the inadequate undergraduate teaching in the UK dental schools about the different subtypes of TMD and their specific management. This was not unexpected for a 'particular' generation of dentists (graduated more than 30 years ago) who might have limited knowledge about different subgroups of TMD (Baharvand *et al.*, 2010) because the most reliable criteria for TMD subgroups diagnoses (RDC/TMD) were published after 1990s (Dworkin and LeResche, 1992). It was, however, also found among the relatively 'younger' dentists in the study sample. In contrast, a recent questionnaire study evaluated the achieved competences in

COFP/TMD teaching at two European dental schools found that 91% and 100% of final-year Swedish and Italian dental students respectively were able to correctly diagnose DDwoR from a clinical case scenario (Alsafi *et al.*, 2014). This difference may highlight the inadequacy of undergraduate teaching about DDwoR in the UK dental schools. In fact, the UK dental schools may cover DDwoR disorder currently but not necessarily the details on its diagnosis and treatment. One reason for this could be attributed to the UK General Dental Council's broad non-specific definition of TMD for the current undergraduate dental curriculum (GDC, 2008), resulting in variations in undergraduate TMD teaching in dental schools.

Another possible reason is the use of generic 'TMD' term in both clinical practice and published literature. As previously mentioned, this may cause limited knowledge about different subtypes of temporomandibular disorders and their specific diagnoses and treatments.

Overall, there could be different reasons for professionals' limited knowledge about TMD in general and DDwoR in particular but it seems that the main reason behind that is the lack of interest in the biopsychosocial TMD amongst the vast majority of clinicians. This lack of interest is highlighted by some participants in this study and was shown in previous studies (Aggarwal *et al.*, 2012; Reissmann *et al.*, 2015). Consequently, the 'uninterested' clinicians may not improve their knowledge and/or skills to manage such kind of patients in their clinical practice.

Making decisions in emergency situations, however, does not rely solely on clinicians' knowledge but also on their past clinical experience with these situations (Cioffi, 2001). Experience has been defined as "a conscious event that is lived through, or undergone, as opposed to one that is imagined or thought about" (APA, 2007). When encountering a new clinical situation, clinicians often use their past clinical experiences in their decision-making process by comparing and matching the present encountered situation to previous experienced situations held in their memory in order to make a decision (Benner, 1982; Cioffi, 2001). However, as seen in the previous sections, the majority of frontline clinicians had never encountered a patient with acute DDwoR due to low incidence of the condition.

The lack of experience with DDwoR coupled with the limited knowledge about DDwoR among frontline clinicians seemingly had several 'inter-related' influences on

their decision-making process leading them to make an early referral decision when confronted with an acute DDwoR. The impact of frontline clinicians' limited knowledge, skills, and experience with DDwoR on other influences (i.e., domains) are summarised as follows:

- First, it caused reduced self-confidence of frontline clinicians' ability to manage DDwoR impacting not only their beliefs about capabilities but also their beliefs about consequences of DDwoR management.
- Second, it affects the frontline clinicians' perceptions in their role to manage DDwoR.
- Third, it made remembering of, and focusing attention to, DDwoR characteristic signs and symptoms difficult and challenging for frontline clinicians, impacting their decision-making processes.
- Fourth, it increased the frontline clinicians' emotionality leading them to express different concerns and worries when encountering such 'unusual' presentations.
- Fifth, it resulted in a lack of intrinsic motivation and intentions among frontline clinicians to increase their knowledge and develop their skills to manage DDwoR.
- Sixth, it lessened the frontline clinicians' optimism about DDwoR management.
- Seventh, it caused the frontline clinicians to seek social support and advice from more experienced clinicians.
- Eighth, it impacted on the frontline clinicians' behavioural regulation given that the DDwoR patients are rarely encountered; that is, the infrequent presentation of uncommon acute DDwoR patients, as opposed to more common mild TMD, did not improve frontline clinicians' growing experience, shaping knowledge, and skills development for DDwoR management.
- Finally, it directly influenced the frontline clinicians' nature of behaviour to refer DDwoR early as compared to other TMD.
- Additional interrelationships of influences (i.e., domains) for DDwoR management were also identified between the following: clinicians' beliefs about consequences and their emotions; clinicians' beliefs about capabilities

and their optimism; clinicians' role and their goals; clinicians' intentions and their goals; environmental context and reinforcement.

All these interrelationships between the domains for DDwoR management are depicted in Figure 6.7 (TDF-model).

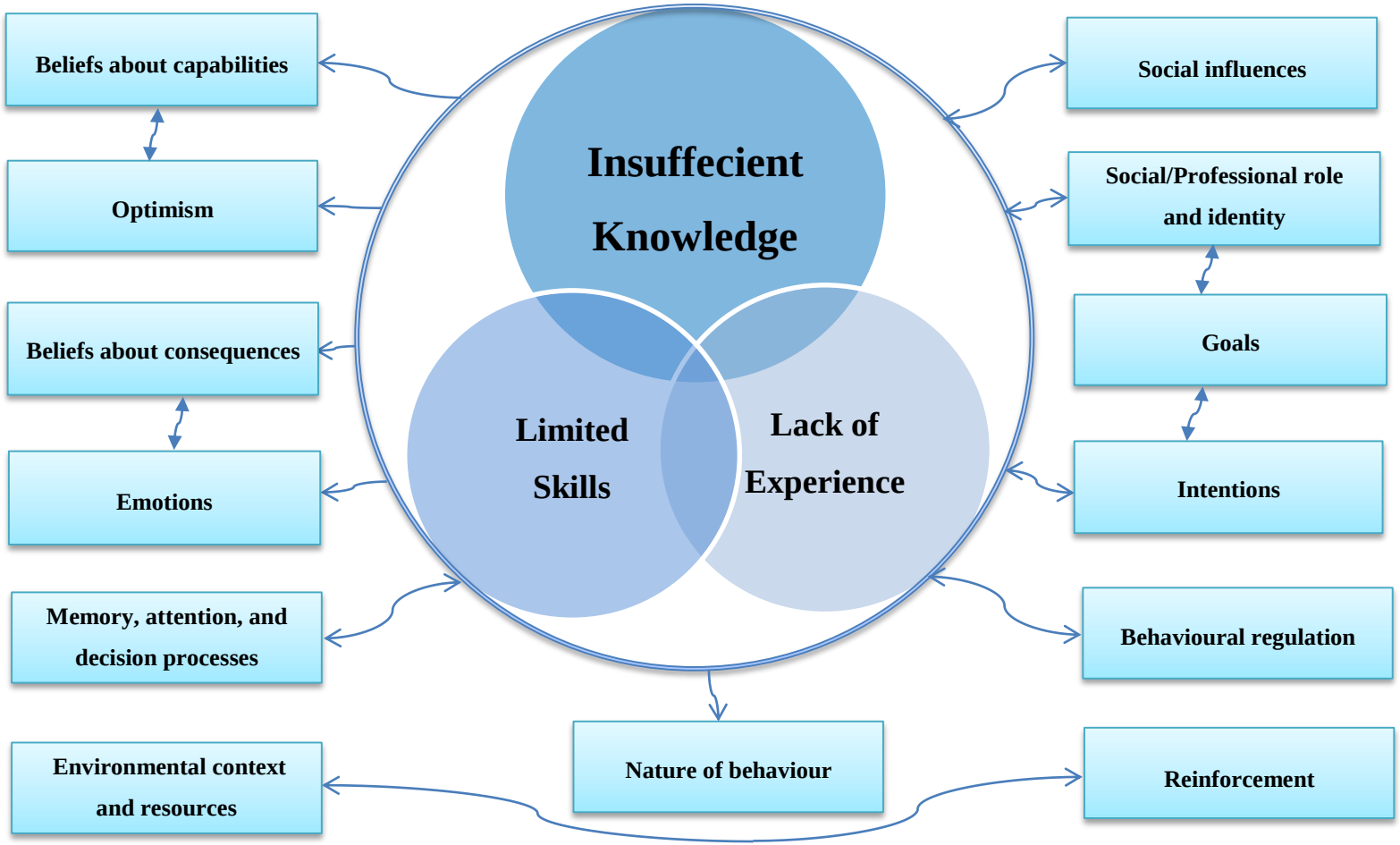


Figure 6.7: Theoretical model representing the interrelationships between the theoretical domains influencing the professionals' clinical decision-making process in DDwoR management.

The intimate relationships between the theoretical domains revealed by the TDF-based analysis (Figure 6.7) indicate that all the domains can have an influence on the clinicians' decision-making processes in managing DDwoR but that they vary in their influential strength on clinicians' decisions. The strongest influential domains appeared to be the professionals' knowledge and skills (and their related construct: 'experience').

As shown in the theoretical model (Figure 6.7), the 'core' barriers to DDwoR patients' receiving care at the first point of contact were clinicians' knowledge about disorder, experience with it, and skills required to diagnose and treat it. This means that there is a need to overcome these three barriers of care. Undergraduate and postgraduate educational and training courses are probably the key to improve the professionals' knowledge and skills in order to circumvent limited professionals' experience (the main barrier for experience-based knowledge and skills development). Although, there is no substitute for experience, simulation practical courses (e.g., by simulated case scenario or hypothetical human patient) have been suggested to overcome the deficiency in professionals' experience (Bond *et al.*, 2004; Croskerry, 2005a). Simulation is not a 'real' clinical experience (Croskerry, 2005a) but it may help clinicians at the frontline to acquire clinical competencies and overcome their limited experience with DDwoR.

In summary, the numerous influences on clinicians' decisions in DDwoR management were identified, tabulated, and summarised domain by domain as problems-solutions and barriers-enablers in Table 6.11 and Table 6.12 respectively. These need to be addressed in the future intervention design in order to support the clinicians' decisions for managing DDwoR at the first point of contact.

Theoretical Domain	Identified problems	Possible solutions
1 Knowledge	- Insufficient education	- Update undergraduate medical and dental curricula - Postgraduate medical and dental educational and training courses - Develop evidence-based guidelines
2 Skills	- Lack of proper training	- Hands-on postgraduate training programmes
• **Experience**	- Lack of experience	- Simulation courses
3 Social/Professional role and identity	- Generalists' perception	- Increase responsibility perception as first-line clinicians
4 Beliefs about capabilities	- Lack of confidence - Lack of perceived ability	- Increase self-efficacy - Set graded practice/tasks under supervised/supported conditions
5 Beliefs about consequences	- Outcome expectancy of disorder progress - Misdiagnosis consequences - Mismanagement consequences - Other barriers of care (fear of litigations and medico-legal consequences)	- Increase awareness about the disorder natural course, its pathophysiology, and its diagnosis and response to conservative treatment. - Increase awareness about the red flags signs and symptoms
6 Optimism	- Pessimism	- Increase awareness about the disorder natural course and good response to conservative management
7 Reinforcement	- Lack of incentives (remuneration) to manage.	- Dental contracting arrangements to ensure remuneration by some level of payment for NHS primary dental care clinicians
8 Intentions	- Lack of motivation to enhance knowledge in uncommon DDwoR	- None identified
9 Goals	- Fear of setting goals	- Establish standardised, pragmatic, and achievable goals

Theoretical Domain	Identified problems	Possible solutions
10 Memory, attention, and decision processes	- Difficulty to remember the characteristic features of DDwoR and its management evidence as well - Lack of attention to DDwoR pathognomonic signs and symptoms - Early referral decision process	- Electronic easily accessible tool to resolve memory and attention problems and to assist clinicians in their decision-making processes to manage DDwoR
11 Environmental context and resources	- Time constraints - Financial barriers - Lack of certain resources in some primary care practices such as: OPG machine, patient information leaflet, and physiotherapy devices.	- Modify NHS contract for remunerating the primary dental care clinicians to compensate for the time needed for treating TMD/DDwoR - Supply primary care practices with the necessary resources
12 Social influences	- Patients' influences - Other barriers of care (Patients' expectations as generalists not specialists)	- None identified
13 Emotions	- Worries and concerns - Fear and anxiety - Negative affect: Feeling useless/helpless - Patient emotion/distress influence	- Educational and training courses about such acute conditions and the red flag signs and symptoms
14 Behavioural regulation	- No growing experience - Lack of feedback especially in single-access emergency care setting	- Enhance the feedback process between healthcare services
15 Nature of behaviour	- Unfamiliarity with the acute severe clinical conditions	- Enhance knowledge and experience with acute TMD.

Table 6.11: Summary findings of identified problems and possible suggested solutions for TMD/DDwoR management.

Theoretical Domain	Barrier	Enabler
1 Knowledge	- Lack of knowledge of DDwoR disorder - Lack of procedural knowledge - Lack of knowledge about red flags - Lack of interest	- Easy contact with secondary and tertiary care clinicians
2 Skills	- Lack of skills required for DDwoR management	- None identified
• **Experience**	- Lack of experience	- None identified
3 Social/Professional role and identity	- Generalists' perception	- First-line professionals' identity
4 Beliefs about capabilities	- Lack of confidence - Lack of perceived ability	- None identified
5 Beliefs about consequences	- Outcome expectancy of disorder progress - Misdiagnosis consequences - Mismanagement consequences - Positive referral consequences - Other barriers of care (fear of litigations and medico-legal consequences)	- Negative referral consequences
6 Optimism	- Pessimism	- None identified
7 Reinforcement	- Lack of incentives (remuneration)	- Self-reward (personal satisfaction)
8 Intentions	- Lack of intention to increase knowledge in uncommon DDwoR	- Intrinsic motivation to improve practice - Intention/willing to help patient - Practitioner's previous experience - Learning manipulation technique
9 Goals	- Professionals' unpredictability to management outcomes - Fear of setting 'formal goals	- Management priority and importance - Symptoms' management Goal: Goal/target setting

Theoretical Domain	Barrier	Enabler
10 Memory, attention, and decision processes	- Memory problem related to low incidence of disorder. Difficulty to remember the characteristic features of DDwoR and its management evidence. - Lack of attention to DDwoR pathognomonic signs and symptoms - Early referral decision process	- First-time experience memory
11 Environmental context and resources	- Time constraints - Financial barriers - Lack of certain resources in primary care practices such as: OPG machine, patient information leaflet, and physiotherapy devices	- Availability of necessary resources - Organisational influences/pressure to management commitment and avoid referrals
12 Social influences	- Patients' influences (social pressure) - Other barriers of care (patients' perceptions and expectations of primary care clinicians as generalists not specialists)	- Professionals' influences: Professional's phone advice (Social support): - Team-work (social support) - Involving patient (patient preference, informed and shared decision)
13 Emotions	- Worries and concerns - Fear and anxiety - Negative affect: Feeling useless/helpless - Patient emotion/distress influence	- Empathy with the patient's suffering. - Limited effects of practitioners' emotions or work stress on their management decisions
14 Behavioural regulation	- No growing experience	- Self-monitoring - Generating alternatives for acute TMD conditions - Motivation to change/willing to receive feedback about referred patients - Clinicians' suggestions to help themselves for DDwoR management
15 Nature of behaviour	- Salient/critical clinical situation	- None identified

Table 6.12: Identified barriers and enablers for DDwoR management.

6.4.5 Strengths and limitations of the qualitative study

This study, as with other qualitative-TDF studies, had strengths and limitations related mainly to study design, study sample, and methods used.

This study, unlike many 'TDF' studies, is the first study that has used the TDF to explore the whole clinical decision-making process in order to identify factors influencing clinicians' decisions. This study was strengthened by using two approaches, rather than a singular approach, to analyse the qualitative data. Firstly, the pattern of clinical decision-making process for each individual practitioner was analysed and depicted in a graphical map. This served three purposes: (1) it facilitated the understanding of clinicians' management pathways (Appendix I); (2) it allowed comparisons between and among different groups of practitioners (Appendix M); (3) it helped the development process of the generic map (Figure 6.6). Secondly, the TDF-based analysis of data was used to identify influences on clinicians' decisions. By using the TDF, the study findings provided new information about influential factors on clinicians' decisions that may otherwise be overlooked if the theoretical framework was not used. Using a framework based on a wide range of psychological theories in data analysis permits the identified factors, as informed by theoretical domains, to be linked to relevant behaviour change techniques to be subsequently implemented in future intervention and, ultimately, support clinicians' decisions to improve patient care.

Some limitations, however, were identified with the use of theoretical framework in this study. One limitation is the use of TDF as a guiding framework for data analysis. This structured approach may restrict the emergence of 'free' themes (McCluskey and Middleton, 2010; McSherry *et al.*, 2012). Although the initial generation of 'free' unrestricted codes should overcome this possible limitation, there is still a possibility of identifying other aspects of clinical practice and experience that might have emerged if another approach for data analysis had been used. This, however, seems unlikely given the comprehensiveness and inclusiveness of the TDF. Actually, the use of TDF facilitated analysis and no factors influencing the clinicians' decisions have emerged that could not be thematically mapped to theoretical domains.

Another limitation of the TDF is that it was designed to be applied to topics where there is a high-quality evidence-based clinical practice guideline. It has been suggested that the TDF might be less useful in topics where the high-quality evidence and guidelines

are lacking because the identified 'behavioural determinants' can vary by variations in participants' attitudes (Francis *et al.*, 2009; McSherry *et al.*, 2012). This, however, did not seem to be an issue in our context because our study aimed to identify the influencing factors on the whole decision-making process and did not aim to identify purely the behavioural determinants (influences) of a specific 'targeted' behaviour.

A further limitation of using the TDF could be the lack of clarity in the definitions of the theoretical domains and some overlap between constructs associated with the domains. This has proved to be a main problem in data analysis in previous studies (Islam *et al.*, 2012). In an attempt to resolve this problem in our study, we referred back to the 'psychological' definitions of the domains and constructs (APA, 2007) and to the theoretical domains interview (TDI) questions. This, however, was challenging when one construct within the 'memory, attention, and decision processes' domain (i.e., decision processes) was found to be relevant to whole decision-making process and when some constructs of TDF domains were found to be relevant to other domains (e.g., action planning construct in 'goals' and 'behavioural regulation' domains). In addition, the TDF was also criticised for not specifying the domains' relationships (Duncan *et al.*, 2012; McSherry *et al.*, 2012). In this study, several relationships between the domains were identified and mapped (Figure 6.7), suggesting that there are links between theoretical domains influencing clinicians' decisions. This highlights the need to explore further the identified relationships between the domains. To give an example, if the professionals' knowledge and skills in DDwoR management are improved, would this affect the professionals' beliefs about their capabilities to manage DDwoR? Further research is needed to explore the relations between the theoretical domains in order to better understand the influences on professionals' behaviour.

The study design and methodology used had also strengths and limits. First, the semi-structured interview method was utilised in this study to collect the data. This type of data collection method allows the researcher to explore 'in-depth' the relevant issues with a 'singular' practitioner (Fitzpatrick and Boulton, 1994). Other data collection methods can be used such as observation of clinicians or focus group discussions, but both seemed impractical for the purposes of this particular study. Observation is time intensive generally and would be impractical not only due to time constraints of the project but also because of the infrequent presentation of DDwoR cases in clinical practice. Focus groups may not allow in-depth focused one-to-one discussion and may

not be balanced and dominated by one vociferous participant especially in our study where we wanted views from a range of healthcare professionals and hierarchy could have affected responses. Second, the two modes of qualitative interview were used in this study: face-to-face and telephone (Novick, 2008). However, comparison between telephone and face-to-face interviews in a study by Sturges and Hanrahan (2004) revealed that the mode of the interview did not significantly affect the generated data and that telephone interviews can have several advantages over the face-to-face interviews. In this study, telephone interviews were conducted to avoid sampling bias when the clinicians were reluctant to participate in a face-to-face interview or when the clinicians agreed to participate but were unable to attend to the Dental Hospital. Third, as this is a qualitative study, the findings from the qualitative data analysis regarding the identified influencing factors cannot be generalisable and represent only the participants' perceptions and views about what might influence their clinical decisions. The identified factors, therefore, may not represent the actual influences on clinicians' decisions in real practice (Francis *et al.*, 2009; Tavender *et al.*, 2014). To give an example, a lack of time to manage TMD may, in reality, reflect a lack of interest in TMD management. It has been suggested that relying solely on participants' perceptions is inadequate for effective intervention implementation (Boscart *et al.*, 2012). This limitation may indicate the need to amalgamate the qualitative study findings with the findings from other study designs for effective intervention implementation.

The composition of the sample used in this study also demonstrated some strengths and weaknesses. The sampling strategy used was purposive, criterion-based, maximum variation sampling. Other qualitative sampling strategies are available and suggested in the literature (Patton, 2002), most commonly theoretical sampling (i.e., sampling is theoretically guided by the emerging concepts) (Glaser and Srauss, 1967). Theoretical sampling, however, was not used because this study was 'pre-informed' by the theoretical domains of behaviour change (Michie *et al.*, 2005). In fact, it has been suggested that developing an intervention that is based on identified domains and takes into account the potential roles of all professionals involved in care of patients is most likely to be 'successful' (Patey *et al.*, 2012). The sampling strategy used in this study strengthened our findings because it gave us the perspectives from the key professional groups responsible for DDwoR management at multiple levels across the care pathways (primary, secondary, and tertiary care). Subsequently, this helps understanding the

multi-level DDwoR care path and contrast between ‘first-line’ and ‘second-line’ care groups around DDwoR management. The ‘second-line’ study sample, however, included only clinicians working in the specialist oral surgery and maxillofacial surgery services. The OMFS clinicians may have different perspectives and ideologies from other specialities with respect to TMD/DDwoR management (Durham *et al.*, 2007), which may bias the qualitative data. In fact, this study could have been further strengthened by recruiting participants from other specialities routinely involved in care of TMD/DDwoR patients such as: restorative dentists, oral medicine dentists, physiotherapists, and ENT clinicians. Clinicians from different specialties, however, were not included because the primary aim of this project was to specifically examine the clinicians’ understandings about DDwoR disorder at the first point of contact and compare that with those at the specialist service; although their management ideas about DDwoR would have provided an interesting comparison with the current data and may also have added further insight about the DDwoR care pathway.

The study sample had further limits. Firstly, more than 100 clinicians were contacted and invited to participate but only about 20% agreed to participate. This low rate is attributed to different potential reasons including: change in practice/clinician contact details (e.g., some clinicians contacted had moved to non-North East Trusts), clinician’s busy schedule and lack of time, or clinician’s lack of interest in COFP/TMD. The latter factor was shown to be one of the reasons for clinicians’ declining to participate in a previous survey study in the UK (Aggarwal *et al.*, 2012) and may cause a potential selection bias in this study because the interviewed participants may represent a subgroup of clinicians who have a higher degree of interest in TMD compared with the non-responding clinicians, thus limiting the generalizability of study findings; although this is less of an issue for DDwoR as all the invited clinicians were not pre-informed about it. Secondly, by using a TDF-based topic guide and analysis, there was a possibility of reaching the saturation prematurely if the participants shared similar opinions (Patey *et al.*, 2012). To overcome such potential limitation, the study sample was maximum variation to ensure participants’ diversity for a range of variables (e.g., gender, years since graduation, clinical practice, qualification, undergraduate school, and practice region), thereby covering a broad range of differing opinions. Thirdly, the sample was restricted to the North East region of England which may again limit the generalizability of study findings elsewhere. For example, the barriers of TMD care in the UK healthcare system may differ from other parts of the world. Nevertheless, most

of the barriers for DDwoR care raised by the study's participants seem likely to be encountered in other similar healthcare systems in other countries. Finally, this study aimed specifically to examine the professionals' understanding of DDwoR. As such, qualitative interviews with DDwoR patients would help understand the DDwoR patient's journey and potentially inform the design of a future intervention for patients. All the aforementioned limitations regarding the study sample, however, were difficult to be overcome due to limited resources and time scale of this project.

6.5 Conclusions

The healthcare professionals' clinical decision-making processes for TMD and DDwoR management were influenced by numerous factors. The domains identified as likely to change clinicians' behaviour to manage patients with TMD and DDwoR were relatively similar but they differ in their influential strengths to change clinicians' behaviour.

Twelve of the fifteen theoretical domains were identified as of potential importance and relevance for future intervention to improve clinical decision-making processes for DDwoR management. Of the 12 domains identified, however, the most frequent and clearly influential on clinicians' decisions were knowledge and skills domains (and their relevant construct 'experience'). There is a need to enhance the professionals' knowledge and skills in managing acute TMD conditions such as DDwoR to circumvent the professionals' limited experience with DDwoR. Nevertheless, all the factors identified represent theoretically-based targets for an intervention to support, and thereby improve, the clinicians' decisions around DDwoR management at the first point of contact.

Chapter 7. Conclusions

7.1 Studies' Conclusions

This thesis aimed to inform the development of a future intervention in order to aid the clinicians at the frontline managing DDwoR disorder. To achieve this aim, three objectives were addressed via three separate studies.

7.1.1 Systematic review of locking duration effects

The first of the listed objectives of this thesis was to assess the effects of locking duration on the clinical outcomes of therapeutic interventions used for patients with acute and chronic DDwoR. From the conducted systematic review, however, neither the transition point from acute to chronic DDwoR nor the effects of locking duration on treatment outcome could be determined. Nonetheless, there was low grade evidence of the need for early intervention in the DDwoR management pathway with the simplest, cheapest, quickest, and most practical first diagnostic and therapeutic approach, probably a mandibular manipulation.

7.1.2 Systematic review of therapeutic interventions effects

The second objective of this thesis was to assess the clinical effectiveness of therapeutic interventions used for managing patients with DDwoR. From the conducted systematic review, there was weak evidence that all the reviewed interventions, whether conservative or surgical, achieved comparable therapeutic effects in managing DDwoR. This strengthened the evidence for managing patients with DDwoR initially with the simplest, least costly, and least invasive interventions, probably education and self-management with early manipulation.

7.1.3 Qualitative study of clinicians' decisions

The final objective of this thesis was to explore the clinicians' decision-making process in managing DDwoR at the frontline and to identify influences on their decisions. From the conducted qualitative study, a number of influences on frontline clinicians' decisions were identified but they were related chiefly to their limited knowledge, skills, and experience with DDwoR. This suggests the need to enhance the clinicians' knowledge and skills in managing DDwoR to circumvent the clinicians' limited experience with DDwoR.

7.2 Summary Conclusion

In summary, this thesis provides evidence for intervening early in DDwoR patients with the most minimal intervention and the need to enhance the professionals' knowledge and skills in order to support their decisions to diagnose and treat, at least initially, patients with DDwoR at the frontline. The various implications of this project are detailed in the next chapter (Chapter 8). The components of proposed intervention to aid clinicians' decision-making should be based on the concluded evidence from this project and are summarised in Section 8.2.

Chapter 8. Implications for Clinical Practice, Future Clinician-based Intervention Implementation, and Future Research

8.1 Implications for clinical practice

Patients with TMD may present to clinicians complaining of different signs and symptoms related to the different underlying subtypes of TMD. Amongst all TMD, patients with DDwoR may present not only with significant pain but also with mouth opening limitation of mechanical cause. The initial management of DDwoR, as for the whole TMD, however, is shown in this project to be somewhat similar: minimal-interventional reversible conservative management. That said, the clinicians managing patients with DDwoR should make particular considerations to the following:

8.1.1 Diagnosis of DDwoR

The clinicians' diagnosis process should involve the following:

- A thorough knowledge about the differential diagnoses for limited mouth opening (Table 2.7).
- A systematic diagnostic approach in order to achieve an accurate diagnosis for a patient presenting with pain and/or limited opening. This involves, in addition to comprehensive history and careful clinical examination, appropriate investigations if necessary and particular attention to the presence of 'trismus' red flags (Table 2.9).

8.1.2 Treatment of DDwoR

In order to achieve the basic treatment goals for patients with DDwoR: relieving pain, improving opening, and restoring jaw function, the current available evidence from the systematic reviews, albeit weak, suggests that the clinicians should treat patients with symptomatic DDwoR in a stepped 'timely-management' approach, as follows:

1. **First-line management:** Start the management initially with the most minimal, simplest, least invasive, and least expensive interventions of education and self-management with 'early' manipulation, as follows:

Patient education: Its main aim is to educate and reassure the patient about the DDwoR disorder. It includes the following:

- A reassurance about the symptoms of DDwoR are not indicative of a serious or sinister pathology.
- A reassurance about the self-limiting nature of the DDwoR disorder and its 'favourable' prognosis (natural course): it is likely to improve in the majority of cases with time alone or with non-interventional simple care. It is not, however, always "curable" and can recur or fluctuate in symptomatology over time.
- A clear explanation to the patient in simple understandable terms about the clinical 'closed lock' condition, its signs and symptoms, and its potential causative biopsychosocial factors.
- A simple clarification to the patient about the mechanism of the articular disc in TMJ and the normal rotating and translating condylar movements and the normal masticatory apparatus functions.
- Education about the harmful effects of long-term use of over-the-counter medications and mouth guards and the lack of evidence for irreversible occlusal treatments.
- An explanation in a neutral manner about the potential risks associated with surgical interventions and the limited available evidence base to support its effectiveness. Further to this, it should be highlighted that current evidence has not demonstrated its superiority over simpler, less costly, and less risky non-invasive interventions.

Self-management programme: Its main aim is to prevent further injury to the musculoskeletal structures and allow for healing to occur by increasing patients' self-efficacy in managing their own DDwoR condition. The programme may include several different self-care strategies, as described in the literature, but all generally involve instructing and advising the patients with respect to the benefits of the following:

- Rest (jaw and muscle relaxation).
- 'Pain-free' soft diet, decaffeinated diet, and balanced chewing.
- Parafunctional habits awareness and modification.
- Diaphragmatic breath training, sleep improving, and posture training.
- Home physiotherapy programme including self-exercises, self-massages, and hot/cold packs application.
- Pharmacotherapy such as oral and/or topical analgesics and anti-inflammatories.
- Psychosocial therapy such as optimistic counselling and biofeedback.

To achieve a successful outcome of patient education and self-management, the clinicians must have good communication skills, be competent in exclusion of red flags, be capable of selecting the appropriate treatment strategy, and must be able to explore patients' beliefs, expectations, and own goals before initiating long-term management strategies. The clinicians should also clarify to the patients that the success of self-management is dependent largely on them, particularly on their cooperation, adherence, motivation, and active participation.

Mandibular manipulation: Its main aim is to improve DDwoR symptoms early in the chronology of the condition. Various 'unlock' manipulation techniques, with/without adjunctive treatments, are described in the literature, but the available evidence supports the application of either the 'anterior teeth' technique for self-manipulation suggested by Yoshida *et al.* (2011) or the 'posterior teeth' technique described by Farrar (1978) and modified in this thesis (Figure 2.9). Before applying this treatment approach in clinical practice, however, the clinicians require:

- A full understanding about the anatomy of condyle-disc complex and the specificity of DDwoR pathophysiology and the potential beneficial effects of early application of manual manipulation.
- A sufficient knowledge and training about the manipulation techniques.
- An adequate knowledge about the possible need for patient analgesia pre-manipulation and splint treatment post-manipulation.

The outcome of this first-line management can be probably reviewed within the first 3 months.

2. **Second-line management:** Escalate management only if needed via rehabilitation by splint therapy, physiotherapy, or a combination of both. Various splint types and physiotherapies are available and suggested in the literature.

The outcome of this second-line management can be probably reviewed within 3-6 months.

3. **Final-line management:** Defer TMJ surgery to around 9-12 months or more of comprehensive conservative treatment and apply it only in the face of objective clinical need (i.e., persistent severe pain and/or disability) and have already confirmed the biomedical cause of symptoms (i.e., confirmed the DDwoR clinical

diagnosis by soft tissue TMJ imaging) and engaged in a carefully constructed programme of conservative management. Start surgery, only if required, by using the most minimally-invasive technique, arthrocentesis.

There could be, however, individual level differences in DDwoR patients' biomedical complaints (e.g., presence/absence of pain or mouth opening limitation) or psychosocial variables which may change the suggested stepped management plan and create a necessity for a specific treatment but this stepped approach is generally the most realistic.

8.1.3 Referral of DDwoR

The frontline clinicians are recommended to refer DDwoR patients in the following circumstances:

- Refer immediately: if there are any concerns about red flags or if there are severe pain and/or limited opening symptoms.
- Refer after one month: if there are persistent high-level symptoms despite initial management.
- Refer after three months: if there is limited symptomatic improvement despite conservative management.

The suggested recommendations are based on the best available evidence to-date but they should be interpreted with caution due to limited quality of current evidence. Future well-conducted research may change or confirm these.

8.2 Implications for future clinician-based intervention implementation

The findings from the qualitative study suggest the need for a future behavioural intervention to support clinicians in DDwoR management at the frontline. The proposed intervention needs to be based on the identified factors, as informed by the TDF, influencing the clinicians' decisions. The intervention design should follow the 'TIDieR' checklist guide proposed for better reporting of behaviour change interventions (Hoffmann *et al.*, 2014). The key components of the proposed intervention for DDwoR management were suggested by study participants to be simple, easy, clear, concise, and practical to help them diagnose and treat DDwoR patients. Participants preferred the electronic intervention to be delivered via an eHealth rather than a

mHealth platform so that clinicians can use it on the practice's computer rather than on their personal mobile devices. Further features about the future intervention design are detailed in Table 8.1.

Item No	Item
1 Brief name	**P/LMO** intervention for Painful/Limited Mouth Opening management
2 Why	To aid the healthcare professionals diagnose and treat patients with painful limited mouth opening conditions, specifically DDwoR.
3 What	**Materials and Procedures** • Simple diagnostic guide (easy, clear, concise, quick and practical) to help recognize closed lock condition and diagnose DDwoR. The guide should also include differential diagnostic signs and symptoms and red flags to help differentiate DDwoR from other conditions with similar 'trismus' symptom. • Patient information leaflet to include self-care instructions that can be printed out and provided to the patients. • Virtual online videos associated to the intervention for e-learning/training (certified professional training videos rather than conventional YouTube videos) about: 1) How to examine the closed lock patient to make the DDwoR diagnosis. 2) Simple explanation about TMJ anatomy, mechanism of the condyle-disc complex, and DDwoR condition and its natural course to both patients and professionals. In addition to educational videos about self-management including instructions to patients about how to care their TMD condition. 3) How to perform the practical manoeuvre of 'unlock' manipulation technique for acute DDwoR and also probably the relocation manipulation technique for acute TMJ dislocation. • Optional feature of the intervention (according to professional specific need): training courses either in a face-to-face setting where clinicians would have hands-on 'real' training or simulation web-based case scenario to learn how to appropriately use proper skills for manipulating the jaw. • A brief bulletin or lecture series to be delivered to all practices. • A questionnaire to assess professionals' performance and feedback them. • Attractive for use by rewarding the professionals with CPD hours/points. • In addition to all relevant domains identified earlier in Table 6.8.
4 Who (provider)	The intervention will be delivered electronically via internet to professionals. The face-to-face training session could be organised by GDC (counting for continuous professional development 'CPD') and delivered by specialists in TMD.

Item No	Item
5 How	The modes of intervention delivery will be provided electronically and individually to professionals. Mode of e-intervention delivery can be via eHealth or mHealth media but the participants preferred the intervention to be delivered on desktop computer screen or iPad (eHealth) rather than on smart phone (mHealth). The face-to-face training session could be provided by specialists in TMD.
6 Where	The intervention can be used electronically individually by professionals at their clinical practice. The face-to-face training session could be held in academic dental schools or dental teaching hospitals.
7 When and How Much	The intervention can be used electronically by professionals at any time. The face-to-face training session could be organised once or twice a year as a full-time study day specified for diagnosing and treating DDwoR.
8 Tailoring	Not applicable
9 Modifications	Not applicable
10 How well	The intervention adherence and fidelity is not assessed yet but it can be assessed by involving a questionnaire for professionals' feedback and evaluation of the intervention. Records can also be kept, electronic ones, on the features of the intervention used, how often, for how long each time; this can later be evaluated against other measures such as numbers of diagnostics, initial treatments and referrals.

Table 8.1: Template for future intervention description for DDwoR management. This is based on items included in the Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann *et al.*, 2014).

8.3 Implications for future research

Different implications for future research were identified from each of the three studies.

8.3.1 Systematic review of locking duration effects

In the systematic review of locking duration effects, neither the transition point from acute to chronic DDwoR nor the effects of locking duration on treatment outcome could be determined and remained controversial. One of the likely reasons is the lack of a standardised diagnostic classification for DDwoR that characterises the clinical staging of DDwoR on the basis of locking duration (i.e., time since DDwoR onset). Future diagnostic classifications for DDwoR should seek to address and define the acute versus the chronic period in relation to duration of locking, given that it is one of the few factors that can be easily addressed from patient's history especially in acute closed lock because patients can often recall the sudden-onset locking of short duration. This classification may then advance understanding and help target the available therapies

for acute and chronic DDwoR more effectively. To examine the effects of locking duration on the outcome of therapeutic interventions for DDwoR in future trials, standardisation is needed for the following:

- Definition of acute and chronic DDwoR in order to allow stratification of treatment groups.
- Other prognostic factors that may predict DDwoR management outcome.
- Multidimensional outcome measures that are of importance in DDwoR.
- Pragmatic success criteria that are of importance for DDwoR patients in order to yield more rigorous research.

Further recommendations for future trials of DDwoR management are suggested below.

8.3.2 Systematic review of therapeutic interventions effects

In the systematic review of therapeutic interventions effects, weak evidence was found to initially manage DDwoR with the simple non-invasive conservative interventions, specifically education, self-management, and early mandibular manipulation. The evidence for managing DDwoR with the minimally-invasive surgical intervention through arthrocentesis and lavage was contradictory. Future high-quality pragmatic RCTs are required to examine the effects of these interventions in order to provide more robust evidence of their efficacy or lack of it. Given the low incidence of DDwoR amongst TMD and the difficulty in recruiting patients with a DDwoR 'acute/chronic' diagnosis, a multi-centre RCT may be the most appropriate. The recommended research design for future RCTs is described in-detail in Appendix N.

8.3.3 Qualitative study of clinicians' decisions

In the qualitative study of clinicians' decisions, a number of problems (Table 6.11) and barriers (Table 6.12) for TMD/DDwoR care were revealed by the study participants; most importantly, insufficient knowledge and training and lack of time and financial incentives to manage TMD/DDwoR. Therefore, there is a necessity for the following:

- Smart commissioning in NHS dentistry and reform of the current NHS dental contract to involve adequate remuneration of GDPs for the time required for TMD/DDwoR management in primary care.

- Update and revise the current undergraduate curriculum in the UK dental and medical schools to involve more detailed education about the different common subtypes of TMD.
- Offer evidence-based postgraduate courses for dental and medical practitioners about TMD/DDwoR management.

If these arrangements are addressed in the future, they will undoubtedly change the current clinical practice and possibly improve the healthcare delivery.

The qualitative TDF-informed method was used to understand the professionals' clinical decision-making processes around TMD/DDwoR management in order to identify possible factors (i.e., domains) influencing these processes. The main outcome of the qualitative study is the first step in an intervention development and implementation process. To complete this process, there is a need for the following sequential steps:

- Design, using the qualitative data, a valid questionnaire (Appendix O) to employ with a representative sample of clinicians in order to determine the frequency of influencing domains for changing practice (Huijg *et al.*, 2014a). This step is an optional step and the developed questionnaire can be utilised, instead, to assess the professionals' performance and provide feedback as well as to evaluate the piloted intervention.
- Engagement with computer scientists for developing an active web-based eHealth and/or mHealth intervention.
- Engagement with potential users (i.e., clinicians) for refining the draft version (Table 8.1) of the pilot intervention (e.g., checking intervention feasibility by focus group discussion).
- Open pilot intervention trial.
- Randomised controlled trial.

Appendices

Appendix A: Characteristics and quality of all the included studies in systematic review of locking duration study (Chapter 4)

A-1: Characteristics and quality of included mandibular manipulation (unlock manipulation 'UM' or pumping manipulation 'PM') studies

Study (Year)	Study design	Participants' characteristics								Main Intervention assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	Overall success rate % (ITT use)	Study design quality
		Sample size (drp/exc)	Study diagnosis	Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Chiba and Echigo (2005)	CR	1	DDwoR (ACL)	-	1	21	-	0.33	-	Farrar's UM [a] under LA + ARS	137	Decreased pain, cMMO≥40mm, & DR on MRI	-	-	**IV**
Correa *et al.* (2009)	CR	1	DDwoR	-	1	18	-	36	-	UM under LA + ARS, NSAIDs, cryotherapy	24	cMMO>40mm	-	-	**IV**
Foster *et al.* (2000)	PNCoSt	55 (19)	22 CL DDwoR & 14 IL	7	48	15-52	24	3-48	13	Forced UM under GA + Self-care ± Splint	3	MMO≥35mm & subjective improvement	Range of LD (6-48) was similar in SG & UG.	CL: 40.9% (no ITT)	**III-3**
Helkimo and Hugoson (1988)	PCS	10	DDwoR	3	7	17-63	29.4	1-36	12.2	Farrar's UM under N_2O/O_2 sedation + SS	6	Improvement in: pain, jaw dysfunction (Di: I-II), LM, & MMO≥40mm	Longer LD in UG 20 (12-36) than in SG 10.8 (1-30).	60%	**IV**
Hernandez and Karibe (2004)	CR	1	DDwoR	-	1	-	28	0.25	-	UM under LA + Med, PT (US), SS, Self-exercises	1	MMO≥40mm	-	-	**IV**
Jagger (1991)	PCS	12	DDwoR	4	8	15-43	21.8	1-9	3	UM (own technique)	-	MMO≥35mm	LD is not an important factor for UM success	66.7%	**IV**
Kai *et al.* (1993)	PCS	12 [b]	DDwoR	1	11	11-61	30.33	0.1-2	0.5±0.53	UM or PM + ARS	1	Improvement in clinical symptoms & MMO≥40mm	58.3% DR on arthrography	66.7%	**IV**
Kurita *et al.* (1999)	PNCoSt	74/215 assessed by MRI	DDwoR	7	67	-	32.5	-	11.4	Farrar's UM + ARS or NSAID or SS	Few wks	DR on MRI	No significant difference in LD between successful DR (10±19.1) and no DR (12.8±24.6).	18% (no ITT) 9% (ITT)	**III-3**
Liu *et al.* (2012b)	RNCoSt	36	23 CL DDwoR & 13 IL	6	30	13-31	19.8	< 3	-	UM under LA + ARS	6	Improvement in: pain, MMO, & jaw dysfunction.	-	DDwoR: 69.6%	**IV**
Martini *et al.* (1996)	PCS	13/1500 reported	DDwoR	-	-	19-56	31.4	0.23-180	36.02±53.47	UM (own technique) + ARS, PT	2-24	Absence of pain, MMO≥35mm, & DR on MRI	LD is not related to UM success.	99.7%	**IV**
Minagi *et al.* (1991)	PCS	35	DDwoR	2	33	12-68	35.94	0.25-18	3.26±4.09	UM (own technique)	-	MMO≥40mm	No difference in success rate between <1mo (50%) & >1mo (53%) LD.	51.4%	**IV**

Study (Year)	Study design	Participants' characteristics								Main Intervention assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	Overall success rate % (ITT use)	Study design quality
		Sample size (drp/exc)	Study diagnosis	Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Mongini *et al*. (1996)	PCS	75 (7)	DDwoR	7	68	13-43	27.8	0.25-120	13.3±21.84	Extra-oral UM under LA + ARS, SS, Med, PT	18-147	No pain or pain present only on jaw movement & MMO≥35mm	No difference in LD between SG & UG. 4.4% DR on MRI.	86.8% (no ITT)	**IV**
Muhtarogullari *et al.* (2013)	PNCoSt	22	DDwoR	3	19	14-48	27.1	-	3.25	UM + ARS if unsuccessful DR: SS+ Self-exercises	6	No pain on palpation, MMO≥40mm, normal LM & PM	15.9% DR on MRI	100%	**III-3**
Murakami *et al*. (1987)	PCS	10	DDwoR	1	9	14-46	28.9	1-9	4.7	PM + CS + ARS	6	AAOMS criteria: increase in cMMO	No difference in LD between SG & UG. PM helps to unlock the CL up to about 6mo.	70%	**IV**
Murakami *et al.* (1995) [c]	PCoSt	108	W: III (CL)	20	88	-	31.43	-	5.0±8.8	NSurg: Med/UM/PS, N=63	6	VAS pain<20, MMO>38 mm, LM & PrM> 6mm, & improved DAL	Patients with >7mo LD did not respond to arthrocentesis	*NSurg: 55.6% (Md:15.9%* UM:18.9% *PS: 33.3%) AC: 70% AS: 91%*	**III-2**
									5.6±6.9	*AC, N=20*					
									6.8±10.2	*AS, N= 25*					
Ohnuki *et al.* (2006) [c]	RCoSt	85	DDwoR	9	76	13-73	41.8	-	*5.1±6.8*	*SS, N=11*	12	VAS pain<20 & MMO>38mm	No significant difference between SG regarding LD. 10% DR on MRI among all groups with no difference between groups.	*Med: 0% SS: 12.9%* PM: 44.6% *AC: 22% AS:100%*	**III-3**
									10.4±13.1	PM, N=33					
									6.6±8	*AC, N=9*					
									14.2±22.2	*AS, N=32*					
Ozawa *et al.* (1996)	RCS	40	DDwoR	4	36	16- 68	38.15	0.1-120	19.58±33.9 98	PM ACL (0.1-0.27),N=5 CCL (2-120),N=35	0.07-3 (ACL:2-3dy CCL:2-3mo)	Improvement in pain & MMO≥35mm	Higher success rate in ACL (100%) than in CCL (37.1%). PM able to release ACL only.	68.6%	**IV**
Ross (1989)	PCS	3	DDwoR	-	1	35	-	33	-	Farrar's UM (+ splint, PT)	2	Increased MMO, decreased pain	-	-	**IV**
				-	2	15-27	-	6-120	-	PM (+PT)	5-9			-	
Segami *et al.* (1990)	PCS	28	DDwoR	3	25	14-57	25.4	0.07-24	4.7	Farrar's UM or PM + ARS & NSAIDs	2	No or slight pain & MMO≥40mm	No relation between MM technique (UM or PM) & LD. 36.7% DR on arthrography.	100%	**IV**

Study (Year)	Study design	Participants' characteristics								Main Intervention assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	Overall success rate % (ITT use)	Study design quality
		Sample size (drp/exc)	Study diagnosis	Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Simmons (2002)	CR	1	DDwoR	-	1	-	14	0.5	-	PM under IV-sedation + ARS	24	Improvement in: cMMO, LM, PrM, subjective improvement, & DR on MRI	-	-	**IV**
Singh *et al.* (2010)	CR	1	DDwoR (Chronic)	-	1	-	32	24	-	UM under LA with CS + IMF screws & elastics + ARS	0.25	Improvement in: VAS pain, cMMO	-	-	**IV**
Totsuka *et al.* (1989)	PCS	33	CL DDwoR	4	29	12-60	29	0.13-24	4	PM 'Farrar's method' (+ ARS+SS)	2-24	Improved MMO>38mm, LM, PrM, mandibular movements without pain	Duration : S/F ≤1mo: 7/5 2-3mo: 5/4 4-6mo: 2/5 7-12mo: 0/2 12-24mo: 1/2 60% unlocked less than 3mo. Only 25% unlocked more than 3mo	46% (15/33)	**IV**
Van Dyke and Goldman (1990)	PCS	41	DDwoR (Acute)	-	-	-	-	≤1.5-2	-	UM under IM-LA (own tech) + ARS	-	MMO≥40mm	-	92.7%	**IV**
Yoshida *et al.* (2005a)	RCT	305	DDwoR	76	229	18-74	-	0.033-<12	-	UM (own technique) + NSAID, N=204 *NSAID only, N=101*	0.25	VAS pain<20, MMO≥36mm, LM≥6mm, & DR on MRI	UM success rate drops significantly with the increase in LD: 1-2dy (100%), <1wk (98.3%), <2wk (94.6%), <3wk (90%), <1m (57.1%), <2mo (16.7%), <6mo (0%).	UM: 84.3% *NSAID: 0%*	**II-2**
Yoshida *et al.* (2013); Yoshida *et al.* (2011)	RCT	148	DDwoR	-	148	19-75	40	0.033-9	1.57	Self-UM, N=74	10 min	Absence of pain & MMO>38mm	LD was shorter in SG (1.18) than in UG (2.92).	S-UM:68% Ctrl:4%	**II-2**
								0.067–11	*1.73*	*No treatment, N=74*					
TOTAL	20studies	-	**DDwoR**	-	-	-	-	**0.03-180**	**8.93**	**UM**	-	-	**DR average success rate: 44% (range: 4.4%-99.7%)**	**67.6%**	-
	6studies	-	**DDwoR**	-	-	-	-	**0.07-120**	**7.31**	**PM**	-	-		**65.98%**	-

Study design abbreviations: RCT: randomised controlled trial, qRCT: quasi-randomised controlled trial, PCoSt: prospective comparative study, RCoSt: retrospective comparative study, PNCoSt: prospective non-comparative study, RNCoSt: retrospective non-comparative study, FSt: follow-up study, PCS: prospective case series, RCS: retrospective case series, BACS: before-after case series, BACR: before-after case report, CR: case report.

Abbreviations used in tables 9.1.1 to 9.1.6: AAOMS: American association of oral and maxillofacial surgery, AC: arthrocentesis, ACL: acute closed lock, ADP: anchored disc phenomenon, ARS: anterior repositioning splint, AS: arthroscopy, CBT: cognitive behavioural therapy, CCL: chronic closed lock, Ch: chronic, CL: closed lock, CMI: craniomandibular index, cMMO: comfortable 'painless' maximum mouth opening, CS: corticosteroids, Ctrl: control, DAL: daily activity limitation, DDwoR: disc displacement without reduction, DFD: downward flexure deformation, DLA: daily living activity, DR: disc recapturing, drp: drop-outs, dy: day, exc: excluded, Exr: exercises, F: female, GA: general anaesthesia, IAOMS: international association of oral and maxillofacial surgery, ID: internal derangement, IL: intermittent locking, IM: intra-muscular, IMF: inter-maxillary fixation, IQ: interquartile, ITT: intention-to-treat analysis, IV: intra-venous, j: joint, LA: local anaesthesia, LDF: limitation in daily function, LM: lateral movement, M: male, Med: medication, MFIQ: mandibular function impairment questionnaire, mm: millimetres, MMO: maximum mouth opening, mo: month, MR: muscle relaxant, MRI: magnetic resonance imaging, N: number of patients, NR: not reported, NSurg: non-surgical, NSAIDs: non-steroidal anti-inflammatory drugs, OAdj: occlusal adjustment, OS: open surgery, PM: pumping manipulation, PrM: protrusive movement, PS: pivot splint, P-HS: pumping sodium hyaluronate, PT: physiotherapy, Reh: rehabilitation, S&S: signs and symptoms, SD: standard deviation, SG: successful group, HS: sodium hyaluronate, SM: self-management, SS: stabilization splint, Sub-ac: sub-acute, TENS: transcutaneous electrical nerve stimulation, Tx: tenoxicam, UFD: upward flexure deformation, UG: unsuccessful group, UM: unlock manipulation, US: ultrasound, VAS: visual analogue scale, VGIR: visually guided irrigation, W: Wilkes staging of internal derangement, wk: week, yr: year.

[a] Description of Farrar's UM technique (Farrar, 1978) is available in Chapter 2 (Figure 2.8).

[b] Separate data provided are for DDwoR patients only.

[c] Study data are also provided in other tables according to main treatment modality assessed.

A-2: Characteristics and quality of included self-management (SM) and physiotherapy (PT) studies

Study (Year)	Study design	Participants' characteristics								Main interventions assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	Overall success rate % (ITT use)	Study design quality
		Sample size (drp/exc)	Study diagnosis	Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Braun (1987)	CR	1	DDwoR	-	1	-	71	0.75	-	Self-exercises + Iontophoresis	1.5	Absence of pain, MMO>40mm, LM>7mm, improved jaw function, & eating normal diet	-	-	**IV**
Cleland and Palmer (2004)	BACR	1	DDwoR	-	1	-	24	19	-	SM + PT	3	VAS pain<20, MMO≥40mm, & improved jaw function	-	-	**IV**
Craane *et al.* (2012a)	RCT	49 (7)	DDwoR	2	47	-	36.6	wks-yrs	-	sExercises, N= 23 Education only, N= 26	13	Improvement in: VAS pain, MMO, & MFIQ	-	- (ITT)	**II-1**
Haketa *et al.* (2010) [a]	RCT	52 (14)	DDwoR	6	46	-	37.6	Over 0.5	-	*Self-care+ SS, N=25* Self-care+ Self-exercise, N=19	2	Improvement in: VAS pain, MMO, & LDF	-	- (ITT)	**II-1**
Minakuchi *et al.* (2004); Minakuchi *et al.* (2001) [a]	RCT	69 (8)	DDwoR	7	62	-	34	-	*3.89±5.56*	*Education only, N=21*	2	Improvement in: VAS pain, MMO, & DAL	-	- (ITT)	**II-1**
									2.81±5.09	Self-care/NSAIDs, N=23					
									3.12±5.03	*SS+ Exercises + Self-care/NSAIDs, N=25*					
Nicolakis *et al.* (2001)	BACS	20 (2)		5	15	-	37.3	1.2-60	15.6	Active & passive jaw exercises	6	Improvement in: VAS pain, MMO, & DLA	-	85% (ITT)	**III-3**
Schiffman *et al.* (2007); Schiffman *et al.* (2014b) [a]	RCT	108 (12)	W: III-IV DDwoR	8	98	-	31.72	Non-ch <6 - ch≥6	-	SM + Med, N=29 *SS + PT + CBT, N=25* *AS + CS, N=26* *OS, N=26*	60	Self-reported success (Patient satisfaction)	-	SM: 72% *Reh: 81%* *AS: 76.2%* *OS: 83.3%* (ITT)	**II-1**
Srisintorn (1992)	CR	1	DDwoR	-	1	-	29	2	-	Self-care/NSAID + Self-exercises	12	cMMO≥40mm	-	-	**IV**
Yuasa *et al.* (2001)	RCT	60 (NR)	DDwoR (15ACL, 45CCL)	12	48	16-69	Median 28	0.53-25.07	Median 2.33	NSAIDs + self-exercise, N=30	1	AAOMS & IAOMS modified criteria: VAS pain≤33 & MMO≥35mm	CCL (>1 mo) responded better to treatment than non-treatment in comparison with ACL (≤1 mo)	SM: 60% *Ctrl: 33%* (ITT)	**II-1**
								0.63-41.8	*3.27*	*No treatment, N=30*					
Total	**2 studies**	-	**DDwoR**	-	-	-	-	**wks-yrs**	-	**PT (Stretching exr.)**	-	-	-	-	-
	7 studies	-	**DDwoR**	-	-	-	-	**0.5-25**	-	**SM (self-care/Med/Exr)**	-	-	-	**66%**	-

[a] Study data are also provided in other tables according to main treatment modality assessed.

A-3: Characteristics and quality of included splint (± other conservative) therapy studies

Study (Year)	Study design	Participants' characteristics								Main intervention assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	Overall success rate % (ITT use)	Study design quality
		Sample size (drp/exc)	Study diagnosis	Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Choi *et al.* (1994)	PCS	10	DDwoR	-	10	14-55	27	0.75-5	2±1.61	SS + PT	3-4	MMO≥40mm	DR on MRI is unlikely to happen in CCL	100%	**IV**
Diracoglu *et al.* (2009) [a]	qRCT	120 (10)	DDwoR	16	104	15-63	34.1	Max. of 0.7	-	*AC, N=54* SS + PT, N= 56	6	Improvement in: VAS pain, MMO, LM, & PM	Both are effective for early DDwoR but AC is superior for pain relief	- (no ITT)	**III-1**
Haketa *et al.* (2010) [a]	RCT	52 (14)	DDwoR	6	46	-	37.6	Over 0.5	-	SS + Self-care, N=25 *Self-care + Self-exercise, N=19*	2	Improvement in: VAS pain, MMO, & LDF	-	- (ITT)	**II-1**
Harth (2012)	CR	1	DDwoR	-	1	-	53	2	-	Decompression splint + Exercises	21	cMMO>38mm	-	-	**IV**
Ismail *et al.* (2007)	RCT	26	21 [b] DDwoR	3	23	-	42.8	Less than 6	-	SS, N=13 SS + Exercises, N=13	3	Improvement in: pain & MMO	-	-	**II-2**
Israel and Syrop (1997)	CRs	2	DDwoR	-	2	14-28	-	0.03-0.5	-	Splint + Self-care/Med + PT	0.5-12	No pain, MMO≥35mm, eating normal diet, & patient satisfaction	-	-	**IV**
Iwase *et al.* (2005)	RNCoSt	52	DDwoR	8	44	-	32.1	≤12 - >12	25.71±56.11	SS+ Self-Exercises+ NSAIDs	-	VAS pain≤30, cMMO≥30mm, & patient satisfaction	Non-responders: 80%>12m symptoms' duration & 20%≤12m Responders: 75.7%>12m & 24.3%≤12m	71.2%	**IV**
Kai *et al.* (1998)	PNCoSt	35	DDwoR	-	35	15-63	37.3	0.5-48	4.9	SS	25-42	Improvement in: pain & MMO≥40mm	-	55.9%	**III-3**
Kuwahara *et al.* (1990)	PCS	8	DDwoR (Acute)	-	-	13-59	-	0.5-6	-	Disc recapturing splint	6-16	MMO>35mm	-	100%	**IV**
Le Bell and Forssell (1993)	PCS	22 (2)	DDwoR	5	17	17-68	Median 27	< 1 - <12	-	SS + OAdj *(<1mo, N=15 <6mo, N=5 >6mo but <12mo, N=2)*	24	Improvement in: pain & jaw movements (Helkimo anamnestic & dysfunction indices: Ai: 0 or 1, Di: II)	-	95.5% (ITT)	**IV**

Study (Year)	Study design	Participants' characteristics								Main intervention assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	Overall success rate % (ITT use)	Study design quality
		Sample size (drp/exc)	Study diagnosis	Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Lee *et al.* (2013) [a]	RCoSt	43	DDwoR	3	40	-	21.9	At least 3	-	*AC + HS & SS, N=17* *SS then AC + HS, N=13* SS only, N=13	6	AAOMS criteria: VAS pain<30 & cMMO≥38mm or increase cMMO≥10mm	-	-	**III-3**
Linde *et al.* (1995)	RCT	33 (2)	DDwoR	5	26	17-68	Median 37	0.5-192	Median 6	SS, N=16 *TENS, N=15*	1.5	VAS Pain reduction ≥50%, MMO≥40mm, LM≥7mm, & PrM≥7mm	-	SS: 53%, *TENS: 6%* (no ITT)	**II-2**
Minakuchi *et al.* (2001); Minakuchi *et al.* (2004) [a]	RCT	69 (8)	DDwoR	7	62	-	34	-	*3.89±5.56*	*Education, N=21*	2	Improvement in: VAS pain, MMO, & DAL	-	- (ITT)	**II-1**
									2.81±5.09	*Self-care/NSAIDs, N=23*					
									3.12±5.03	SS+ Exercises + Self-care/NSAIDs, N=25					
Murakami *et al.* (1995) [a]	PCoSt	108	W: III (CL)	20	88	-	31.43	-	5.0±8.8	NSurg: Med/UM/PS, N=63	6	VAS pain<20, MMO>38 mm, LM & PrM> 6mm, & improved DAL	Patients with >7mo LD not responded to arthrocentesis	NSurg: 55.6% (*Md:15.9%* *UM:18.9%* PS: 33.3%) *AC: 70%* *AS: 91%*	**III-2**
									5.6±6.9	*AC, N=20*					
									6.8±10.2	*AS, N= 25*					
Murakami *et al.* (2002)	FSt [c]	63 (7)	W: III (CL)	8	42	13- 75	33.2	-	5.0±8.8	Med (NSAIDs + MR), or UM, or PS	120	Improvement in: VAS pain, Jaw function, & DAL	-	89.3% (ITT)	**IV**
Ohnuki *et al.* (2006) [a]	RCoSt	85	DDwoR	9	76	13-73	41.8	-	5.1±6.8	SS, N=11	12	VAS pain<20 & MMO>38mm	No significant difference between SGs regarding LD.	SS: 12.9% *PM: 44.6%* *AC: 22%* *AS: 100%*	**III-3**
									10.4±13.1	*PM, N=33*					
									6.6±8	*AC, N=9*					
									14.2±22.2	*AS, N=32*					
Schiffman *et al.* (2007); Schiffman *et al.* (2014b) [a]	RCT	108 (12)	W: III-IV DDwoR	8	98	-	31.72	Non-ch <6 - ch≥6	-	*SM + Med, N=29* SS + PT + CBT, N=25 *AS + CS, N=26* *OS, N=26*	60	Self-reported success (Patient satisfaction)	-	*SM: 72%* Reh: 81% *AS: 76.2%* *OS: 83.3%* (ITT)	**II-1**
Shoji (1995)	CR	1	DDwoR Chronic	-	1	-	16	6	-	SS	1.5	Reduced pain & MMO≥35mm	-	-	**IV**

Study (Year)	Study design	Participants' characteristics								Main intervention assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	Overall success rate % (ITT use)	Study design quality
		Sample size (drp/exc)	Study diagnosis	Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Stiesch-Scholz *et al.* (2002b)	PNCoSt	55	DDwoR	7	48	15–77	41.96	<0.25 - >6	-	PS Acute(<3), N=19 Sub-acute (3–6), N=19 Chronic (>6), N=17	45-50	VAS pain=0, MMO≥40mm, improved LM, PrM, & chewing ability	The success rate of treatment decreased with longer LD: acute (84.2%), Sub-acute (63.2%), & chronic (64.7%). DR in 3 patients with <1wk.	72.7%	**III-3**
Stiesch-Scholz *et al.* (2005)	RCT	40	DDwoR	5	35	18-64	33.65	-	3.83±3.45	SS, N=20	3	Improvement in: pain, MMO, LM, & PrM	-	-	**II-1**
									4.68±2.9	PS, N=20					
Tanaka *et al.* (2000)	CR	1	W: IV DDwoR	-	1	-	22	60	-	Splint + Exercises	60	Improved pain & MMO	-	-	**IV**
Vineet and Gnanasundaram (2011)	CR	1	DDwoR	-	1	40	-	12	-	Med (analgesics) + SS	-	-	-	-	**IV**
Yoshida *et al.* (2005b)	PNCoSt	40	DDwoR	-	40	16-64	29.85	-	51.6±57.6	SS-UFD, N=20	6	No pain or pain present only on jaw movement & increased MMO	-	Overall: 57.5% UFD: 20% DFD: 95%	**III-3**
									33.6±39.6	SS-DFD, N=20					
TOTAL	**12 studies**	-	**DDwoR**	-	-	-	-	**0.25-192**	**15.53**	**Splint only**	-	-	-	**60.1%**	-
	11 studies	-	**DDwoR**	-	-	-	-	-	**10.28**	**Splint + others**	-	-	-	**84.1%**	-

[a] Study data are also provided in other tables according to main treatment modality assessed.

[b] DDwoR patients in study sample ≥ 80%.

[c] Follow-up report of Murakami *et al.* (1995).

A-4: Characteristics and quality of included arthrocentesis (AC) studies

Study (Year)	Study design	Participants' characteristics								Main interventions assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	% Overall success rate (ITT use)	Study design quality
		Sample size (drp/exc)	Study diagnosis	Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Aktas *et al.* (2010b)	PCoSt	25	DDwoR	2	23	17–64	30.4	0.1-24	6.76	AC alone, N=13 AC + SH, N=12	12	AAOMS criteria: VAS pain≤30mm, MMO ≥35mm, & improved jaw function	Mean LD was higher in UG 9.6 (1–24) than SG 3.92 (0.1-24)	Overall 80% AC:84.6%, AC+SH: 75%	**III-2**
Aktas *et al.* (2010a)	RCT	21	DDwoR	4	17	15-52	26.43	0.1–24	5.29	AC alone, N= 14 AC + TX., N= 7	6	AAOMS criteria: VAS pain≤30mm, MMO ≥35mm, improved jaw function	-	Overall 83.3% AC:85.7%, AC+TX: 71.4%	**II-2**
Alpaslan and Alpaslan (2001)	RCT	15 [a]	DDwoR (CL)	1	14	15-53	31.90	2-72	18.5	AC alone, N=4 AC + HS, N=11	3-28	Improvement in: pain, MMO, LM, & jaw function	-	-	**II-2**
Alpaslan *et al.* (2008)	RCT	67 (12)	DDwoR	-	-	18-51	30.1	0.03-18	6.73	AC alone, N=14 AC + soft splint, N=9 AC + hard splint, N=22	6	Improvement in: pain, MMO, & LM	-	- (no ITT)	**II-2**
Bhargava *et al.* (2012)	CR	1	DDwoR	-	1	-	32	3	-	AC + CS	1	MMO≥35mm & VAS pain=0	-	-	**IV**
Dhaif and Ali (2001)	RNCoSt	62 (22)	ADP	9	53	16-50	28.9	0.75-12	11.43±8.35	AC, N=40	36	VAS pain<2, MMO≥38mm, LM≥5mm, PrM≥5mm, improved DLA	-	95%	**IV**
Dimitroulis *et al.* (1995a)	FSt [b]	46	ADP	2	44	25-39	32.5	1-84	13	AC	6-30	Improvement in: VAS pain, VAS jaw dysfunction (chewing ability), & MMO	-	97.8%	**IV**
Diracoglu *et al.* (2009) [c]	qRCT	120 (10)	DDwoR	16	104	15-63	34.1	Max. of 0.7	-	AC, N=54 *SS + PT, N= 56*	6	Improvement in: VAS pain, MMO, LM, & PrM	Both are effective for early DDwoR but AC is superior for pain relief	- (no ITT)	**III-1**
Emshoff and Rudisch (2004) [d]	PNCoSt	29	DDwoR (ID III)	7	22	17-69	34.6	Non-ch≤6-Ch>6<24	8.76	AC (Non-chronic, N=15 Chronic, N=14)	2	Absence of DDwoR S&S and VAS Pain reduction≥85%	Symptoms' duration was lower in SG (5.28±4.03) than in UG (12.23±6.83).	37.9%	**III-3**

Study (Year)	Study design	Participants' characteristics								Main interventions assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	% Overall success rate (ITT use)	Study design quality
		Sample size (drp/exc)	Study diagnosis	Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Emshoff and Rudisch (2007) [d]	PNCoSt	37	DDwoR (ID III)	6	31	17-69	28.3	-	8.68±6.9	AC	2	MMO≥35 mm & pain reduction >50%	No statistical significant difference in duration of symptoms between SG (9.25±5.53) and UG (7.95±8.5).	56.8%	**III-3**
Emshoff *et al.* (2000) [d]	PNCoSt	15	DDwoR (ID III)	-	15	18-71	38.7	1-9	5.7	AC	2	Improvement in: VAS pain & MMO	-	-	**III-3**
Emshoff *et al.* (2003b) [d]	PNCoSt	38	DDwoR (ID III)	6	32	17-69	33.8	-	7.13±6.1	AC	2	Absence of DDwoR symptoms (VAS pain & MMO)	No statistical significant difference in duration of symptoms between SG (7.38±5.78) and UG (6.68±6.8).	63.2%	**III-3**
Emshoff (2005) [d]	PNCoSt	64	DDwoR (ID III)	6	58	17-69	33.4	Non-ch ≤6 - ch>6	12.31	AC	2	Absence of DDwoR symptoms (VAS pain & MMO)	Mean symptoms' duration was lower in SG (10.15±9.35) than UG (14.48±21.25) but the difference was not statistically significant.	53.1%	**III-3**
Emshoff *et al.* (2006) [d]	PNCoSt	28	DDwoR (ID III)	8	20	17-69	30.9	Less than 12	-	AC	2	Improvement in: VAS Pain on jaw function & MMO	-	-	**III-3**
Gateno (1994) [c]	CRs	2	DDwoR (ACL)	-	2	25-31	-	0.5-0.7	-	AC	3	MMO≥38mm & VAS pain≤4	-	-	**IV**
Ghanem (2011)	PCoSt	20	DDwoR (ACL)	-	20	24-54	34	Less than 1	-	AC + CS, N=10 AC + CS & SS, N=10	12	Improvement in: VAS Pain, MMO, LM, PrM, & jaw dysfunction	AC+SS are the treatment of choice for ACL (<1mo) with bruxism	Overall: 60% AC: 30% AC+SS: 90%	**III-2**
Hosaka *et al.* (1996)	FSt [e]	20 (1)	W: III (CL)	-	-	-	31.2	-	5.6±6.9	AC	36	VAS pain<2, MMO> 38mm, LM>6mm, PrM>6mm, normal diet & improved jaw function, daily activity.	-	78.9%	**IV**
Kaneyama *et al.* (2007b)	PCS	14	ADP	5	9	15-70	34.3	0.5-12	4±4.1	AC	1-12	No or mild pain, MMO>38mm, eating normal diet	Symptoms' duration was longer in SG (0.5-12) than UG (1-4).	64.3%	**IV**

Study (Year)	Study design	Participants' characteristics								Main interventions assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	% Overall success rate (ITT use)	Study design quality
		Sample size (drp/exc)	Study diagnosis	Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Kaneyama *et al.* (2007a)	PNCoSt	66	DDwoR	4	62	14-73	36	1-24	2	AC + CS	2-13	No or mild VAS pain, MMO>38mm, LM>6mm, & PrM>6mm	-	77%	**III-3**
Kaneyama *et al.* (2004)	PCS	17	DDwoR	5	12	17-76	40	0.8-60	19	AC + CS	3	No or mild VAS pain, MMO>38mm, LM>6mm, & PrM>6mm	No correlation between duration of symptoms and clinical symptoms	88%	**IV**
Lee *et al.* (2013)[c]	RCoSt	43	DDwoR	3	40	-	21.9	At least 3	-	AC + HS & SS, N=17 SS then AC + HS, N=13 *SS only, N=13*	6	AAOMS criteria: VAS pain<30 & cMMO≥38mm or increase cMMO≥10mm	-	-	**III-3**
Mohanavalli *et al.* (2011)	CR	1	CL	-	1	-	28	More than 12	-	AC + CS	9	VAS pain=0, MMO≥40 mm, LM & PrM≥ 6mm, & improved function	-	-	**IV**
Murakami *et al.* (1995)[c]	PCoSt	108	W: III (CL)	20	88	-	31.43	-	*5.0±8.8* *5.6±6.9* *6.8±10.2*	*NSurg: Med. or UM or PS, N=63* *AC, N=20* *AS, N= 25*	6	VAS pain<20, MMO>38 mm, LM & PrM> 6mm, & improved DAL	Patients with >7mo LD not responded to arthrocentesis	*NSurg: 55.6% (Md:15.9% UM:18.9% PS: 33.3%) AC: 70% AS: 91%*	**III-2**
Ness (1996)	RCS	15	CL	-	-	-	-	0.23–1 4–109	0.6 ACL 38.1 CCL	AC +CS (ACL<4 mo, N=6 CCL>4 mo, N=9)	-	MMO >40 mm, no or mild pain, and normal eating	-	64%	**IV**
Nishimura *et al.* (2004); Nishimura *et al.* (2001)	PNCoSt	100	95[f] DDwoR	11	89	13-73	Median 31	0.07-36	5.67	AC + CS	0.25	No or mild VAS pain & MMO>38mm	Mean LD was lower in SG 4.33 (0.033-36.5) than UG 8.43 (0.13-36.7) but the difference was not statistically significant.	70.9%	**III-3**
Nitzan *et al.* (1991b)	PCS	17	ADP	3	14	16-65	32.6	2-60	11.8±12.9	AC + CS	4-14	VAS pain≤4 of 15, VAS jaw dysfunction≤4 of 15, MMO≥35mm, PrM & LM>7mm, & patient satisfaction	One patient with the longest duration of symptoms (60 mo) showed marked increase in MMO but no significant decrease in pain & jaw dysfunction.	91%	**IV**

Study (Year)	Study design	Participants' characteristics								Main interventions assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	% Overall success rate (ITT use)	Study design quality
		Sample size (drp/exc)	Study diagnosis	Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Nitzan (1994)	PCS	29	ADP	8	21	-	-	-	13.9	AC + CS	Mean 22.2	Improvement in: VAS Pain, VAS jaw dysfunction, & MMO	-	96.5%	**IV**
Nitzan *et al.* (1997)	PNCoSt	39	ADP	8	31	14-53	28.9	0.5-48	11.43±8.35	AC	6-37	Improvement in: VAS Pain & VAS jaw dysfunction, MMO≥35mm, PrM & LM≥5mm, & patient satisfaction	Increased duration of symptoms seemed to affect joint function and deteriorate it.	95%	**III-3**
Ohnuki *et al.* (2006) [c]	RCoSt	85	DDwoR	9	76	13-73	41.8	-	*5.1±6.8*	*SS, N=11*	12	VAS pain<20 & MMO>38mm	No significant difference between SGs regarding LD.	*SS: 12.9%* *PM: 44.6%* AC: 22% *AS: 100%*	**III-3**
									10.4±13.1	*PM, N=33*					
									6.6±8	AC, N=9					
									14.2±22.2	*AS, N=32*					
Ross (1989)	PCS	7	DDwoR	1	6	17-34	25.3	1.5-36	10.43±12.7	AC (± splint/PT)	0.5-3	Increased MMO, decreased pain	-	71.43%	**IV**
Sahlstrom *et al.* (2013)	RCT	45 (8)	DDwoR	4	41	-	34.9	≤3	-	*LA only, N=25* AC, N=20	3	Reduction in VAS pain≥30% during jaw movement	-	*LA: 76%* AC: 55% (ITT)	**II-1**
Sakamoto *et al.* (2000)	PCS	18	DDwoR	1	17	17-67	33.3	2.3-46	14±12.8	AC	3	AAOMS criteria: MMO≥40mm & VAS pain<33	Symptoms' duration in SG (8.4±5.4) was significantly shorter than in UG (19.6±15.6).	50%	**IV**
Sanroman (2004) [c]	PCoSt	26 (2)	ADP	6	20	16-35	24.3	0.23-3	1.21	*AS + SH, N=16* AC + SH, N=8	24-36	VAS pain≤ 2 of 15, MMO≥35mm, LM≥7mm & PrM≥10mm	-	100%	**III-2**
Santos *et al.* (2013)	CR	1	DDwoR	-	1	19	-	2	-	AC+CS (+ Med/SM, SS, PT)	6	MMO>40mm without pain	-	-	**IV**
Sato *et al.* (1997b)	PCoSt	76	DDwoR	2	74	11-74	29.9	*0.1-60*	*5.9*	*Pumping HS [g], N= 26*	6	AAOMS Criteria: little or no pain, MMO≥35 mm, LM or PrM> 4mm, eating normal diet & improved jaw function.	-	*P-SH: 73.1%* *Ctrl:36%*	**III-2**
								0.1-48	*6.5*	*No treatment, N=50*					

Study (Year)	Study design	Participants' characteristics								Main interventions assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	% Overall success rate (ITT use)	Study design quality
		Sample size (drp/exc)	Study diagnosis	Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Sato *et al.* (2001a)	RCoSt	146 (25)	DDwoR	9	107	-	-	*3> - 3≤*	-	*Pumping HS[g], N= 59/72* *No treatment, N= 62/74*	12	AAOMS Criteria: Little/no pain & MMO≥35mm	Patients with LD for <3 mo are more likely to benefit from treatment than those with locking duration for ≥3 m.	*P-SH: 75%* *Ctrl: 63.5% (ITT)*	**III-3**
Sato and Kawamura (2008)	PCoSt	59	DDwoR	-	59	13-61	34.95	*0.2-336*	*31.6*	*Pumping HS[g] + Self-exercises, N=23*	12	AAOMS Criteria: Little/no pain, MMO≥35mm	-	*Overall: 69.49%* *P-SH+ Ex: 60.9%* *P-SH only: 75%*	**III-2**
								0.03-440	*36.4*	*Pumping HS, N=36*					
Sembronio *et al.* (2008b)	PNCoSt	33	DDwoR	2	31	21-73	41.8	0.25-24	8.5	AC + HS + UM (ACL<1, N=8 CCL>1, N=25)	12	VAS pain< 2, MMO >38 mm, ADL <4/16, & improved jaw function, chewing & swallowing, & eating normal diet	Higher success rate in ACL (87.5%) than CCL (68%). DR was possible only in ACL and no DR in all CCL cases.	72.7%	**III-3**
Thomas *et al.* (2012)	PCS	32	ACL	5	27	18-27	23	1-3	-	AC	6	Improvement in: VAS pain, VAS jaw dysfunction (chewing ability), & MMO.	-	90.6%	**IV**
Yura *et al.* (2011)	PNCoSt	50	DDwoR (CCL)	5	45	12-71	Median 44	3-48	Median 4	AC (under high pressure) + CS	2	Improvement in: MMO≥40mm, VAS pain at opening≤5mm, & VAS pain on biting=0	-	-	**III-3**
TOTAL	**36 studies**	-	**All CL**	-	-	-	-	**0.03-109**	**9.89**	**AC**	-	-	-	**72.6%**	-
	29 studies	-	**DDwoR**	-	-	-	-	**0.03-109**	**10.08**	**AC**	-	-	-	**65.3%**	-
	7 studies	-	**ADP**	-	-	-	-	**0.23-84**	**9.54**	**AC**	-	-	-	**91.4%**	-

[a] Separate data provided are for CL patients only.

[b] Follow-up report of Nitzan and Dolwick (1991) study.

[c] Study data are also provided in other tables according to main treatment modality assessed.

[d] Studies seem to share part of their CL study sample in multiple publications.

[e] Follow-up study of Murakami *et al.* (1995) study.

[f] DDwoR patients in study sample ≥ 80%.

[g] Excluded from the total due to intervention difference.

A-5: Characteristics and quality of included arthroscopy (AS) studies

Study (Year)	Study design	Participants' characteristics								Main interventions assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	Overall success rate % (ITT use)	Study design quality
		Sample size (drp/exc)	Study diagnosis	Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Casares *et al.* (1999)	PNCoSt	26	ADP (static disc)	-	26	20-56	37.5	3-24	7.8	AS	10	Pain free & MMO>30mm	A relationship between LD and adhesions type was found	92.3%	**III-3**
Chen *et al.* (2010)	PCS	352	W: III-IV 343/419j[a]	50	302	15-72	33.3	2-240	24.1	AS coblation with disc suturing	3	Improvement in S&S and MRI findings	-	92.8%	**IV**
Clark *et al.* (1991)	PNCoSt	18	17 DDwoR & 1 ADP	1	17	15-52	27	Sub-ac =3-9 to ch>9	12.4±12	AS	21-30	Improvement in: VAS pain, jaw function, & MMO	LD was not a predictor of arthroscopy success or failure.	83.3%	**III-3**
Dimitroulis (2002)	PCS	56	49 DDwoR	9	47	15-70	36	1.5-12	3.4	AS + CS	1.5	Improvement in: VAS pain, MMO, & patient satisfaction	-	66%	**IV**
Furst *et al.* (2001)	RCT	32	26 DDwoR	2	30	-	-	-	42.5±36.1	AS only	0.07	Pain reduction	-	-	**II-2**
									18.5±17	AS + bupivacaine					
									61.4±61.3	AS + morphine					
									63.3±79.7	AS + bupivacaine & morphine					
Gateno (1994) [b]	CR	1	CL	-	1	-	24	3	-	AS	-	No pain & MMO>40mm	-	-	**IV**
Go *et al.* (1996)	PCS	10	CL	-	10	20-59	31.2	0.75-3.75	2.2	AS	4-68	No or mild pain & MMO>30mm	-	80%	**IV**
Hamada *et al.* (2003) [c]	PNCoSt	69 (39)	DDwoR (CCL)	5	25	20-64	41.6	1-72	15.5	AS (2^{nd} VGIR) + SH, N=30	-	VAS pain<20 & <60% of preoperative level, increased cMMO, & cMMO≥38mm	-	60% (no ITT)	**III-3**
Hamada *et al.* (2005) [c]	PNCoSt	68 (20)	DDwoR (CCL)	9	39	20–70	42.8	2–127	Median 9.5	AS (2^{nd} VGIR), N=48	3–36	VAS pain=0 & cMMO≥38mm	No significant correlation between duration of symptoms and treatment outcome with fibrous adhesion.	62.5% (no ITT)	**III-3**
Hamada *et al.* (2006a)[c]	PNCoSt	64 (3)	DDwoR (CCL)	9	52	19-70	40.7	2-127	Median 7	AS (1^{st} VGIR), N=64	12	VAS pain<20 & <60% of preoperative level, increased cMMO, & cMMO≥38mm	No significant difference in the duration of symptoms between SG 8 (2-108) and UG 5 (2-127).	72.1% (no ITT)	**III-3**

Study (Year)	Study design	Sample size (drp/exc)	Study diagnosis	Participants' characteristics						Main interventions assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	Overall success rate % (ITT use)	Study design quality
				Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Hamada *et al*. (2006b)[c]	PNCoSt	36 (2)	DDwoR (CCL)	6	30	27-59	46.5	IQ 3–17	Median 7.5	AS (VGIR), N=36	-	VAS pain<20 & <60% of preoperative level, increased cMMO, & cMMO≥38mm	No significant difference in the duration of symptoms between SG 8 (5.5–17) and UG 6 (3–8).	69.4% (no ITT)	**III-3**
Hamada *et al*. (2008a); Hamada *et al*. (2008b)[c]	PNCoSt	58 (2)	DDwoR (CCL)	8	48	29-56	Median 46	IQ 3-12.5	Median 7	AS (1st VGIR), N=56	6-13	VAS pain<20 & <60% of preoperative level, increased cMMO, & cMMO≥38mm	No significant difference in duration of symptoms between SG 8 (5.8–12.3) and UG 6 (3–8).	67.9% (no ITT)	**III-3**
Holmlund *et al*. (2001)	RCT	22 (2)	CCL	2	18	22–53	34.5	*2-24*	*8.5*	*OS, N=10*	12	VAS pain<20, MMO>35mm, PrM>5mm, MFIQ<7	No difference in improvement between patients having <6 mo & >6 mo symptoms' duration in both groups.	*OS: 70%,* AS: 50% (no ITT)	**II-2**
								2–60	20.5	AS, N=10					
Kim *et al*. (2009)	PCS	15	DDwoR	3	12	15-64	32.1	3-72	21.4	AS (ultrathin) + SH	10-40	VAS pain ≤20 & <60% of preoperative level, increased MMO≥5mm, & no recurrence of symptoms.	-	80%	**IV**
Kondoh *et al.* (2003a)[c]	PNCoSt	20	DDwoR	4	16	20-69	44	1-72	17.4	AS (VGIR) + SH	6	VAS pain<20 & <60% of preoperative level, & cMMO>38mm	-	80%	**III-3**
Kumagai *et al.* (2010)[c]	PNCoSt	45	DDwoR (CCL)	13	32	24-65	36.5	More than 3	-	AS (VGIR), N=45	2-23	VAS pain <20 and <60% of preoperative level, & cMMO≥38mm	-	71.1%	**III-3**
Kurita *et al.* (1998a)	PNCoSt	14	DDwoR	1	13	20-72	44.6	9-163	24.9	AS + CS	13–66	AAOMS & IAOMS criteria: No or slight dysfunction (MMO≥35mm, VAS≤33)	No difference in LD between SG 27 (9-163) & UG (10 & 14).	85.7%	**III-3**
Lewis (1987)	CR	1	DDwoR (CCL)	-	1	-	48	12	-	AS	0.25	Little pain & MMO=35mm	-	-	**IV**

Study (Year)	Study design	Sample size (drp/exc)	Study diagnosis	Participants' characteristics						Main interventions assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	Overall success rate % (ITT use)	Study design quality
				Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Machon *et al.* (2012)	PNCoSt	50	Chronic DDwoR	-	-	-	-	(<12 - >12)	-	AS, N=50 (<12 mo, N=28; >12 mo, N= 22)	6	No or minimal pain (0 or 1 out 6), & MMO>35mm	Higher success rate (89%) in patients with shorter duration of symptoms <12 mo than the rate (72%) in those with longer symptoms' duration >12 mo.	82%	**III-3**
Murakami (1990)	PCS	32	DDwoR	4	28	14-70	39	1-18	6.6	AS	2-60	Little or no complaints and good jaw opening & function	Patients with ≥6 mo LD had poor response to AS. Higher pain relief in patients with <6mo LD as compared to patients with longer duration.	84.4%	**IV**
Murakami *et al.* (1995) [b]	PCoSt	108	W: III (CL)	20	88	-	31.43	-	*5.0±8.8*	*NSurg: Med. or UM or PS, N=63*	6	VAS pain<20, MMO>38 mm, LM & PrM> 6mm, & improved DAL	Patients with >7mo LD did not respond to arthroscopy.	*NSurg: 55.6% (Md:15.9% UM:18.9% PS: 33.3%) AC: 70%* AS: 91%	**III-2**
									5.6±6.9	*AC, N=20*					
									6.8±10.2	AS, N= 25					
Nakaoka *et al.* (2009)	PNCoSt	56 (16)	CCL	-	-	IQ 29–55	Median 43	IQ 5–12	median 7	AS (2nd VGIR), N=40	-	VAS pain<20 & <60% of preoperative level, increased cMMO, & cMMO≥38mm	No significant difference in symptoms' duration between SG 8 (5.5–12.5) and UG 5 (3–12).	72.5% (no ITT)	**III-3**
Nitzan *et al.* (1990)	PCS	20	8 DDwoR	-	20	19-40	26.3	6-96	34.8±26.04	AS + CS	6-24	Improvement in: VAS Pain, VAS jaw dysfunction, & MMO	-	DDwoR 87.5%	**IV**
Ohnuki *et al.* (2003)	RNCoSt	43	40 DDwoR	4	39	15-68	41.4	-	12.6±20.1	AS + CS + SH	12	VAS pain<20 & MMO>38mm	No statistically significant difference in LD between SG (14.2±22.2) and UG (7.9±11.4).	74.4%	**IV**
Ohnuki *et al.* (2006) [b]	RCoSt	85	DDwoR	9	76	13-73	41.8	-	*5.1±6.8*	*SS, N=11*	12	VAS pain<20 & MMO>38mm	No significant difference between SGs regarding LD.	*SS: 12.9% PM: 44.6% AC: 22%* AS: 100%	**III-3**
									10.4±13.1	*PM, N=33*					
									6.6±8	*AC, N=9*					
									14.2±22.2	AS, N=32					

Study (Year)	Study design	Sample size (drp/exc)	Study diagnosis	Participants' characteristics						Main interventions assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	Overall success rate % (ITT use)	Study design quality
				Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Politi *et al.* (2007) [b]	RCT	20	DDwoR (CCL)	6	14	25-67	42.8	*6-27*	*15.1*	*OS , N=10*	12	VAS pain≤20, MMO≥35mm, PrM>5mm, MFIQ ≤ 7	-	*OS: 80%,*	**II-2**
								8-24	14.7	AS + SH, N=10				AS: 70%	
Saitoa *et al.* (2010)	PNCoSt	64 (3)	CCL	9	52	19-70	40.7	2-127	Median 7	AS (VGIR)	3-40	VAS pain<20 & <60% of preoperative level, & cMMO≥38mm	No statistically significant difference in LD between SG 8 (2-108) and UG 5 (2-127).	72.1% (no ITT)	**III-3**
Sanders (1986)	PCS	21 [d]	DDwoR	1	20	11-49	27.1	1-120	19.62±24.2	AS + CS	7-10	Little pain & improved MMO	-	95.2%	**IV**
Sanroman (2004) [b]	PCoSt	26 (2)	ADP	6	20	16-35	24.3	0.25-3	1.21	AS + SH, N=16 *AC + SH, N=8*	24-36	VAS pain≤ 2 of 15, MMO≥35mm, LM≥7mm & PrM≥10mm	-	100%	**III-2**
Schiffman *et al.* (2007); Schiffman *et al.* (2014b) [b]	RCT	108 (12)	W: III-IV DDwoR	8	98	-	31.72	Non-ch<6 - Ch≥6	-	*SM + Med., N=29* *SS + PT + CBT, N=25* AS + CS, N=26 *OS, N=26*	60	Self-reported success (Patient satisfaction)	-	*SM: 72%* *Reh: 81%* AS: 76.2% *OS: 83.3%* (ITT)	**II-1**
Yoshida *et al.* (2008)	PCS	55	DDwoR	-	-	-	-	2-10.5	4.25	AS (thin fiber & laser)	3	Improvement in: VAS pain, MMO, & patient satisfaction.	-	94.5%	**IV**
Zhang *et al.* (2009a)	RNCoSt	1506	W: III-IV 1479 [a]	281 1225		12–73	29.79	0.5-96	6.97	AS Adhesion group, N=490 Non-adhesion group, N=1230	-	-	LD was significantly higher in adhesion (6.97±8.38) than non-adhesion (5.42±4.34) group.	-	**IV**
TOTAL	**32 studies**	-	**All CL**	-	-	-	-	**0.25-163**	**19.04**	**AS**	-	-	-	**79%**	-
	30 studies	-	**DDwoR**	-	-	-	-	**0.5-163**	**20.37**	**AS**	-	-	-	**77.7%**	-
	2 studies	-	**ADP**	-	-	-	-	**0.25-24**	**4.51**	**AS**	-	-	-	**96.2%**	-

[a] DDwoR patients in study sample ≥ 80%.

[b] Study data are also provided in other tables according to main treatment modality assessed.

[c] Studies seem to share part of their CL study sample in multiple publications.

[d] Separate data provided are for CL patients only.

A-6: Characteristics and quality of included open surgery (OS) studies

Study (Year)	Study design	Sample size (drp/exc)	Study diagnosis	Participants' characteristics						Main interventions assessed	Longest follow-up duration (months)	Success criteria	Study findings in relation to locking duration (LD)	Overall success rate % (ITT use)	Study design quality
				Gender		Age (years)		Locking duration (months)							
				M	F	Range	Mean	Range	Mean ± SD						
Holmlund *et al.* (2001) [b]	RCT	22 (2)	CCL	2	18	22–53	34.5	2-24	8.5	OS (Discectomy), N=10	12	VAS pain<20, MMO>35mm, PrM>5mm, MFIQ<7	No difference in improvement between patients having <6mo & >6mo symptoms' duration in both groups.	OS: 70%, *AS: 50%* (no ITT)	**II-2**
								2–60	*20.5*	*AS, N=10*					
Kondoh *et al.* (2003b)	PCS	7 [a]	DDwoR (CL)	-	7	20-51	32.57	14-42	24.57±9.22	Disc Reshaping without repositioning	60	Improvement in: pain & MMO	-	DDwoR 100%	**IV**
Ozkan *et al.* (2012)	RNCoSt	46 [a]	Uni/bilat. DDwoR	8	38	18-63	34.7	-	22.9	High condylectomy ± disc repositioning, discectomy, or osteoplasty.	18-156	Improvement in: pain, MMO, & patient satisfaction	-	-	**IV**
Politi *et al.* (2007) [b]	RCT	20	DDwoR (CCL)	6	14	25-67	42.8	6-27	15.1	OS (High condylectomy & disc repositioning), N=10	12	VAS pain≤20, MMO≥35mm, PrM>5mm, MFIQ ≤ 7	-	OS: 80%, *AS: 70%*	**II-2**
								8-24	*14.7*	*AS + SH, N=10*					
Schiffman *et al.* (2007); Schiffman *et al.* (2014b) [b]	RCT	108 (12)	DDwoR (W: III-IV)	8	98	-	31.72	Non-ch<6 - ch≥6	-	*SM + Med, N=29* *SS + PT + CBT, N=25* *AS + CS, N=26* OS (Arthroplasty), N=26	60	Self-reported success (patient satisfaction).	-	*SM: 72%* *Reh: 81%* *AS: 76.2%* OS: 83.3% (ITT)	**II-1**
Turley (1993)	CR	1	DDwoR (CL)	-	1	-	23	5	-	Arthroplasty (discectomy with sialistic implant replacement)	72	MMO≥40mm, improved function, & stable occlusion	-	-	**IV**
Widmark *et al.* (1997)	RCS	20 (4)	DDwoR	1	15	21-71	37	18-150	48	Discectomy	6-42	Improvement in: VAS Pain & jaw function (CMI)	-	88% (no ITT)	**IV**
Zhang *et al.* (2010)	PNCoSt	81	W: III-IV 69 [c]	23	58	23-74	38.5	0.5-60	12.06	Disc repositioning by bone anchores	0.25	DR on MRI	-	96.3%	**III-3**
TOTAL	**8 studies**	**-**	**DDwoR**	**-**	**-**	**-**	**-**	**0.5-150**	**21.86**	**OS**	**-**	**-**	**-**	**86.3%**	**-**

[a] Separate data provided are for CL patients only.

[b] Study data are also provided in other tables according to main treatment modality assessed.

[c] DDwoR patients in study sample ≥ 80%.

Appendix B: PROSPERO protocol for the systematic review of therapeutic interventions for DDwoR (Chapter 5) (Al-Baghdadi *et al.*, 2012)[12].

THE UNIVERSITY of York
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PROSPERO International prospective register of systematic reviews

Interventions for the management of temporomandibular joint disc displacement without reduction (a systematic review)

Mohammed Al-Baghdadi, Justin Durham, Vera Araujo-Soares, James Steele, Shannon Robalino, Linda Errington

Citation

Mohammed Al-Baghdadi, Justin Durham, Vera Araujo-Soares, James Steele, Shannon Robalino, Linda Errington. Interventions for the management of temporomandibular joint disc displacement without reduction (a systematic review). PROSPERO 2012:CRD42012003153 Available from http://www.crd.york.ac.uk/PROSPERO_REBRANDING/display_record.asp?ID=CRD42012003153

Review question(s)

To investigate the effects of different surgical and non-surgical therapeutic interventions used for the management of patients with temporomandibular joint (TMJ) disc displacement without reduction (DDwoR).

Searches

Detailed search strategies have been developed for each database in order to identify the studies to be included or considered for this review. The search strategies are primarily developed for the MEDLINE and will be revised appropriately for each database to take account of differences in controlled vocabulary and syntax rules.

For the MEDLINE search, the subject search will be run with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials (RCTs) in MEDLINE: sensitivity maximising version (2011 revision) as referenced in Chapter 6.4.11.1 of the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0 (updated March 2011) (Lefebvre et al., 2011). The full search strategy for the MEDLINE is provided.

The following electronic bibliographic databases will be searched:

•Cochrane Central Register of Controlled Trials (CENTRAL) (via the Cochrane Library, current issue)

•MEDLINE via OVID (1966 to the present)

•EMBASE via OVID (1980 to the present)

•SCOPUS via SciVerse (1966 to the present).

Searching other resources (Hand-searching): Other resources will be used to identify any additional studies such as: citation search of the included studies, reference lists of included studies, along with the reference lists of relevant review articles and textbooks' chapters.

In addition, the following journals have been identified as being potentially important to be hand-searched for this review:

•Journal of Oral and Maxillofacial Surgery (from 2010 to October 2012).

•Cranio: The journal of craniomandibular practice (from 1996 to October 2012).

•Journal of Prosthetic Dentistry (from 1999 to September 2012).

•Journal of Oral Rehabilitation (from 2004 to October 2012).

[12] First page of the registered protocol is attached. The full-text published protocol is available online at the PROSPERO database: http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42012003153.

Appendix C: Inclusion/Exclusion criteria for studies in the systematic review of therapeutic interventions for DDwoR (Chapter 5).

Inclusion criteria	Exclusion criteria
Types of studies	**Types of studies**
Randomised clinical trials (RCTs) that involve patients with TMJ DDwoR and comparing any form of conservative (non-surgical) or surgical interventions against each other, placebo or no treatment. Quasi-randomised studies, such as those allocating patients by using alternate days of the week, birth date, or consecutive attendance considered only if the baseline demographic details (e.g., severity of condition) of each comparable group were approximately similar. Included quasi-random trials were, however, subject to a sensitivity analysis. Studies which involve other heterogeneous groups of TMD patients (e.g. osteoarthritis, myofacial pain, disc displacement with reduction) in addition to patients with DDwoR were considered only if separate data were provided for DDwoR patients. If the separate data had not been provided but the percent of DDwoR patients in the study sample was more than 70%, the study was examined to be included.	Studies comparing different types or techniques of similar intervention group (such as trials comparing different techniques of arthroscopy, different techniques of arthrocentesis, or those comparing between different types of occlusal splints). Studies evaluating a treatment modality after an initial surgical intervention (such as trials evaluating different medications or splints after arthroscopy or arthrocentesis).
Types of participants	**Types of participants**
Patients of any age, gender, and of all degree of severity with clinical and/or radiological diagnosis of TMJ DDwoR as diagnosed according to: American Association of Orofacial Pain (AAOP) guidelines for acute or chronic DDwoR (de Leeuw, 2008); research diagnostic criteria for temporomandibular disorders (RDC/TMD) for DDwoR with (IIb) or without (IIc) limited mouth opening (Dworkin and LeResche, 1992); Wilkes staging for internal derangement (stage III or IV) (Wilkes, 1989); or any other compatible criteria for DDwoR diagnosis. Confirming the disc position by soft tissue imaging was not a prerequisite to include the study. Studies which involve participants with confirmed diagnosis of DDwoR disorder with comorbid disorders.	Patients with systemic diseases.
Types of interventions	**Types of interventions**
Different forms of conservative (non-surgical) and surgical therapeutic interventions such as: patient education, self-management, psychosocial therapy, pharmacological therapy, physiotherapy, splint therapy, intra-articular medication injection, arthrocentesis, arthroscopic surgery, and open joint surgery. Studies that evaluate these therapeutic interventions against each other, placebo or no treatment were included. Standardized combinations of treatments were also included.	Studies comparing different types or techniques of similar intervention group. Studies evaluating a treatment modality after an initial surgical intervention.

Appendix D: Data extraction sheet for studies included in the systematic review of therapeutic interventions for DDwoR (Chapter 5).

DATA EXTRACTION FORM			
Study ID		**Report ID**	
EXTRACTED NON-NUMERICAL DATA			
Methods (study design)	Allocation: Blindness: Duration: Setting and study Location:		
Participants	Number: Gender: Age: Diagnosis: Diagnostic criteria: Imaging: Co-morbidity: Symptoms' duration: Previous TMD treatment: Inclusion criteria: Exclusion criteria:		
Interventions	Number of groups: Pre-intervention (all patients): <u>Interventions:</u> 1. Group 1: 2. Group 2: 3. Group 3: 4. Group 4: Post-intervention (all patients):		
Follow-up time points			
Outcomes	TMJ Pain: MMO: Other mandibular movements: QoL/mandibular function: Therapy cost: Operation/admission duration: Adverse events:		
Drop-outs	Number: Reasons: Intention-to-treat (ITT) analysis:		
Funding source and conflicts of interest			
Authors' conclusion			
Authors' comments			
Reviewers' comments			
EXTRACTED NUMERICAL DATA			
Results	Outcomes (Tool and unit of measurement, Scales' upper and lower limits)		
SR Primary outcomes:	- Short-term ≤ 3 months - Long-term > 3 months		
SR Secondary outcomes:	- Short-term ≤ 3 months - Long-term > 3 months		
RISK-OF-BIAS			
Domain		**Judgement**	**Support for judgement**
Random sequence generation (selection bias)			Quote or Comment:
Allocation concealment (selection bias)			Quote or Comment:
Blinding (performance bias and detection bias) (All outcomes)			1) Participants and health-care providers: 2) Outcome assessor: (a) Patient-reported outcomes: (b) Clinician-measured outcomes: 3) Data analyst:
Incomplete outcome data (attrition bias) (All outcomes)			Quote or Comment:
Selective outcome reporting (reporting bias)			Quote or Comment:
Other bias			Quote or Comment:

Appendix E: Characteristics of included studies in the systematic review of therapeutic interventions for DDwoR (Chapter 5).

Study (year)[h]	Study design				Participants						Interventions	Follow-up time-points	Main assessed outcomes	Adverse events	Dropouts (groups)
	Allocation	Blinding	Setting, Country	Fund	Sample size (PA used)[a]	Age (years)	Gender	Locking duration	Diagnostic criteria	Soft tissue imaging					
Lundh *et al.* (1992)	Random	NR	University, Sweden	Yes	51 (No)	Mean 29	5m,46f	NR	Eriksson criteria[b]	Arthrogr.	Splint, N=25 Control, N=26	6, 12 mo	Pain	NR	No
Petersson *et al.* (1994)	Random	Single-blind	University, Sweden	NR	34 (No)	Mean 33	5m,29f	NR	Eriksson criteria[b]	Arthrogr.	Arthrocentesis, N=16/17 Arthrography, N=17	2 mo	Pain, MMO, LM, PrM, Self-questionnaire	No	Total=1 (AC=1)
Linde *et al.* (1995)	Random	NR	University, Sweden	Yes	33 (2 exc) (No)	Median 37	5m,26f	Median 6mo (range 2wk-16yr)	Own study criteria	No	TENS, N=16/17 Splint, N=15	6 wk	Pain, MMO, LM, PrM, Frequency and severity of complaints	Yes (TENS: unclear)	Total=2: (TENS=1, unclear=1)
Fridrich *et al.* (1996)	Random	NR	University, USA	NR	19 (15 DDwoR) (No)	Mean 31	19f	NR	Own study criteria	MRI	Arthroscopy, N=11 Arthrocentesis, N=8	1 wk, 1, 3, 6, 12, 24 mo	Pain, MMO, LM, PrM, dietary alterations	No	Total=15 at 24 mo (unclear)
Schiffman *et al.* (1996)	Random	Double-blind	University, USA	Yes	27 (No)	Mean 29	3m,24f	NR	AACMDs and own criteria[c]	None	Active iontoph., N=9 Control iontoph., N=9 Placebo iontoph., N=9	1 wk	Pain (SSI), Function (CMI), MMO, LM	Yes (N: unclear)	None
Goudot *et al.* (2000)	Random	NR	University, France	NR	62 (54 DDwoR) (No)	Mean 38	75%f	> 6mo	Own study criteria	MRI	Arthroscopy, N=33 Arthrocentesis, N=29	12 mo	Pain, MMO	Total=4: (AS=2, AC=2)	None
Holmlund *et al.* (2001)	Random	NR	University, Sweden	NR	22 (2 exc) (No)	Mean 34.5	2m,18f	Mean 14.5mo (range 2-60mo)	Own study criteria	None	Open surgery (Discectomy), N=10 Arthroscopy, N=10/12	3, 12 mo	Pain, MMO, PrM, MFIQ	Yes (N: unclear, As=1)	Total=2: (AS=2)
Minakuchi *et al.* (2001) Report: Minakuchi *et al.* (2004)	Random	Single-blind	University, Japan	Yes	69 (No)	Mean 34	7m,62f	Mean 98dy ±SD 156.8dy	Own study criteria	MRI	Education, N=21 Self-management, N=23 Combination therapy, N=25	2, 4, 8 wk	Pain, MMO, DAL, self-questionnaire	NR	Total=10 (Educ=2; SM=2; Comb=4; Unclear=2) (ITT used)

Study (year)[h]	Study design				Participants						Interventions	Follow-up time-points	Main assessed outcomes	Adverse events	Dropouts (groups)
	Allocation	Blinding	Setting, Country	Fund	Sample size (PA used)[a]	Age (years)	Gender	Locking duration	Diagnostic criteria	Soft tissue imaging					
Yuasa *et al.* (2001) Report: Yuasa *et al.* (2003)	Random	NR	University, Japan	NR	60 (Yes)	Median 28	12m,48f	Median 84dy (range 16-1254dy)	AAOMS & IAOMS criteria[d]	MRI	Self-management, N=30 No treatment, N=30	2, 4 wk	Pain, MMO, interference with daily life	None	Yes (unclear) (LOCF use)
Maloney *et al.* (2002)[e]	Random	NR	University, USA	Yes	24 DDwoR (No)	NR	NR	NR	RDC/TMD	MRI	Therabite+Splint, N=10 WTDs+Splint, N=7 Splint, N=7	4 wk	Pain, MMO, LM, PrM	NR	No
Peroz *et al.* (2004)[e]	Multi-centre Random	Double-blind	University, Germany	Yes	31 DDwoR (No)	Mean 44	83%f	≥ 6mo	RDC/TMD	MRI in some patients	Active PEMF, N=13/14 Placebo PEMF, N=17	9 dy, 6 wk, 4 mo	Pain, MMO, LM, PrM, RDLA	NR	Total=1: (Active PEMF=1)
Yoshida *et al.* (2005a)	Random	NR	University, Japan	NR	305 (No)	Range (18-74)	76m,229f	(range 1dy-<1yr)	Own study criteria	None	MM+NSAID, N=204 NSAID, N=101	Unclear (1 wk)	Pain, MMO	NR	NR
Ismail *et al.* (2007)	Random	only data analyst	University, Germany	NR	26 (21 DDwoR) (Yes)	Mean 43	3m,23f	< 6mo	RDC/TMD	MRI	Exercises+Splint, N=13 Splint, N=13	1 wk, 1, 2, 3 mo	Pain, MMO, PrM	NR	No
Politi *et al.* (2007)	Random	NR	University, Italy	NR	20 (No)	Mean 43	6m,14f	Mean 14.9mo (range 6-27mo)	Own study criteria	MRI	Open surgery (Condylectomy), N=10 Arthroscopy, N=10	12 mo	Pain, MMO, PrM, MFIQ	Yes (N: unclear)	No
Schiffman *et al.* (2007) Report: Schiffman *et al.* (2014b)	Random	Single-blind	University, USA	Yes	108 (2 exc) (Yes)	Mean 32	8m,98f	< 6mo and ≥ 6mo	Wilkes (III or IV)	MRI	Self-management, N=27/29 Combination therapy, N=23/26 Arthroscopy, N=24/27 Open surgery (Arthroplasty), N=24/26	3, 6, 12, 18, 24, 60 mo	Pain (SSI), Function (CMI), Therapy Cost	Total=1 (OS=1)	Total=12: (Comb=3, AS=4, OS=5) (ITT used)
Diracoglu *et al.* (2009)	Alternate[f] (qRCT)	Single-blind	University, Turkey	NR	120 (No)	Mean 34	16m,104f	≤ 3wk	Own study criteria	MRI	Arthrocentesis, N=54/60 Combination therapy, N=56/60	1, 3, 6 mo	Pain, MMO, LM, PrM	NR	Total=10 (unclear)
Haketa *et al.* (2010)[g]	Random	Single-blind	University, Japan	Yes	52 (Yes)	Mean 38	6m,46f	> 2wk	Own study criteria	MRI	Self-management, N=19/24 Splint, 25/28	1, 2 mo	Pain, MMO, LDF	None	Total=14: (SM=9; Splint=5)

Study (year)[h]	Study design				Participants						Interventions	Follow-up time-points	Main assessed outcomes	Adverse events	Dropouts (groups)
	Allocation	Blinding	Setting, Country	Fund	Sample size (PA used)[a]	Age (years)	Gender	Locking duration	Diagnostic criteria	Soft tissue imaging					
Yoshida *et al.* (2011) Report: Yoshida *et al.* (2013)	Random	NR	University, Japan	NR	148 (No)	Mean 40	148f	Mean 50dy (range 1-360dy)	Own study criteria	None	Self-MM, N=74 No treatment, N=74	10 min	MMO, LM, PrM	NR	NA
Craane *et al.* (2012a)[g]	Random	Single-blind	University, Belgium	No	49 (Yes)	Mean 37	2m,47f	several wk to several yr	RDC/TMD (IIb, IIc)	MRI in only 6/49	Jaw exercise, N=20/23 Education, N=22/26	3, 6, 12, 26, 52 wk	Pain, MMO, MFIQ	NR	Total=7: (Exr=3; Educ=4) (ITT used)
Sahlstrom *et al.* (2013)[g]	Random	Single-blind	University, Sweden	No	45 (Yes)	Mean 35	4m,41f	Median 24mo (range 3-360mo)	RDC/TMD	MRI	Arthrocentesis, N=14/20 Extra-articular LA, N=23/25	1, 3 mo	Pain, MMO, JFLS	None	Total=8: (AC=6; LA=2) (ITT used)

Abbreviations: AC: arthrocentesis, Arthrogr: arthrography, AS: arthroscopy, CMI: craniomandibular index, Comb: combination therapy of splints + physiotherapy + medication/education, Ctrl: control, DAL: daily activity limitations, Dx: diagnosis, dy: days, Educ: education, exc: excluded; Exr: exercises, f: female, FOC: frequency of complaints, iontoph.: iontophoresis, ITT: intention-to-treat analysis, JFLS: jaw functional limitation scale, LA: local anaesthetic, LDF: limitation of daily functions, LM: lateral movement, LOCF: last observation carried forward, m: male, MM: mandibular manipulation, MFIQ: mandibular function impairment questionnaire, MMO: maximum mouth opening, min: minutes, mm: millimetres, mo: months, MRI: magnetic resonance imaging, N: number, NA: not applicable, NR: not reported, NSAIDs: non-steroidal anti-inflammatory drugs, OS: open surgery, PA: power-analysis, PEMF: pulsed electromagnetic fields, PrM: protrusive movement, PT: physiotherapy, q-RCT: quasi-randomised clinical trial, RDC/TMD: research diagnostic criteria of temporomandibular disorders, RDLA: restriction of daily life activities, SD: standard deviation, self-ex: self-exercise, SM: self-management, self-MM: self- mandibular manipulation, SSI: symptoms severity index, TENS: transcutaneous electric nerve stimulation, wk: weeks, WTDs: wooden tongue depressors, yr: years.

[a] *A priori* power-analysis was done in 7 RCTs. In the remaining 13 trials, a *post-hoc* power-analysis was performed using the G*3power statistical software (version 3) and 8 trials were found under-powered (<80%) for their level of significance for the two primary outcomes (pain and MMO) (Petersson *et al.*, 1994; Linde *et al.*, 1995; Schiffman *et al.*, 1996; Holmlund *et al.*, 2001; Minakuchi *et al.*, 2001; Maloney *et al.*, 2002; Peroz *et al.*, 2004; Politi *et al.*, 2007).
[b] Criteria suggested by Eriksson and Westesson (1983).
[c] Criteria suggested by American academy of craniomandibular disorders (AACMDs) in addition to own study's authors criteria (Schiffman *et al.*, 1989; McNeill, 1990).
[d] Criteria suggested by American association of oral and maxillofacial surgeons (AAOMS) and international association of oral and maxillofacial surgeons (IAOMS) (Dolwick *et al.*, 1984; Goss, 1993).
[e] Separate data for DDwoR patients are available and/or obtained from the contacted authors (personal e-mail communication).
[f] Patients were allocated to undergo either arthrocentesis or conservative treatment (a combination of splint and physiotherapy) according to their admission to the TMJ clinic (consecutively 1 to each group).
[g] Statistical data (unpublished) were provided by the study authors (personal e-mail communication).
[h] Studies are in chronological order.

Appendix F: Characteristics of excluded studies in the systematic review of therapeutic interventions for DDwoR (Chapter 5).

Study	Reason for exclusion
Aktas *et al.* (2010b)	Allocation: unclear; Participants: DDwoR; Interventions: evaluates the effect of sodium hyaluronate (SH) after arthrocentesis. The interventions are arthrocentesis with sodium hyaluronate and arthrocentesis without sodium hyaluronate.
Aktas *et al.* (2010a)	Allocation: random; Participants: DDwoR; Interventions: evaluates the effect of tenoxicam after arthrocentesis. The interventions are arthrocentesis with tenoxicam and arthrocentesis without tenoxicam.
Alpaslan and Alpaslan (2001)	Allocation: random; Participants: DDwR and DDwoR; Interventions: evaluates the effect of sodium hyaluronate (HS) after arthrocentesis. The interventions are arthrocentesis with sodium hyaluronate and arthrocentesis without sodium hyaluronate.
Alpaslan *et al.* (2008)	Allocation: random; Participants: DDwoR; Interventions: evaluates the effect of soft and hard splints after arthrocentesis. The interventions are arthrocentesis with soft splint and arthrocentesis with hard splint.
Arinci *et al.* (2009)	Allocation: unclear; Participants: DDwR and DDwoR; Interventions: evaluates arthroscopy with or without BTX-A injection to the lateral pterygoid muscle. The interventions are arthroscopy with BTX-A injection and arthroscopy without BTX-A injection.
Bertolami *et al.* (1993)	Allocation: random; Participants: no separate extractable data for DDwoR group.
Bertolucci and Grey (1995a); Bertolucci and Grey (1995b)	Allocation: random; Participants: no clear criteria for DDwoR clinical and radiological diagnosis and the participants presented with a primary diagnosis of active degenerative disease (DDwoR seems to be only a secondary diagnosis). In addition, violation to study protocol recognized as one patient complained from side effects excluded and replaced by another new participant from the population during the conduct of the study.
Bryant *et al.* (1999)	Allocation: random; Participants: TMJ arthralgia and internal derangement; Interventions: evaluates the effect of morphine and naloxone after arthroscopy. The interventions are arthroscopy with morphine ± naloxone and arthroscopy without morphine.
Carmeli *et al.* (2001)	Allocation: random; Participants: no specific diagnosis for TMJ disc displacement.
Ekberg (1998); Ekberg and Nilner (1999); Ekberg and Nilner (2002); Ekberg *et al.* (2002); Ekberg *et al.* (1998)	Allocation: random; Participants: the comparable DDwoR subgroups were small and no separate data reported.
Elsholkamy *et al.* (2013)	Allocation: unclear; Participants: DDwoR; Interventions: evaluates the effect of sodium hyaluronate (SH) after arthrocentesis. The interventions are arthrocentesis with sodium hyaluronate and arthrocentesis without sodium hyaluronate.
Emes *et al.* (2013)	Allocation: random; Participants: internal derangement (Wilkes stages II-V); Interventions: compares the effect of second arthrocentesis + SH versus intra-articular tenoxicam injection without second arthrocentesis. All the participants were treated previously by a surgical intervention (arthrocentesis).
Furst *et al.* (2001)	Allocation: random; Participants: DDwR and DDwoR; Interventions: evaluates the effect of morphine and bupivacaine after arthroscopy. The interventions are arthroscopy with morphine and/or bupivacaine and arthroscopy without morphine and/or bupivacaine.
Ghanem (2011)	Allocation: unclear; Participants: DDwoR; Interventions: evaluates the effect of stabilisation splint after arthrocentesis. The interventions are arthrocentesis with stabilisation splint and arthrocentesis without stabilisation splint.
Gray *et al.* (1991)	Allocation: random; Participants: no specific diagnosis for TMJ pain and dysfunction.

Study	Reason for exclusion
Gray *et al.* (1994b); Gray *et al.* (1995)	Allocation: random; Participants: no specific diagnosis for TMJ pain and dysfunction.
Gu *et al.* (1998)	Allocation: unclear; Participants: DDwR and DDwoR.
Hall *et al.* (2005a)	Allocation: not random.
Hamed (2012)	Allocation: random; Participants: DDwR and DDwoR; Interventions: evaluates the effect of tramadol and Cox-2 inhibitor after arthrocentesis. The interventions are arthrocentesis with tramadol and arthrocentesis with Cox-2 Inhibitor.
Hammuda *et al.* (2013)	Allocation: random; Participants: DDwoR; Interventions: evaluates the effect of Ozone after arthrocentesis. The interventions are arthrocentesis with ozonized water and arthrocentesis with normal saline solution.
Hirota (1998)	Allocation: random; Participants: TMJ internal derangement; Interventions: sodium hyaluronate (SH) injection; Outcomes: synovial fluid analysis study.
Kaplan *et al.* (1989)	Allocation: random; Participants: TMJ internal derangement; Interventions: evaluates the omnipaque and hypaque contrast agents in TMJ arthrography.
Katyayan *et al.* (2014)	Allocation: random; Participants: only few patients diagnosed with DDwoR and no separate data provided.
Kulekcioglu *et al.* (2003)	Allocation: random; Participants: no comparable groups for DDwoR subgroup.
Long *et al.* (2009)	Allocation: random; Participants: DDwoR; Interventions: evaluates the effect of injecting sodium hyaluronate (HS) into the inferior versus superior TMJ space. The interventions are sodium hyaluronate injection to superior joint space and sodium hyaluronate injection to inferior joint space.
Machon *et al.* (2012)	Allocation: not random; Participants: DDwoR; Interventions: evaluates early versus late intervention by arthroscopy.
Marini *et al.* (2010)	Allocation: random; Participants: DDwoR or OA. No separate data for DDwoR and the percentage of DDwoR in the sample was < 70% to include the study.
Matsumoto *et al.* (2011)	Allocation: random; Participants: closed lock; Interventions: evaluates two different puncture techniques for pumping manipulation treatment (conventional versus image-guided). The interventions are conventional puncture technique to superior joint space and image-guided puncture technique to superior joint space.
McCain *et al.* (1989)	Allocation: random; Participants: TMJ disorders; Interventions: evaluates the effect of sodium hyaluronate (HS) after arthroscopy. The interventions are arthroscopy with sodium hyaluronate and arthroscopy without sodium hyaluronate.
McNamara *et al.* (1996)	Allocation: random; Participants: no separate data for DDwoR.
Miyamoto *et al.* (1999)	Allocation: random; Participants: DDwoR; Interventions: evaluates two different techniques of arthroscopy (lysis and lavage versus anterolateral capsular release). The interventions are arthroscopy with lysis and lavage only and arthroscopy with lysis and lavage plus anterolateral capsular release.
Morey-Mas *et al.* (2010)	Allocation: random; Participants: DDwR and DDwoR; Interventions: evaluates the effect of sodium hyaluronate (HS) after arthroscopy. The interventions are arthroscopy with sodium hyaluronate and arthroscopy without sodium hyaluronate.
Murakami *et al.* (1995)	Allocation: not random.
Nascimento *et al.* (2013)	Allocation: random; Participants: only one patient diagnosed with DDwoR.
Nguyen *et al.* (2001)	Allocation: random; Participants: no specific diagnosis for TMJ pain.
Nilsson and Ekberg (2010); Nilsson *et al.* (2009); Nilsson *et al.* (2011)	Allocation: random; Participants: only two patients diagnosed with DDwoR.
Nunez *et al.* (2006)	Allocation: randomised cross-over study; Participants: no specific diagnosis for TMJ pain and limitation in mouth opening.

Study	Reason for exclusion
Oliveras-Moreno *et al.* (2008)	Allocation: random; Participants: diagnosed with TMJ DDwR (Wilkes stage II).
Prager *et al.* (2007)	Allocation: random; Participants: DDwR and DDwoR; Interventions: evaluates the effect of buprenorphine after arthrocentesis. The interventions are arthrocentesis with buprenorphine and arthrocentesis without buprenorphine.
Reid *et al.* (1994)	Allocation: random; Participants: no separate data for DDwoR.
Sanroman (2004)	Allocation: not random; Participants: diagnosed with anchored disc phenomenon (ADP).
Sato *et al.* (1997b)	Allocation: not random.
Sato *et al.* (2001b)	Allocation: not random.
Sato and Kawamura (2008)	Allocation: not random.
Schmitter *et al.* (2005c)	Allocation: random; Participants: DDwoR; Interventions: evaluates two different types of splint (centric versus distraction). The interventions are centric splint and distraction splint.
Stegenga *et al.* (1993c)	Allocation: random; Participants: no separate data for DDwoR.
Stiesch-Scholz *et al.* (2002a)	Allocation: not random.
Stiesch-Scholz *et al.* (2005)	Allocation: random; Participants: DDwoR; Interventions: evaluates two different types of splint (stabilization versus pivot). The interventions are stabilization splint and pivot splint.
Wahlund (2003); Wahlund *et al.* (2003)	Allocation: random; Participants: no specific diagnosis for TMJ disc displacement subgroup.
Yucel *et al.* (2014)	Allocation: not random.
Ziegler *et al.* (2010)	Allocation: random; Participants: no specific diagnosis for TMJ pain.
Zuniga *et al.* (2007)	Allocation: random; Participants: no specific diagnosis; Interventions: evaluates the effect of morphine and bupivacaine after TMJ arthroplasty. The interventions are arthroplasty with morphine and/or bupivacaine and arthroplasty without morphine and/or bupivacaine.

Appendix G: Summary of findings for secondary outcomes of the systematic review of therapeutic interventions for DDwoR (Chapter 5).

Comparison (Study)	Secondary outcome	Follow-up (short/long-term)	No. of Patients (Trials)	Relative effect (95%CI)	*p* value for between-group difference [e]	Overall Risk of Bias	Outcome measuring tool/scale
1. UM vs. No treatment (Yoshida *et al.*, 2011)	Protrusion[a]	10 min (ST)	148 (1 RCT)	MD 0.00 (-0.43 to 0.43)	NS	High	mm
	Contralateral[a]	10 min (ST)	148 (1 RCT)	MD 2.00 (1.54 to 2.46)	*p*<0.001 favours UM	High	mm
	Ipsilateral[a]	10 min (ST)	148 (1 RCT)	MD 2.00 (1.46 to 2.54)	*p*<0.001 favours UM	High	mm
2. Jaw exercises vs. Education only (Craane *et al.*, 2012a)	pMMO	3 mo (ST)	45 (1 RCT)	MD -3.20 (-7.00 to 0.60)	NS	Unclear	mm
	pMMO	13 mo (LT)	42 (1 RCT)	MD -3.60 (-7.42 to 0.22)	NS	Unclear	mm
	Function	3 mo (ST)	42 (1RCT)	MD 4.20 (-2.68 to 11.08)	NS	Unclear	MFIQ
	Function	13 mo (LT)	42 (1RCT)	MD 0.40 (-6.28 to 7.08)	NS	Unclear	MFIQ
3. Self-management vs. Education only (Minakuchi *et al.*, 2001)	pMMO	2 mo (ST)	44 (1 RCT)	MD -1.70 (-7.18 to 3.78)	NS	Unclear	mm
	cMMO	2 mo (ST)	44 (1 RCT)	MD -0.40 (-6.36 to 5.56)	NS	Unclear	mm
	Function	2 mo (ST)	44 (1 RCT)	MD -0.50 (-2.48 to 1.48)	NS	Unclear	DAL
4. Self-management vs. Splint (Haketa *et al.*, 2010)	cMMO	2 mo (ST)	44 (1 RCT)	MD 6.20 (2.06 to 10.34)	*p*<0.01 favours SM	Unclear	mm
	Function[b]	2 mo (ST)	44 (1 RCT)	MD -3.62 (-6.81 to -0.43)	*p*<0.01 favours SM	Unclear	LDF
5. Splint vs. TENS (Linde *et al.*, 1995)	Protrusion	6 wk (ST)	31 (1 RCT)	MD -1.22 (-2.73 to 0.29)	NS	High	mm
	Total lateral	6 wk (ST)	31 (1 RCT)	MD -0.98 (-4.33 to 2.37)	NS	High	Baseline change
	Complaints frequency	6 wk (ST)	31 (1 RCT)	RR 6.40 (0.87 to 47.12)	NS	High	N reduction of FOC
6. Combination therapy[c] vs. Education only (Minakuchi *et al.*, 2001)	pMMO	2 mo (ST)	46 (1 RCT)	MD 1.00 (-4.09 to 6.09)	NS	Unclear	mm
	cMMO	2 mo (ST)	46 (1 RCT)	MD 1.30 (-4.43 to 7.03)	NS	Unclear	mm
	Function	2 mo (ST)	46 (1 RCT)	MD 1.30 (-0.90 to 3.50)	NS	Unclear	DAL
7. Combination therapy vs. Self-management (Minakuchi *et al.*, 2001; Schiffman *et al.*, 2007)	pMMO	2 mo (ST)	48 (1 RCT)	MD 2.70 (-2.96 to 8.36)	NS	Unclear	mm
	cMMO	2 mo (ST)	48 (1 RCT)	MD 1.70 (-4.14 to 7.54)	NS	Unclear	mm
	Function	2 mo (ST)	48 (1 RCT)	MD 1.80 (-0.13 to 3.73)	NS	Unclear	DAL
	Function	3 mo (ST)	51 (1 RCT)	MD -0.05 (-0.13 to 0.03)	NS	Unclear	CMI
	Function	60 mo (LT)	50 (1 RCT)	MD 0.00 (-0.09 to 0.09)	NS	Unclear	CMI

Comparison (Study)	Secondary outcome	Follow-up (short/long-term)	No. of Patients (Trials)	Relative effect (95%CI)	*p* value for between-group difference [e]	Overall Risk of Bias	Outcome measuring tool/scale
8. Jaw exercise + splint vs. Splint (Maloney *et al.*, 2002; Ismail *et al.*, 2007)	Protrusion	1-3 mo (ST)	50 (2 RCTs)	MD 1.83 (0.51 to 3.16)	$p<0.01$ favours exr + sp	High	mm
	Right lateral	1 mo (ST)	24 (1 RCT)	MD 1.35 (-0.71 to 3.41)	NS	High	mm
	Left lateral	1 mo (ST)	24 (1 RCT)	MD 3.72 (2.20 to 5.24)	$p<0.001$ favours exr + sp	High	mm
9. Active PEMF vs. Placebo PEMF (Peroz *et al.*, 2004)	pMMO	6 wk (ST)	31 (1 mRCT)	MD -3.53 (-9.52 to 2.46)	NS	Low	mm
	pMMO[b]	4 mo (LT)	30 (1 mRCT)	MD 0.00 (-5.27 to 5.27)	NS	Unclear	mm
	Function	6 wk (ST)	31 (1 mRCT)	MD 18.38 (2.80 to 33.96)	$p<0.05$ favour placebo	Low	RDLA
	Function[b]	4 mo (LT)	30 (1 mRCT)	MD 10.70 (-7.04 to 28.44)	NS	Unclear	RDLA
10. Active iontoph. vs. Placebo iontoph. (Schiffman *et al.*, 1996)	pMMO	1 wk (ST)	18 (1 RCT)	MD -2.20 (-9.86 to 5.46)	NS	Unclear	mm
	Contralateral	1 wk (ST)	18 (1 RCT)	MD -2.00 (-4.70 to 0.70)	NS	Unclear	mm
	Function	1 wk (ST)	18 (1 RCT)	MD -0.04 (-0.19 to 0.11)	NS	Unclear	CMI
11. Arthrocentesis vs. Arthrography (Petersson *et al.*, 1994)	Protrusion	2 mo (ST)	33 (1 RCT)	MD -0.20 (-2.05 to 1.65)	NS	Unclear	mm
12. Arthrocentesis versus LA ATN block (Sahlstrom *et al.*, 2013)	cMMO	3 mo (ST)	37 (1 RCT)	MD -5.93 (-11.55 to -0.31)	$p<0.05$ favours LA	Unclear	mm
	pMMO	3 mo (ST)	37 (1 RCT)	MD -2.20 (-7.49 to 3.09)	NS	Unclear	mm
	Function	3 mo (ST)	36 (1 RCT)	MD 1.10 (0.14 to 2.06)	$p<0.05$ favours LA	Unclear	JFLS
13. Arthrocentesis vs. Combination therapy (Diracoglu *et al.*, 2009)	Protrusion	3 mo (ST)	110 (1 qRCT)	MD 0.81 (0.10 to 1.52)	$p<0.05$ favours AC	High	mm
	Protrusion	6 mo (LT)	110 (1 qRCT)	MD 0.38 (-0.23 to 0.99)	NS	High	mm
	Right lateral	3 mo (ST)	110 (1 qRCT)	MD 1.13 (0.49 to 1.77)	$p<0.001$ favours AC	High	mm
	Right lateral	6 mo (LT)	110 (1 qRCT)	MD 0.47 (-0.14 to 1.08)	NS	High	mm
	Left lateral	3 mo (ST)	110 (1 qRCT)	MD 0.63 (-0.00 to 1.26)	$p=0.05$ towards AC	High	mm
	Left lateral	6 mo (LT)	110 (1 qRCT)	MD 0.94 (0.11 to 1.77)	$p<0.05$ favours AC	High	mm
14. Arthroscopy vs. Self-management (Schiffman *et al.*, 2007)	Function	3 mo (ST)	52 (1 RCT)	MD -0.06 (-0.15 to 0.03)	NS	Unclear	CMI
	Function	60 mo (LT)	51 (1 RCT)	MD 0.01 (-0.08 to 0.10)	NS	Unclear	CMI

Comparison (Study)	Secondary outcome	Follow-up (short/long-term)	No. of Patients (Trials)	Relative effect (95%CI)	*p* value for between-group difference [e]	Overall Risk of Bias	Outcome measuring tool/scale
15. Arthroscopy vs. Combination therapy (Schiffman *et al.*, 2007)	Function	3 mo (ST)	45 (1 RCT)	MD -0.01 (-0.09 to 0.07)	NS	Unclear	CMI
	Function	60 mo (LT)	47 (1 RCT)	MD 0.01 (-0.07 to 0.09)	NS	Unclear	CMI
16. Open surgery vs. Self-management (Schiffman *et al.*, 2007)	Function	3 mo (ST)	49 (1 RCT)	MD -0.06 (-0.14 to 0.02)	NS	Unclear	CMI
	Function	60 mo (LT)	51 (1 RCT)	MD 0.03 (-0.06 to 0.12)	NS	Unclear	CMI
17. Open surgery vs. Combination therapy (Schiffman *et al.*, 2007)	Function	3 mo (ST)	42 (1 RCT)	MD -0.01 (-0.08 to 0.06)	NS	Unclear	CMI
	Function	60 mo (LT)	47 (1 RCT)	MD 0.03 (-0.06 to 0.12)	NS	Unclear	CMI
18. Arthroscopy *vs.* Arthrocentesis (Goudot *et al.*, 2000)	Adverse effects	12 mo (LT)	4 (1 RCT)	RR 0.88 (0.13 to 5.85)	NS	High	Adverse events
19. Open surgery vs. Arthroscopy (Holmlund *et al.*, 2001; Politi *et al.*, 2007; Schiffman *et al.*, 2007)	Protrusion	12 mo (LT)	40 (2 RCTs)	RR 0.90 (0.75 to 1.09)	NS	High	PrM>5mm
	Function	12 mo (LT)	40 (2 RCTs)	MD 1.58 (-3.95 to 0.79)	NS	High	MFIQ
	Function	3 mo (ST)	43 (1 RCT)	MD 0.00 (-0.08 to 0.08)	NS	Unclear	CMI
	Function	60 mo (LT)	48 (1 RCT)	MD 0.02 (-0.07 to 0.11)	NS	Unclear	CMI
Other secondary outcomes							
• **Therapy cost**							
Self-management (Schiffman *et al.*, 2014b).	Therapy cost [d]	60 mo (LT)	Each patient (1 RCT)	Mean $1385 (Range $410–$3555)	Patients treated by self-management strategy incurred significantly lower average costs than combination therapy, arthroscopy, and open surgery patients.	Unclear	$ These costs do not include imaging costs, which were the same for all treatment strategies.
Combination therapy (Schiffman *et al.*, 2014b).	Therapy cost [d]	60 mo (LT)	Each patient (1 RCT)	Mean $2379 (Range $1375–$5240)		Unclear	
Arthroscopic surgery (Schiffman *et al.*, 2014b).	Therapy cost [d]	60 mo (LT)	Each patient (1 RCT)	Mean $7890 (Range $5830–$15.940)		Unclear	
Open joint surgery (Schiffman *et al.*, 2014b).	Therapy cost [d]	60 mo (LT)	Each patient (1 RCT)	Mean $13.128 (Range $11.085– $15.280)		Unclear	

Comparison (Study)	Secondary outcome	Follow-up (short/long-term)	No. of Patients (Trials)	Relative effect (95%CI)	*p* value for between-group difference [e]	Overall Risk of Bias	Outcome measuring tool/scale
• **Admission/operative duration**							
Open surgery (Holmlund *et al.*, 2001)	Operative duration	12 mo (LT)	10 (1 RCT)	Mean 70 minutes	-	High	Minutes
Arthroscopy (Holmlund *et al.*, 2001)	Operative duration	12 mo (LT)	10 (1 RCT)	Mean 25 minutes	-	High	Minutes
Open surgery (Holmlund *et al.*, 2001)	Admission duration	12 mo (LT)	10 (1 RCT)	Mean 3 days	-	High	Days
Arthroscopy (Holmlund *et al.*, 2001)	Admission duration	12 mo (LT)	10 (1 RCT)	Mean 1 hour	-	High	Hours
Open surgery (Politi *et al.*, 2007)	Admission duration	12 mo (LT)	10 (1 RCT)	Mean 5 days	-	High	Days
Arthroscopy (Politi *et al.*, 2007)	Admission duration	12 mo (LT)	10 (1 RCT)	Mean 5 days	-	High	Days

Abbreviations: AC: arthrocentesis, AS: arthroscopy, ATN LA block: auriculotemporal nerve local anaesthesia block, CI: confidence interval, CMI: craniomandibular index, cMMO: comfortable maximum mouth opening, DAL: daily activity limitations, Educ: education, exr+sp: exercises plus splint, FOC: frequency of complaints, JFLS: jaw functional limitation scale, LDF: limitation of daily functions, MD: mean difference, MFIQ: mandibular function impairment questionnaire, mins: minutes, mm: millimetres, mo: months, mRCT: multi-centre randomised clinical trial, N: number of patients, NS: non-significant, OS: open surgery, PEMF: pulsed electromagnetic fields, pMMO: passive maximum mouth opening, PrM: protrusive movement, qRCT: quasi-randomised clinical trial, RDLA: restriction of daily life activities, RR: risk ratio, SM: self-management, TENS: transcutaneous electric nerve stimulation, UM: unlock manipulation, wks: weeks, WTDs: wooden tongue depressors.

[a] Mean and SD were calculated from median, range according to Hozo *et al.* (2005).

[b] Unpublished data provided by the study authors via e-mail communication.

[c] Combination therapy: combination of (splint + physiotherapy + medication ± cognitive behavioural therapy) conservative interventions.

[d] These costs did not include the imaging costs, which were similar for all patients in the trial.

[e] Statistical significance (p-value<0.05) for between-group statistical differences.

Appendix H: Statistical analysis for within-group difference from baseline for primary outcomes of each individual intervention of the systematic review of therapeutic interventions for DDwoR (Chapter 5).

H-1: Change from baseline for TMJ pain intensity (during jaw function) primary outcome.

Study[a] (Year)	Intervention	Follow-up time-point	Pre-treatment	Post-treatment	Change[b] from baseline	*p*-value[c] for within-group difference from baseline	Overall Risk-of-Bias
			Mean ± SD	Mean ± SD	Mean ± SD		
Yoshida *et al.* (2005a)	MM	1 wk (ST)	45.5	29	-16.5	NR	High
	NSAID only	1 wk (ST)	NR	NR	NR	NR	High
Yoshida *et al.* (2011)	MM	Unassessed outcome	NA	NA	NA	NA	NA
	No treatment						
Craane *et al.* (2012a)[d]	Jaw exercises	3 mo (ST)	51.15 ± 12.91	21.63 ± 16.77	-29.52 ± 14.96	$p<0.05$	Unclear
	Education	3 mo (ST)	54.14 ± 15.93	17.82 ± 16.09	-36.32 ± 16.01	$p<0.05$	Unclear
	Jaw exercises	13 mo (LT)	51.15 ± 12.91	8.10 ± 10.46	-43.05 ± 11.75	$p<0.05$	Unclear
	Education	13 mo (LT)	54.14 ± 15.93	7.48 ± 9.55	-46.66 ± 13.13	$p<0.05$	Unclear
Minakuchi *et al.* (2001)	Comb. therapy	2 mo (ST)	47.7 ± 25.2	26.2 ± 19.5	-21.5 ± 22.53	$p<0.001$	Unclear
	Self-management	2 mo (ST)	55.8 ± 25.8	24.6 ± 25.7	-31.2 ± 25.75	$p<0.001$	Unclear
	Education	2 mo (ST)	59.0 ± 24.0	29.0 ± 25.5	-30 ± 24.76	$p<0.001$	Unclear
Yuasa *et al.* (2001)	Self-management	1 mo (ST)	Median 53.5	Median 25.5	Median -20	$p<0.01$	Unclear
	No treatment	1 mo (ST)	Median 57	Median 22	Median -6	$p<0.05$	Unclear
Haketa *et al.* (2010)	Self-management	2 mo (ST)	63.1 ± 21.4	21.3 ± 26.4	-41.8 ± 24.04	$p<0.001$	Unclear
	Splint	2 mo (ST)	58.9 ± 28.2	36.5 ± 28.7	-22.4 ± 28.45	$p<0.001$	Unclear
Lundh *et al.* (1992)	Splint	12 mo (LT)	NR	NR	NR	NR	High
	Control	12 mo (LT)	NR	NR	NR	NR	High
Linde *et al.* (1995)	Splint	6 wk (ST)	51	NR	NR	$p<0.001$	High
	TENS	6 wk (ST)	63	NR	NR	$p<0.001$	High
Maloney *et al.* (2002)[e]	Exercises + Splint	1 mo (ST)	49.41 ± 29.26	32.35 ± 26.37	-17.06 ± 27.85	$p<0.05$	High
	Splint	1 mo (ST)	44.29 ± 32.07	38.57 ± 24.10	-5.72 ± 28.37	NS	High
Ismail *et al.* (2007)	Exercises + Splint	3 mo (ST)	45 ± 20	NR	-28 ± 21	$p<0.05$	Unclear
	Splint	3 mo (ST)	42 ± 22	NR	-23 ± 22	$p<0.05$	Unclear
Peroz *et al.* (2004)[f]	Active PEMF	6 wk (ST)	44.82 ± 22.15	32.64 ± 25.54	-12.88 ± 23.91	$p<0.01$	Low
	Placebo PEMF	6 wk (ST)	48.50 ± 33.58	32.41 ± 25.94	-16.09 ± 30.00	$p<0.01$	Low
	Active PEMF	4 mo (LT)	44.82 ± 22.15	39.08 ± 25.82	-5.74 ± 24.10	$p<0.05$	Unclear
	Placebo PEMF	4 mo (LT)	48.50 ± 33.58	19.59 ± 25.43	-28.91 ± 29.79	$p<0.05$	Unclear
Schiffman *et al.* (1996)[g]	Active iontoph.	1 wk (ST)	0.57 ± 0.1	0.47 ± 0.2	-0.10 ± 0.16	NS	Unclear
	Placebo iontoph.	1 wk (ST)	0.52 ± 0.2	0.50 ± 0.2	-0.02 ± 0.20	NS	Unclear
Schiffman *et al.* (2007)	Self-management	3 mo (ST)	0.61 ± 0.23	0.33 ± 0.22	-0.28 ± 0.23	$p<0.0001$	Unclear
	Comb. therapy	3 mo (ST)	0.72 ± 0.17	0.42 ± 0.27	-0.30 ± 0.23	$p<0.0001$	Unclear
	Arthroscopy	3 mo (ST)	0.70 ± 0.19	0.34 ± 0.25	-0.36 ± 0.22	$p<0.0001$	Unclear
	Open surgery	3 mo (ST)	0.76 ± 0.22	0.26 ± 0.24	-0.50 ± 0.23	$p<0.0001$	Unclear
	Self-management	60 mo (LT)	0.61 ± 0.23	0.23 ± 0.25	-0.38 ± 0.24	$p<0.0001$	Unclear
	Comb. therapy	60 mo (LT)	0.72 ± 0.17	0.23 ± 0.23	-0.49 ± 0.20	$p<0.0001$	Unclear
	Arthroscopy	60 mo (LT)	0.70 ± 0.19	0.26 ± 0.20	-0.44 ± 0.20	$p<0.0001$	Unclear
	Open surgery	60 mo (LT)	0.76 ± 0.22	0.28 ± 0.25	-0.48 ± 0.24	$p<0.0001$	Unclear
Petersson *et al.* (1994)[h]	Arthrocentesis	2 mo (ST)	56.75 ± 20.14	33.63 ± 27.02	-23.12 ± 23.83	$p<0.01$	High
	Arthrography	2 mo (ST)	61.12 ± 18.23	49.65 ± 27.99	-11.47 ± 23.62	NS ($p=0.06$)	High
Sahlstrom *et al.* (2013)[d]	Arthrocentesis	3 mo (ST)	60.6 ± 26.7	55.0 ± 30.7	-5.6 ± 28.77	NS	Unclear
	ATN LA block	3 mo (ST)	58.1 ± 23.2	30.4 ± 22.6	-27.7 ± 22.90	$p<0.0001$	Unclear
Diracoglu *et al.* (2009)	Arthrocentesis	3 mo (ST)	62.6 ± 23.5	31.5 ± 25.2	-31.1 ± 23.3	$p<0.01$	High
	Comb. therapy	3 mo (ST)	56.6 ± 24.7	50.8 ± 24.2	-6.2 ± 15.8	$p<0.01$	High
	Arthrocentesis	6 mo (LT)	62.6 ± 23.5	15.1 ± 18.2	-47.4 ± 21.4	$p<0.01$	High
	Comb. therapy	6 mo (LT)	56.6 ± 24.7	43.9 ± 23.1	-12.2 ± 17.6	$p<0.01$	High
Fridrich *et al.* (1996)	Arthroscopy	6-24mo (LT)	64.5	17	-47.5	$p<0.05$	High
	Arthrocentesis	6-24mo (LT)	66	23	-43	$p<0.05$	High
Goudot *et al.* (2000)	Arthroscopy	12 mo (LT)	57 ± 9	19 ± 24	-38 ± 24	$p<0.0001$	High
	Arthrocentesis	12 mo (LT)	56 ± 8	9 ± 21	-47 ± 21	$p<0.0001$	High
Holmlund *et al.* (2001)	Open surgery	12 mo (LT)	62 ± 28.2	6 ± 12.7	-56 ± 21.87	$p<0.001$	High
	Arthroscopy	12 mo (LT)	71 ± 9.9	25 ± 32.1	-46 ± 23.75	$p<0.01$	High
Politi *et al.* (2007)	Open surgery	12 mo (LT)	80 ± 13.3	13 ± 12.5	-67 ± 13.15	$p<0.01$	High
	Arthroscopy	12 mo (LT)	79 ± 12	19 ± 18.5	-60 ± 15.59	$p<0.01$	High

Abbreviations: ATN LA block: auriculotemporal nerve local anaesthesia block, LT: long-term, MM: mandibular manipulation, mo: months, NA: not-applicable, NR: not-reported, NS: non-significant,

NSAID: non-steroidal anti-inflammatory drug, PEMF: pulsed electromagnetic fields, ST: short-term, TENS: transcutaneous electric nerve stimulation, wk: weeks.

[a] Studies are ordered in accordance with the study order in the summary of findings table (Table 5.3).

[b] Mean change and Standard deviation (SD) for mean change were reported in only three studies (Goudot *et al.*, 2000; Ismail *et al.*, 2007; Diracoglu *et al.*, 2009). In the remaining studies, difference in means and SD for difference were calculated using an Excel sheet (version 14.0) by applying the following formulae: [$Mean_{change\ from\ baseline} = Mean_{post} - Mean_{pre}$], and [$SD_{change\ from\ baseline} = \sqrt{(SD_{pre})^2 + (SD_{post})^2/2}$] respectively according to guidance in the literature (Cohen, 1988; Markiewicz *et al.*, 2008; Fritz *et al.*, 2012; Katsnelson *et al.*, 2012).

[c] Statistical significance (p-value<0.05) for within-group statistical difference from baseline as reported in the studies. In Petersson *et al.* (1994), the p-value was not reported, but was calculated by the Paired T-Test for summarised data (mean differences) using Minitab statistical package (version 16).

[d] Unpublished statistical data were provided by the study authors (personal e-mail communication).

[e] Therabite + splint group and WTDs + splint group were merged together as one group jaw exercises + splint.

[f] Separate data for DDwoR patients are available and/or obtained from the contacted authors (personal e-mail communication).

[g] Only comparison between active iontophoresis by dexamethasone + lidocaine and placebo iontophoresis by normal saline was considered and reported.

[h] Estimated from Figure 2 in the published trial.

H-2: Change from baseline for maximum mouth opening (unassisted/active MMO) primary outcome.

Study[a] (Year)	Intervention	Follow-up time-point	Pre-treatment	Post-treatment	Change[b] from baseline	*p*-value[c] for within-group difference from baseline	Overall Risk-of-Bias
			Mean ± SD	Mean ± SD	Mean ± SD		
Yoshida *et al.* (2005a)	MM	1 wk (ST)	26.5	33.25	+6.75	NR	High
	NSAID only	1 wk (ST)	28.4	28.4	0	NS	High
Yoshida *et al.* (2011)[d]	MM	10min (ST)	27 ± 3.83	38 ± 3.83	+11 ± 3.83	$p<0.001$	High
	No treatment	10min (ST)	29 ± 2.5	30 ± 3.17	+1 ± 2.85	$p<0.01$	High
Craane *et al.* (2012a)[e]	Jaw exercises	3 mo (ST)	35.8 ± 7.4	39.4 ± 6.3	+3.6 ± 6.87	$p<0.05$	Unclear
	Education	3 mo (ST)	36.2 ± 7.1	42.5 ± 6.9	+6.3 ± 7.0	$p<0.05$	Unclear
	Jaw exercises	13 mo (LT)	35.8 ± 7.4	42.7 ± 5.7	+7.8 ± 6.2	$p<0.05$	Unclear
	Education	13 mo (LT)	36.2 ± 7.1	46.5 ± 7.1	+10.1 ± 8.2	$p<0.05$	Unclear
Minakuchi *et al.* (2001)	Comb. therapy	2 mo (ST)	33.6 ± 9.68	42.4 ± 10.1	+8.8 ± 9.89	$p<0.001$	Unclear
	Self-management	2 mo (ST)	36.1 ± 9.98	39.6 ± 10.2	+3.5 ± 10.09	$p<0.001$	Unclear
	Education	2 mo (ST)	36.7 ± 10.36	41 ± 8.39	+4.3 ± 9.43	$p<0.001$	Unclear
Yuasa *et al.* (2001)	Self-management	1 mo (ST)	Median 29	Median 37.5	Median +7	$p<0.0001$	Unclear
	No treatment	1 mo (ST)	Median 30	Median 33.5	Median +1.5	$p<0.05$	Unclear
Haketa *et al.* (2010)	Self-management	2 mo (ST)	32.2 ± 5.5	41.0 ± 5.4	+8.8 ± 5.45	$p<0.001$	Unclear
	Splint	2 mo (ST)	30.3 ± 7.7	35.0 ± 5.8	+4.7 ± 6.82	$p<0.001$	Unclear
Lundh *et al.* (1992)	Splint	Unassessed outcome	NA	NA	NA	NA	NA
	Control						
Linde *et al.* (1995)	Splint	6 wk (ST)	NR	NR	+5.9 ± 4.18	$p<0.0001$	High
	TENS	6 wk (ST)	NR	NR	+6.06 ± 6.72	$p<0.01$	High
Maloney *et al.* (2002)[f]	Exercises + Splint	1 mo (ST)	28.06 ± 3.51	34 ± 4.61	+5.94 ± 4.1	$p<0.01$	High
	Splint	1 mo (ST)	28.29 ± 6.05	29.86 ± 6.47	+1.57 ± 6.26	NS	High
Ismail *et al.* (2007)	Exercises + Splint	3 mo (ST)	30.1 ± 5.4	40.8 ± 4.1	+10.4 ± 5.4	$p<0.05$	Unclear
	Splint	3 mo (ST)	28.6 ± 5.8	35.9 ± 4.8	+7.3 ± 6.2	$p<0.05$	Unclear
Peroz *et al.* (2004)[g]	Active PEMF	6 wk (ST)	32.25 ± 9.5	36.71 ± 8.36	+4.46 ± 8.95	$p<0.05$	Low
	Placebo PEMF	6 wk (ST)	35 ± 7.7	39.18 ± 7.87	+4.18 ± 7.79	$p<0.05$	Low
	Active PEMF	4 mo (LT)	32.25 ± 9.5	38 ± 7	+5.57 ± 8.34	$p<0.05$	Unclear
	Placebo PEMF	4 mo (LT)	35 ± 7.7	39 ± 7.1	+4.0 ± 7.41	$p<0.05$	Unclear
Schiffman *et al.* (1996)[h]	Active iontoph.	1 wk (ST)	32.2 ± 6.5	38.2 ± 10.2	+6 ± 8.55	$p<0.05$	Unclear
	Placebo iontoph.	1 wk (ST)	34 ± 7.8	36.3 ± 5.6	+2.3 ± 6.8	NS	Unclear
Schiffman *et al.* (2007)	Self-management	3 mo (ST)	NR	NR	NR	$p<0.0001$	Unclear
	Comb. therapy	3 mo (ST)	NR	NR	NR	$p<0.0001$	Unclear
	Arthroscopy	3 mo (ST)	NR	NR	NR	$p<0.0001$	Unclear
	Open surgery	3 mo (ST)	NR	NR	NR	$p<0.0001$	Unclear
	Self-management	60 mo (LT)	NR	NR	NR	$p<0.0001$	Unclear
	Comb. therapy	60 mo (LT)	NR	NR	NR	$p<0.0001$	Unclear
	Arthroscopy	60 mo (LT)	NR	NR	NR	$p<0.0001$	Unclear
	Open surgery	60 mo (LT)	NR	NR	NR	$p<0.0001$	Unclear
Petersson *et al.* (1994)	Arthrocentesis	2 mo (ST)	27.4 ± 6.0	32.6 ± 10.8	+5.2 ± 8.74	$p<0.05$	High
	Arthrography	2 mo (ST)	30.7 ± 8.1	35.6 ± 8.1	+4.9 ± 8.1	$p<0.05$	High
Sahlstrom *et al.* (2013)[e]	Arthrocentesis	3 mo (ST)	34.4 ± 7.2	37.8 ± 7.4	+3.4 ± 7.3	NS	Unclear
	ATN LA block	3 mo (ST)	33.1 ± 9.1	42.7 ± 8.1	+9.6 ± 8.61	$p<0.05$	Unclear
Diracoglu *et al.* (2009)	Arthrocentesis	3 mo (ST)	31.20 ± 7.03	35.13 ± 6.72	+3.92 ± 6.10	$p<0.01$	High
	Comb. therapy	3 mo (ST)	29.89 ± 4.82	33.20 ± 7.61	+4.17 ± 7.80	$p<0.01$	High
	Arthrocentesis	6 mo (LT)	31.20 ± 7.03	37.89 ± 6.53	+6.68 ± 6.20	$p<0.01$	High
	Comb. therapy	6 mo (LT)	29.89 ± 4.82	35.54 ± 6.41	+6.20 ± 6.50	$p<0.01$	High
Fridrich *et al.* (1996)	Arthroscopy	6-24 mo (LT)	30 ± 8.7	47.5 ± 4.7	+17.5 ± 6.99	$p<0.0001$	High
	Arthrocentesis	6-24 mo (LT)	33 ± 12.2	41 ± 4.9	+8 ± 9.3	$p<0.05$	High
Goudot *et al.* (2000)	Arthroscopy	12 mo (LT)	29 ± 4.8	38.6 ± 4.2	+9.6 ± 5.8	$p<0.0001$	High
	Arthrocentesis	12 mo (LT)	29.4 ± 3.1	33.8 ± 4.4	+4.3 ± 4.4	$p<0.0001$	High
Holmlund *et al.* (2001)	Open surgery	12 mo (LT)	NR	NR	NR	$p<0.001$	High
	Arthroscopy	12 mo (LT)	NR	NR	NR	$p<0.01$	High
Politi *et al.* (2007)	Open surgery	12 mo (LT)	NR	NR	NR	$p<0.01$	High
	Arthroscopy	12 mo (LT)	NR	NR	NR	$p<0.01$	High

Abbreviations: ATN LA block: auriculotemporal nerve local anaesthesia block, LT: long-term, min: minutes, MM: mandibular manipulation, mo: months, NA: not-applicable, NR: not-reported, NS: non-significant, NSAID: non-steroidal anti-inflammatory drug, PEMF: pulsed electromagnetic fields, ST: short-term, TENS: transcutaneous electric nerve stimulation, wk: weeks.

[a] Studies are ordered in accordance with the study order in the summary of findings table (Table 5.3).

[b] Mean change and Standard deviation (SD) for mean change were reported in five studies (Linde *et al.*, 1995; Goudot *et al.*, 2000; Ismail *et al.*, 2007; Diracoglu *et al.*, 2009; Craane *et al.*, 2012a). In the remaining studies, difference in means and SD for difference were calculated using an Excel sheet (version 14.0) by applying the following formulae: [$Mean_{change\ from\ baseline} = Mean_{post} - Mean_{pre}$], and

[$SD_{change\ from\ baseline} = \sqrt{(SD_{pre})^2 + (SD_{post})^2/2}$] respectively according to guidance in the literature (Cohen, 1988; Markiewicz *et al.*, 2008; Fritz *et al.*, 2012; Katsnelson *et al.*, 2012).

[c] Statistical significance (*p*-value <0.05) for within-group statistical difference from baseline as reported in the studies. In Fridrich *et al.* (1996), the *p*-value was not reported, but was calculated by the Paired T-Test for summarised data (mean differences) using Minitab statistical package (version 16).

[d] Mean (SD) were calculated from the reported median (range) in the published trial according to Hozo *et al.* (2005).

[e] Unpublished statistical data were provided by the study authors (personal e-mail communication).

[f] Therabite + splint group and WTDs + splint group were merged together as one group jaw exercises + splint.

[g] Separate data for DDwoR patients are available and/or obtained from the contacted authors (personal e-mail communication).

[h] Only comparison between active iontophoresis by dexamethasone + lidocaine and placebo iontophoresis by normal saline was considered and reported.

Appendix I: Newcastle University's ethical approval for qualitative study (Chapter 6).

Newcastle University

04 March 2013

Mohammed Al-Baghdadi
Dental Clinical Research Facility
Research Office 4.026
Level 4
School of Dental Sciences

Faculty of Medical Sciences

Newcastle University
The Medical School
Framlington Place
Newcastle upon Tyne
NE2 4HH United Kingdom

Professor Michael Whitaker
FIBiol FMed Sci
Dean of Research & Innovation

FACULTY OF MEDICAL SCIENCES: ETHICS COMMITTEE

Dear Mohammed

Title: Clinical decision-making in the management of temporomandibular joint disorders
Application No: 00632/2013
Start date to end date: 01 April 2013 to 01 December 2014

On behalf of the Faculty of Medical Sciences Ethics Committee, I am writing to confirm that the ethical aspects of your proposal have been considered and your study has been given ethical approval.

The approval is limited to this project: **00632/2013**. If you wish for a further approval to extend this project, please submit a re-application to the FMS Ethics Committee and this will be considered.

During the course of your research project you may find it necessary to revise your protocol. Substantial changes in methodology, or changes that impact on the interface between the researcher and the participants must be considered by the FMS Ethics Committee, prior to implementation.*

At the close of your research project, please report any adverse events that have occurred and the actions that were taken to the FMS Ethics Committee.*

Best wishes,

Yours sincerely

M. Holbrough

Marjorie Holbrough
On behalf of Faculty Ethics Committee

cc.
Professor Michael Whitaker, Dean of Research & Innovation
Ms Lois Neal, Assistant Registrar (Research Strategy)

*Please refer to the latest guidance available on the internal Newcastle Biomedicine web-site.

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The University of Newcastle upon Tyne trading as Newcastle University

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Appendix J: Standardised invitation letter, participant information sheet, and consent form for qualitative study (Chapter 6).

J-1: Standardised invitation letter

Invitation Letter

Dear Dr. …….,

We would like to invite you to take part in our research study. This study forms part of a PhD thesis entitled "Clinical Decision-Making in the Management of Temporomandibular Joint Disorders".

The research aims to build an understanding of the clinical decision-making process in the management of temporomandibular joint disorders. This will help identify problematic areas in the clinical decision-making process that might benefit from new evidence generation or find the basis for a virtually delivered decision support tool for clinicians in their therapeutic decisions in the management of temporomandibular joint disorders.

The research involves a single interview with a trained interviewer in which we will ask you your opinion, perspectives, and experiences of managing Temporomandibular Joint Disorders. The interview is not to explicitly critique your practice or knowledge, but to help enhance our understanding of the problems frontline clinicians face in relation to managing this group of disorders. The interview will take approximately one hour and you will be remunerated for any reasonable expenses and also for your time at a set rate. More information about the purpose of this study and its conduct is provided in the attached information sheet. Please read through the information sheet carefully and contact us if you need further clarification before you decide whether or not to take part.

If you are interested in taking part please let us know by sending your reply to this e-mail: m.k.s.al-baghdadi@newcastle.ac.uk and we will arrange a mutually convenient time to take informed consent from you and conduct the interview.

Signature

Kind Regards

Mohammed Al-Baghdadi

On the behalf of TMJ management clinical decision-making research team

Newcastle Dental Hospital

0191 208 7017

J-2: Participant information sheet

Participant Information Sheet:

Study title: Clinical decision-making in the management of temporomandibular joint disorders

Qualitative interviews

Principal investigator – Dr Justin Durham
Chief investigator – Dr Mohammed Al-Baghdadi

We would like to invite you to take part in our research study. Before you decide, we would like you to understand our research topic and why the research is being done and what it would involve for you. This invitation is to interview you to share your opinion and perspectives about temporomandibular disorders management and will form a part of a PhD thesis titled "*Clinical Decision-Making in the Management of Temporomandibular Joint Disorders*".
Please read the following information carefully and contact us if there is anything that requires further explanation before you decide whether or not to take part. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.
Part 1 tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study.

Part 1

What is the purpose of the study?
Temporomandibular disorders (TMDs) are an area of controversy and their management regarded as challenging for many dental and medical practitioners. This study aims to explore, understand and therefore attempt to eventually provide support for the clinical decision-making in TMDs management.

Why have I been invited?
We are looking for a wide range of professionals with different levels of clinical expertise among different dental and medical specialities who may be contacted by TMDs patients as a first point of contact. There may be more than twenty clinicians to interview in this study. You fit the criteria outlined above.

Do I have to take part?
It is up to you to decide to join the study, while we very much hope that you will take part, you are free to decide not to. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. If you do, you are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?
You will be invited to an interview for about one hour with the research student named above.

Expenses and payments:
We appreciate your time is valuable and therefore will reimburse you £77 for one hour of your time. If you have to travel to see us for the interview, as opposed to undertaking the interview at your place of work, we will reimburse reasonable travel expenses on the production of a receipt. No other payments will be made.

What will I have to do?
If you agree to participate you will be asked to sign a consent form. In agreeing to participate you will be invited to an interview with research student. The semi-structured interview will take place over one hour and are explicitly not intended to critique your practice; its aim is to gather enough data from a wide range of clinicians so that we can accurately portray any recurrent problems with managing TMDs. You will be encouraged to talk about your practice e.g.; your mainstay of treatment and how you define success, as much as is possible and we will ensure that the topic guide is covered by occasionally asking specific questions related to specific TMDs subgroup.

What are the possible benefits of taking part?
It is hoped that, in the future, the information gained by this study will allow us to design an intervention to support clinicians in managing patients with specific subgroups of TMDs, which will help improve patients' health care. Apart from the knowing that you have been part of the research there would be no other direct benefit to yourself.

What if there is a problem?
Any complaint about the way you have been dealt with during the study will be addressed. The detailed information on this is given in Part 2.
If you have a complaint please contact Dr Justin Durham at the Newcastle Dental School, Level 5, Framlington Place, Newcastle NE2 4BW.

Will my taking part in the study be kept confidential?
Yes. All the data from your participation in this study will be kept confidential. The details are included in Part 2.

Contact details:
If you require any further information please contact:
Dr Mohammed Al-Baghdadi
Oral and Maxillofacial Surgery
C/O Sue Wilkinson
Oral and Maxillofacial Surgery Secretary Level 3
School of Dental Sciences
Newcastle University
Framlington Place
Newcastle upon Tyne
NE2 4BW
0191 208 7017
m.k.s.al-baghdadi@ncl.ac.uk

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?
If you wish to withdraw from the study at any point just tell the research team and your involvement will end immediately. The team will ask if it is possible to include your data in the analysis of the study. You are; however, free to withdraw your data from the study at any point. If you withdraw consent for your interview to be analysed, the recording and the written transcript for the interview will be destroyed and discarded.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (0191 208 7828).

Complaints:
In the event that something does go wrong and you are harmed during the research study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against Newcastle University but you may have to pay your legal costs.

Will my taking part in this study be kept confidential?
The interviews will be recorded digitally and transcribed verbatim by a professional company, once transcribed the recordings will be wiped from the recorder and computer.
All the information you give during this study will be annonymised through the use of a code number unique to you. Your interview transcript will have this code number on thereby ensuring your confidentiality. A list of participants' age (years of experience), gender, and title against their code numbers will be recorded in a separate secure 'master coding sheet' to be held along with your consent form. In relation to personal identifiable data, the hard-copy transcripts will be kept with an indication of your years of experience, gender, occupation, and area of country; no names will be retained with the transcriptions.
Any audio recordings from the study and their related transcriptions will be identified by your individual code number only and will not be linked to your name in any way. Your data will be analysed by the research team of this study. Once analysed, the results of this study may be published in a scientific journal or presented at a research conference, possibly with literal quotes from yourself, however your identity and institution will be kept anonymous. In either case your name will not be mentioned as part of the publication. Your practice and ideologies will not at any time be attributed to you and no reference will be included to the names of practitioners interviewed in paper nor will your practice be reported to any external organisations.

What will happen to the results of the research study?
When the study is complete the researcher will process the information gathered and the results published in a recognised journal and presented scientific meetings.

Who is organising and funding the research?
This study has been organised by the School for Dental Sciences, Newcastle University, and is being carried out as part of a clinical PhD programme funded from PhD bench fees by the Higher Committee for Education Development in Iraq (HCED). The researcher is not being paid for this research.

Who has reviewed the study?
Most research is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Newcastle University Research Ethics Committee. It has also been subject to review by the postgraduate student's PhD supervisors.

Further information and contact details
If there is anything not clear in this information sheet and/or should you wish to make further contact, please find the contact details for contacting the investigators:

Dr Justin Durham
Room 5.019, Level Five.
School of Dental Sciences,
Newcastle University
Newcastle upon Tyne
NE2 4BW
0191 208 7828

Dr Mohammed Al-Baghdadi
Oral and Maxillofacial Surgery
C/O Sue Wilkinson, Oral and Maxillofacial Surgery Secretary Level 3
School of Dental Sciences
Framlington Place
Newcastle University
Newcastle upon Tyne
NE2 4BW
0191 208 7017
m.k.s.al-baghdadi@ncl.ac.uk

You will be given copies of this information sheet together with a signed consent form to keep.

Thank you for considering participating or for taking time to read this sheet.

J-3: Consent form

Centre Number:

Study Number:

Participant Identification Number for this study:

CONSENT FORM

Title of Project: **Clinical Decision-Making in the Management of Temporomandibular Joint Disorders**

Name of Researcher: **Mohammed Al-Baghdadi**

Please **INITIAL** all boxes

1. I confirm that I have read and understand the information sheet dated 1st January (Version-1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. ☐

3. I understand that all the information related to my identity will be kept strictly confidential. The procedures regarding confidentiality of my data have been clearly explained (e.g. use of pseudonyms, anonymisation of data) to me. ☐

4. The use of the data in research, publications, sharing and archiving has been explained to me. ☐

5. I understand that other researchers will have access to this data only if they agree to preserve the confidentiality of the data and if they agree to the terms I have specified in this form. ☐

6. I agree to interviews conducted with me being audio-recorded and I understand that transcripts of my interview will be annonymised, but that I may be anonymously quoted verbatim in published literature. ☐

7. I agree to take part in the above study. ☐

Name of Participant	Signature	Date
Name of Researcher	Signature	Date

Appendix K: Topic guide for qualitative study (Chapter 6).

Guide for TDF-interview[13]:

- To get started, please can you tell me a little bit about yourself? I mean your job, training, clinical interests.
- When I mention the term "chronic orofacial pain" what does that mean to you? **(Knowledge)**
- What do you know about the chronic conditions that may occur in the orofacial region? **(Knowledge)**
- Do you have any thoughts as to how these chronic pain conditions occur? I mean the aetiology of chronic pain? **(Knowledge)**
- What do you feel your role is in treating such chronic conditions? **(Professional role & identity)**
- If we move on to focus on one particulate type of COFP which is: the Temporomandibular Disorders, please could you tell me a little bit about your thoughts and experiences with these disorders? **(Knowledge; Experience)**
- What are your perspectives on the aetiology of Temporomandibular Disorders? **(Knowledge)**
- In your practice, how often do you come across new patients with TMD? **(Experience)**
- How easy or difficult do you find to diagnose a patient with TMD? **(Beliefs about capabilities)**
- Do you usually mange those patients? How? If the patient not responds to your initial management, do you consider alternative approaches? Why/why not? **(Skills)**
- When you would start to think about referring? Why you think sending them will be better for them? What factors might guide your decision to refer? To whom you usually prefer to refer those patients? Do you think that the specialists can cure those patients? **(Skills; Beliefs about consequences)**
- Could you remember any particular pat you find difficulty in managing? Any particular patient you need further investigations to reach a diagnosis? **(Memory, attention, & decision processes)**
- For how long you review/follow-up this patient (wait before referral)? Why you decided on such a time-frame? **(Goals)**
- Do you use any guidelines to help you in managing TMD patients? **(Knowledge)**
- What factors or thought processes might guide your decision to manage a patient with TMD? **(Memory, attention, & decision processes)**
- Do you set goals for yourself or your practice with regard to managing TMD patients? What are your measures of clinical success? **(Goals)**

[13] Throughout the interviews, the topic guide was developed by adding questions and revised slightly to address issues related to interview length and questions' clarity and repetitiveness.

- Do you feel, in general, you have success in the way you manage TMD? **(Optimism)**
- How much expertise or experience do you think the general practitioner needs to have to manage TMD effectively? Why do you think that? **(Skills)**
- Would you discuss your views on potential management with others (e.g., your colleagues) to reach an opinion about how to manage such patients? Does this influence your decision on how to manage your TMD patients? How? **(Social influences)**
- What about the patients, would you discuss the management options with them to reach an opinion about how to manage them? To what extent does this discussion facilitate or hinder the management? How? **(Social influences)**
- Do the patients' emotions or their concerns or apparent distress ever affect your decision to manage them or not? **(Social influences)**
- What about your emotions, Do your own emotions or work stress ever affect your decision to manage or your treatment plan for those patients? **(Emotions)**

• If we move on to focus on discussing a specific subgroup of TMJ disorders: DDwoR, also known as closed lock, please can you tell me what you understand by this term? **(Knowledge)**

- In your practice, had you ever come across such a patient with closed lock condition? Can you describe what you did with such…? **(Experience)**
- OR: that's fine, since you haven't seen such a case, if I tell you that such a patient is when *a patient presented to your clinic with lots of TMJ pain and limited mouth opening*. Imagine such a patient with a painful limited opening coming to your clinic tomorrow and talk to me through:
- What you might do with such a patient with these signs and symptoms? Why you do that? **(Skills)**
- How you start to think about the diagnosis? How confident you feel when you diagnose such a patient? **(Beliefs about capabilities)**
- What are the sources of information you look for in such a patient? **(Memory, attention, & decision processes)**
- In the future, if you confronted with such a patient, where would you go if you want to get more information on such a closed lock condition? **(Environmental context & resources)**
- Would you be worried when you diagnose DDwoR? Why? What you would worry about missing? Like what? **(Beliefs about consequences; Emotions)**
- From your perspectives, what other conditions might have similar limited opening symptom and cause confusion in diagnosis? **(Knowledge)**
- Would you thought about using other investigations/diagnostic methods such as radiographs to help you with the diagnosis? Do you think it is important to take an X-ray to TMJ? What investigations would you order at this consultation for such a case? Why/why not? **(Knowledge; Skills)**

- Would you try to manage such patient? Why? Can you describe how you decided what to include in your treatment plan for this patient? **(Skills; Beliefs about capabilities)**
- How easy or difficult do you feel it would be to manage such a patient? **(Beliefs about capabilities)**
- Is managing such a patient (i.e. painful LMO) possible from your perspective as a ….. practitioner? **(Professional role & identity)**
- What skills do you feel are required to treat such patient successfully? Do you feel you possess these?
- How important do you feel it is to personally manage patient in primary care? **(Skills)**
- What are the advantages of managing patient in primary care? What are the disadvantages? **(Beliefs about consequences)**
- Do you prefer to refer? Why/why not? If prefer to refer, why is that for DDwoR but you would try to manage other TMD? To whom you usually prefer to refer such a patient? Specialty? **(Beliefs about capabilities; Nature of behaviour)**
- Do you want think it is important to receive a feedback about such a patient from secondary care? Why? **(Behavioural regulation)**
- What do you think it will happen to the patients if you don't treat and refer them, from both positive & negative sides? **(Beliefs about consequences)**
- Do you have any idea what are the sorts of treatment might be given to such a pat in secondary care? **(Knowledge)**
- Do your own emotions ever affect your decision to manage the patient? **(Emotions)**
- Does managing such a pat evoke/ elicit an emotional response (worry or concern) in you (e.g., stress)? **(Emotions)**
- Do the patient's emotions/concerns (e.g., apparent distress) ever affect your decision to manage the patient? **(Social influences)**
- Are you aware of any particularly good evidence about managing DDwoR? **(Knowledge)**
- Okay, if I tell you that: There is current research and the evidence from this research suggests that DDwoR/CL can be managed with conservative interventions such as patients' education and self-care instructions and early jaw manipulation. With that in mind, in terms of aiming to manage this condition in primary care, what do you think might need to be done differently to help with DDwoR management in primary care? **(Behavioural regulation; Nature of behaviour)**
- So, if a virtually delivered tool/intervention[14] designed (e.g., a mobile phone application/online internet) to help you in managing such a painful LMO condition, would you think then it will be possible for you can use such a tool to help you diagnosing & managing those patients? **(Behavioural regulation)**

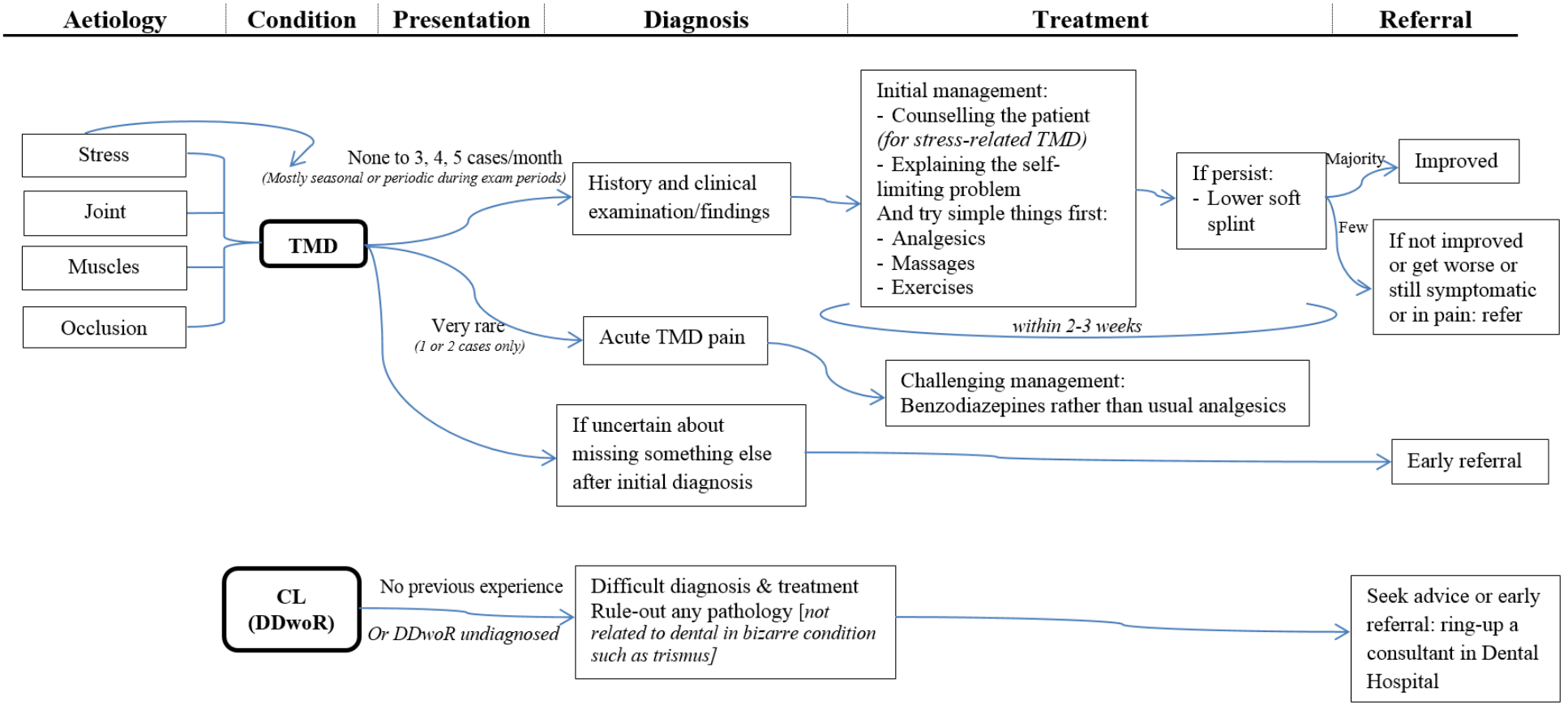
[14] Question about the feasibility of using an electronic-tool was added following the seventh interview.

- If we talk about another condition which is the TMJ dislocation[15], did you confronted with such a case before? How often? **(Experience)**
- Can you describe how you (do you know how?) manage such a case? How? Would you try/be confident to manipulate the jaw? What you did with such a case? If know, Why knows about it not CL? **(Knowledge)**
- From where you learned/got such a kind of information (about manipulation technique) do you think? **(Environmental context & resources)**
- As you think back over your clinical experience, has your approach to manage the TMJ problems in your patients changed? Why/why not? **(Behavioural regulation)**
- In the future, what could influence you to change your current clinical management of TMDs in general? (reduce referral) **(Intentions)**
- From your perspective, are there any problems/difficulties in providing care for patients with DDwoR or TMDs in general in primary care? What would help you to overcome these problems/difficulties? **(Environmental context & resources)**
- Are there any competing tasks or time constraints that might influence your treatment plan to/whether or not you treat/ TMD patients? **(Environmental context & resources)**
- Are there any incentives that motivate you to manage TMD/DDwoR patients? **(Reinforcement)**
- In your practice, are the resources available to facilitate your work and to help you when you diagnose and manage such TMD patients? (e.g., equipment or devices) **(Environmental context & resources)**
- You've mentioned a number of problems with managing TMD, would you be able to identify the top two problems that general practitioners need help with in order to encourage TMD management in primary care? What would help you to overcome these problems/difficulties? **(Behavioural regulation)**
- Is there is anything else you would like to tell me about managing patients with DDwoR or TMD in general? You are Free to make comments.

That's all the questions I have for you, Thanks very much.

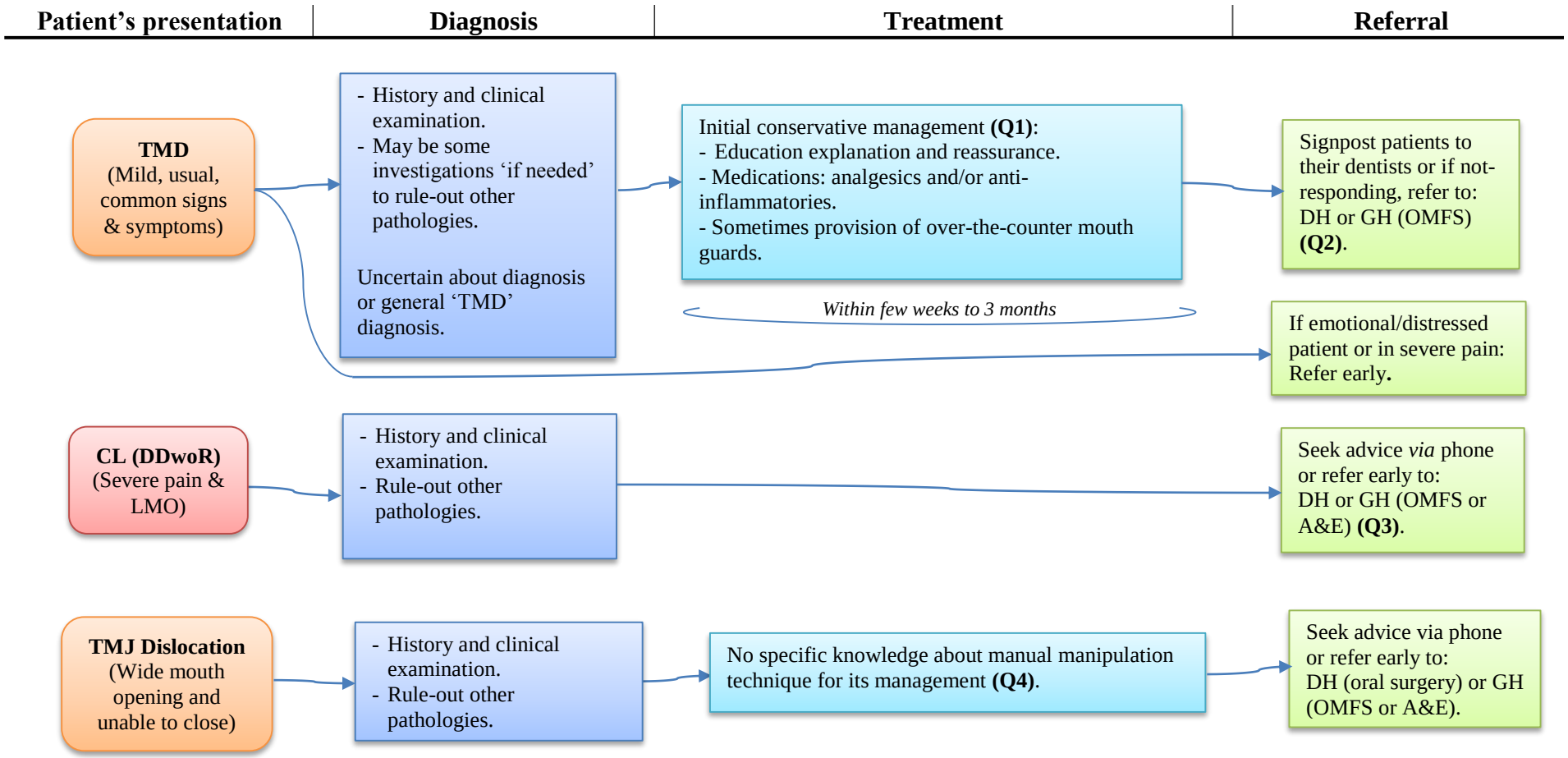
[15] Questions about the acute TMJ dislocation condition were added following the first interview to compare it with the acute DDwoR condition.

Appendix L: Worked example of mapping the clinical decision-making process for the first interviewee (EMGDP1) of qualitative study (Chapter 6).



Appendix M: Professionals' clinical decision-making processes' maps of qualitative study (Chapter 6).

M-1: GMPs' management pathway



Representative quotes of GMPs' decision-making process

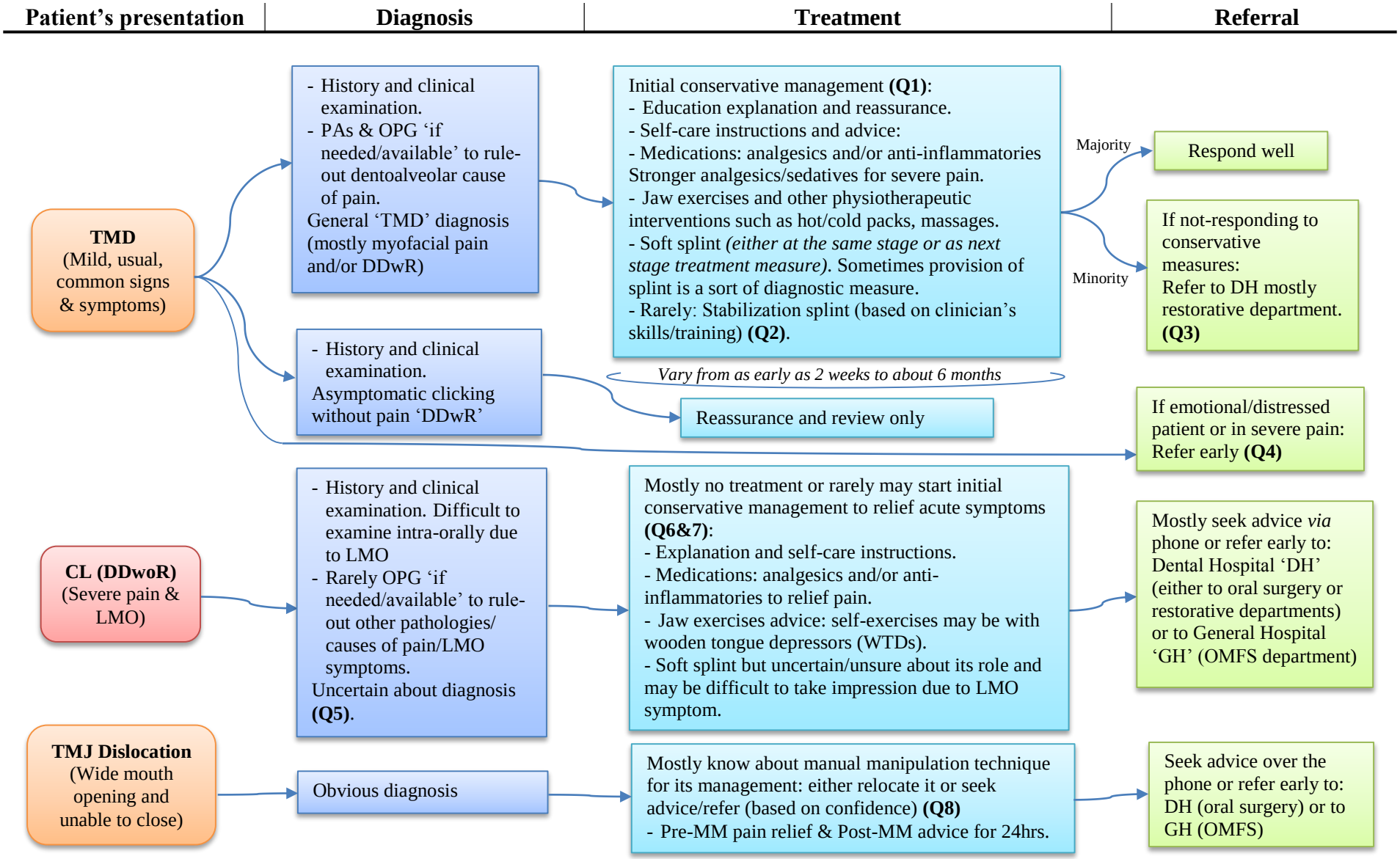
Quote 1: *"if they [TMD patients] wanted Ibuprofen then...and that's fine so they're seen in a couple of weeks, regular Ibuprofen, if that doesn't help you try a stronger anti-inflammatory like Naproxen. If they had started the Naproxen you could try asking them to buy a mouth guard over the counter, try that every night and see them in 2 weeks and those are the two – three main forms of treatment that I would tend to use erm and if you tried those in various forms and maybe a little bit of codeine and that doesn't help then you have to – I suppose you have to tell the patient whether you need to refer them or not"* (GMP9).

Quote 2: *"When they [TMD patients] come to see me, if they've not seen anybody else, I do always ask them if they see their dentist regularly and encourage them to do that"* (GMP7).

Quote 3: *"That's probably the sort of patient [DDwoR] I'd ring the maxfax on-call about and just get advice as to whether it's something I should be referring on that day or what to do about it"* (GMP9).

Quote 4: *"If it's dislocated presumably at some stage it will be an advantage to reduce it, to relocate it but erm I'm merely that's from kind of first principles rather than any observation of previous case"* (GMP7).

M-2: GDPs' management pathway



Representative quotes of GDPs' decision-making process

Quote 1: *"For simple basic management [to TMD patients] I would advise…against wide opening first of all, yawning things like that. Advise against chewy foods, chewing gums especially, tough meats. Parafunctional habits, nail biting, trying to educate those types of things, provide analgesic advice, you know, advise on anti-inflammatory depending on medical history. Erm I'd say that was having improvements and then sort of we have a sheet of advice sort of for erm exercises for them to try and sort of reduce the symptoms of the condition and that would probably be my first stage of management so basic management… [If the patient is not responding to initial management] my next stage would be to try a soft splint"* (NGDP5).

Quote 2: *"I am aware of stabilisation splints, hard splints and I've had training on them but I've never actually done one. But if I got a treatment plan from secondary care that said to provide one I'd be happy to do so"* (EMGDP3).

Quote 3: *"Alternative approach. Erm if I try, if I've gone through all the things that I feel I can advise, like the soft diet, the rest, the pain killers, the splint then I've got to admit I do tend to refer erm because I don't feel confident in any…, you know, anything else that, you know, but if they're still suffering then I would refer to the dental hospital"* (EGDP18).

Quote 4: *"If they [patients] look like they're in a lot of distress then I guess erm if, you know, maybe you would refer a bit sooner than if they didn't because they might not want to try, you know, what you're suggesting might sound very simple and not effective and sometimes you think they do feel better being referred to get a specialist opinion when they're suffering with so much pain"* (EGDP18).

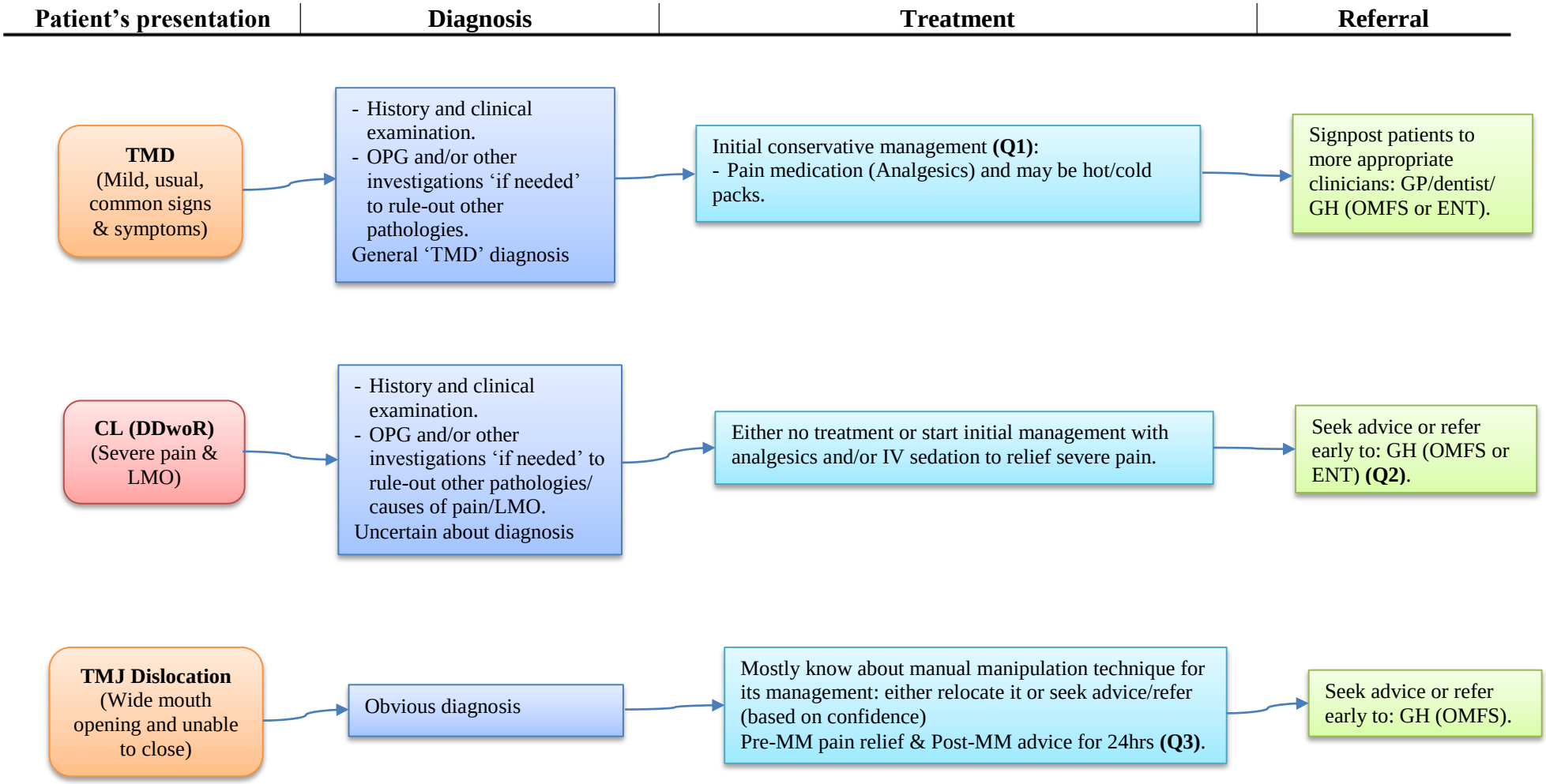
Quote 5: *"Q: How do you start to think about the diagnosis of this [DDwoR] condition? R: Yeah I think it's eliminating any obvious things that I could think of that could be causing it, erm making sure there's been no trauma like I said or any dental, any problems with their teeth or any infections and then just I suppose eliminating things like that and then, you know, if I've really felt I've gone through everything and with nothing I can think of that might be causing it then that's when I would refer"* (EGDP18).

Quote 6: *"I would go on to again giving them sort of advice on the condition [DDwoR] itself and explaining the condition, what it is. Erm providing them with an information and exercise sheet er so sort of exercises that can be performed. Erm if it's a severe pain I would probably be looking at trying to make them a stabilisation splint as soon as possible. Erm but if they've got very limited opening on that occasion it might [not] be possible to take an impression but if it is then I would be trying to take an impression and get them that splint made as soon as possible. Erm I would have give them advice on analgesics, er hot and cold compresses, erm and then sort of review, er get the splint made up as soon as possible for them to provide them with the splints and review after a few weeks to see if we've had any improvements at all with that condition"* (NGDP5).

Quote 7: *"It's not difficult to manage them [DDwoR patients] in the sense that I could see them but I don't think I necessarily would be able to do erm very much other than advise them and then refer at the appropriate time"* (EGDP12).

Quote 8: *"if somebody comes in and they've dislocated their jaw it's propped open, they can't close, erm I've never done it but I think what you do is you put… you basically get hold of the patient's jaw, you put your thumbs on their molars with your fingers underneath here [referring to chin] and you push down with your thumbs as you rotate slightly forwards. So you push down and then back so you've pushed – yeah you push down and then back and then move your thumbs out the way quick and close them and basically say don't open wide, don't do anything, don't smile, don't laugh for the next kind of day"* (NGDP14).

M-3: A&E clinicians' management pathway



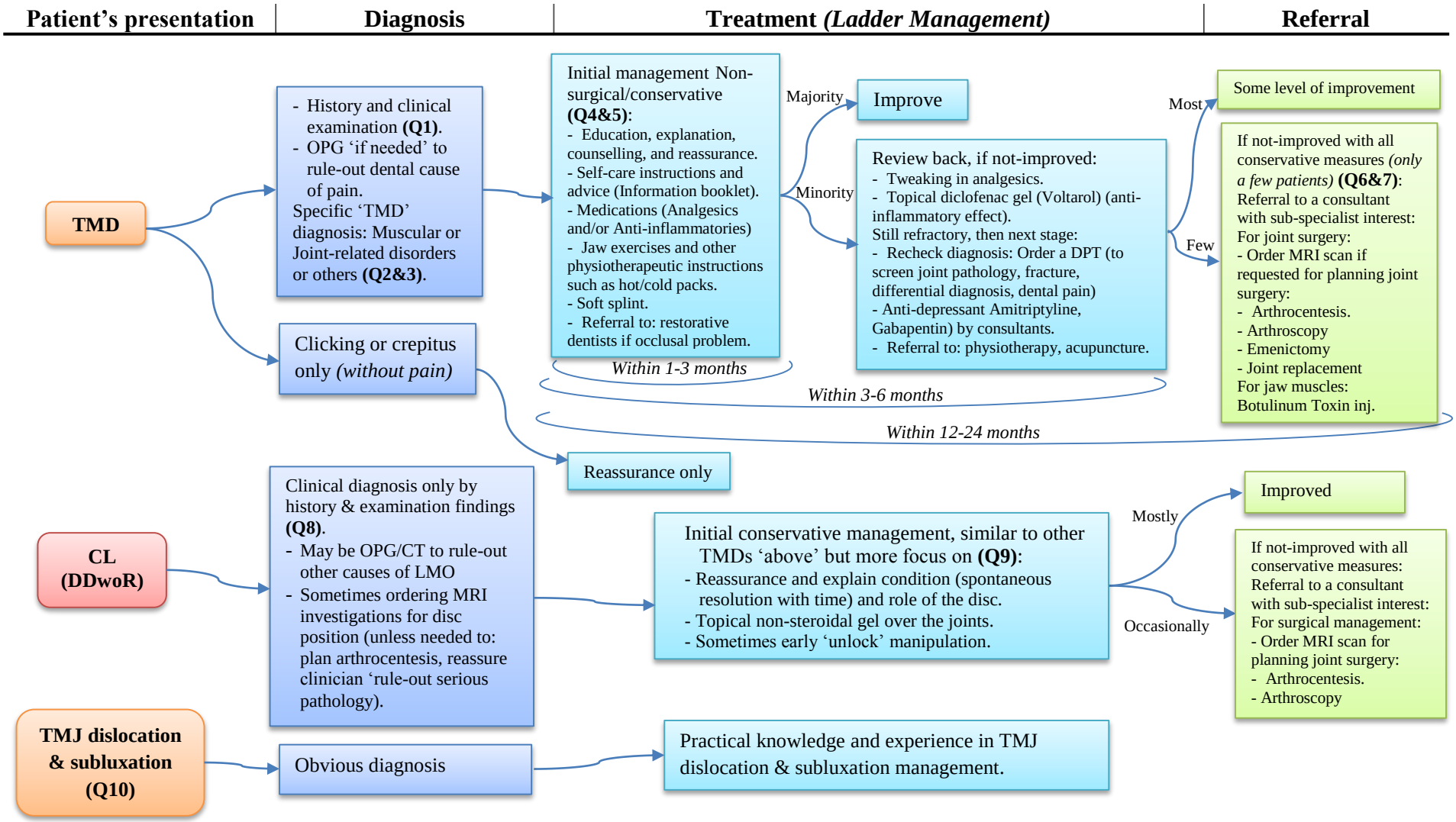
Representative quotes of A&Es' decision-making process

Quote 1: *"If it was a chronic problem I may offer them some pain relief if they didn't have any then and there but a lot of the time for chronic pain I would have to be realistic with them and explain that from an A&E point of view there's probably little I can do for a long-term benefit and that I would have to signpost them to a more appropriate person"* (A&E6).

Quote 2: *"if the patient has limited opening and an anatomical defect I would phone maxfac and say I've got this going on what should I do. Again that takes 2 or 3 minutes to do that by the time you've actually got through to someone to answer the plea"* (A&E/GMP17).

Quote 3: *"Well with those [TMJ dislocation] patients it's a case of erm analgesia and muscle relaxation and then just the reduction and then just the general advice afterwards of trying to reduce their mouth opening for, also not open their mouth wide for 24 hours and then if they're still undergoing treatment just to notify whoever's treating them that they're still having problems"* (A&E16).

M-4: OMFS clinicians' management pathway



Representative quotes of OMFSs' decision-making process

Quote 1: *"Well obviously you take a full history as you would do anyway, examination and the history often gives a characteristic pattern so it can often be kind of like a dull ache type pain. You can even get sharper pains as well particularly if they've come in with an acute flair up of the condition [TMD] erm and then the social history will pick out, you know, you can sort of raise your suspicions as to it being a psychological aspect of it"* (OMFS4).

Quote 2: *"Well I tend to in my mind split it [TMD] up into three main problems I guess. Erm and that would be something that they're maybe having pain from the musculature around the joint or that there's maybe a problem with the disc itself or there may be a problem with the joint itself so erm and I'd find that the majority by far usually fit into group one or group one and two"* (OMFS19).

Quote 3: *"I think it's relatively straightforward to decide that it's a TMJ problem in most cases…so diagnostically it's relatively straightforward but not always"* (OMFS11).

Quote 4: *"I would generally try and give them [TMD patients] a little explanation, erm maybe with some really terrible diagrams I draw and erm then we have a skull to hand so to try and explain the anatomy really and erm but if it was just a muscular thing maybe to discuss with them the things that they might be doing to erm them making the problem worse"* (OMFS19).

Quote 5: *"[I] describe the exercise and the one I tend to go through is the one where you curl your tongue to the back of your mouth and open with your tongue touching the top of your palate. If you repeat that 5 times and you do that in itself for 5 times a day and suggest that normally it's quite a good thing to do when you're watching TV so you can practice"* (OMFS4).

Quote 6: *"If the [TMD patients] come back and they haven't been able to wear the soft splint or things haven't got much better then I tend to refer them to physiotherapy"* (OMFS20).

Quote 7: *"we have got a good pain clinic and they provide good support as well so if we're struggling to manage a patient with chronic pain we can refer on through our chronic pain team in the hospital"* (OMFS11).

Quote 8: *"The history from the patient and then examination findings have reduced it to a sizeable distance. I'd anticipate er there'd be some tenderness over the jaw joint, I'd anticipate a deviation towards the affected side on opening which may then erm correct itself on late opening but they would be the typical findings I'd expect to find"*; *"I mean there are clearly, you know – very rarely there might be a pathological process going on. Erm if the patient is developing an ankylosis erm that would have a different history...and if that [limited mouth opening] was due to a tumour again that would be incredibly rare. The other issue I suppose is that at the other end of the spectrum they may not have a disorder within the jaw joint, they might not have an internal derangement they may simply have a pain and muscle spasm or...muscular discomfort which is restricting the mouth opening, and obviously then there's the infective causes, you know, if a patient has got an untreated abscess but again there would be elements in the history that would point towards I'd say this is probably a nasty pericoronitis from a wisdom tooth or parapharyngeal abscess. There's [are] usually other diagnostic clues that would rule that out"* (OMFS11).

Quote 9: *"With the closed lock, erm I think it would be – essentially I'd reassure them, I'd encourage them to continue with soft diet if they had muscle pain or if they had pain over the joint or the muscles I'd encourage them to use an Ibuleve or a topical non-steroidal gel on the joints and the muscles on the affected side. Erm and I suppose that would be my suggestion to them and because there may well be spontaneous resolution just with erm I think it's probably the time as much as anything else which may encourage that to settle"* (OMFS11).

Quote 10: *"This is [TMJ dislocation] less common than the closed lock I would say"* (OMFS11).

Appendix N: Detailed design of recommended research from the systematic reviews studies (Chapter 4 and Chapter 5).

Research recommendations based on a gap in the management of temporomandibular joint disc displacement without reduction (DDwoR)		
Core elements	**Issues to consider**	**Status of research for this review**
Evidence (E)	What is the current state of evidence?	A systematic review identified 20 RCTs which matched the eligibility criteria, but most were assessed as 'unclear to high' risk of bias. The current evidence, albeit weak, suggests that the patients with TMJ DDwoR can be improved with only minimal intervention.
Population (P)	Diagnosis, disease stage, comorbidity, risk factor, sex, age, ethnic group, specific inclusion or exclusion criteria, clinical setting	Adult patients of any age or gender, of all degree of severity, and had a primary diagnosis of acute or chronic DDwoR according to AAOP, RDC/TMD (IIb or IIc), Wilkes stages (III or IV), or any compatible criteria. Preferably use the recently recommended diagnostic criteria (DC/TMD) for DDwoR with/without limited mouth opening. Consideration needs to be given to prognostic factors that may affect DDwoR treatment response such as the closed lock chronicity. Developing a valid and standardised diagnostic criterion to define the duration of locking in relation to acute and chronic DDwoR clinical stages should be considered. Future research should identify subgroups of patients presenting with acute and chronic DDwoR. This would allow stratification of acute and chronic DDwoR sample to different treatment groups, thereby, allowing further comparison across subgroups to be studied.
Intervention (I)	Type, frequency, dose, duration, prognostic factor	Any non-surgical or surgical therapy for DDwoR. Future research needs to address the minimal non-invasive interventions, in particular patient education and self-management and early 'unlock' mandibular manipulation. Regarding patient education and self-management and combination therapy, future research should describe the intervention components in sufficient details (e.g., using TIDieR checklist) and needs also to clarify how the individual active components in the treatment strategies involving the combination of different conservative interventions interact and improve the outcomes. Regarding mandibular manipulation (MM), there is no consensus on the most effective and practical technique of manual manipulation applied, the time after which the MM should not be attempted, who delivers the intervention (patient or clinician), and what, if any, post-MM conservative intervention is further needed to ensure the long-term successful 'stable' results. Future research should also include pre- and post-manipulation TMJ imaging in order to assess its effect on disc position. Future studies need to be conducted in primary or emergency settings to explore whether early intervention by MM can improve DDwoR symptoms on the long-term. This is certainly appearing to be the case for early MM intervention to manage short-onset DDwoR ('acute' closed lock). The minimally invasive surgical intervention by arthrocentesis and lavage needs to be compared with the non-invasive conservative interventions in high-quality pragmatic RCTs.

Research recommendations based on a gap in the management of temporomandibular joint disc displacement without reduction (DDwoR)		
Core elements	**Issues to consider**	**Status of research for this review**
Comparison (C)	Type, frequency, dose, duration, prognostic factor	Placebo/sham treatment with frequency, dose and duration comparable to the intervention. Comparison with inactive treatment or other alternative therapeutic modality. Comparison with no treatment 'time effect' (e.g., waiting list) to be compared in future trials (true control) to clarify the 'real' effect of the therapeutic interventions against DDwoR natural course for a long follow-up period.
Outcome (O)	Which clinical or patient related outcomes will the researcher need to measure, improve, influence or accomplish? Which methods of measurement should be used?	Standardised multidimensional outcome measures that are of importance in DDwoR need to be assessed. These include the following: Pain associated with TMJs, involving not only pain intensity but also multi-dimensional pain assessment, probably by following the suggested IMMPACT recommendations for outcomes assessment in pain clinical trials (Dworkin *et al.*, 2005; Dworkin *et al.*, 2008). Extent of mandibular movements including: maximum moth opening (active and passive), protrusive movement, and lateral movements toward the unaffected and affected sides rather than reporting the direction of the lateral movement (right or left). There is a need to address and determine the minimal clinically important difference (MCID) in MMO from the patient's perspective after receiving a therapeutic intervention (preferably from biopsychosocially representative samples of patients with DDwoR). Functional limitations and health-related quality of life (QoL) or patient satisfaction outcomes should be considered as an important comorbidity. Future trials need to encompass all the aspects (i.e. physical, social, and psychological) of QoL probably by following the suggested QoL criteria by Locker and Allen (2007). Number of visits or days absent from work Adverse events (harmful adverse events should be clearly addressed and reported in future trials. Even if not observed, adverse events should be clearly stated as 'no finding of any adverse effects for the interventions used'). Operative and admission durations for surgical trials. Patient compliance with treatment or instructions and advice provided especially for self-care interventions. Therapy costs: Cost-effectiveness trials are needed to evaluate the opportunity costs of using a particular intervention over other alternatives. Developing a valid and standardised outcome measures and clinical assessments would contribute to the development of future research. Future research should take in consideration the various factors which could affect the evaluation of the subjective and objective outcomes such as: age, gender, ethnicity, stature, and personal perceptions. Consensus on standardised, but 'pragmatic', success criteria are also needed to yield more rigorous research
Time stamp (T)	Date of literature search or recommendation	November 2013

Research recommendations based on a gap in the management of temporomandibular joint disc displacement without reduction (DDwoR)		
Core elements	**Issues to consider**	**Status of research for this review**
Study type	What is the most appropriate study design to address the proposed question?	Design: randomised controlled trial Allocation: concealment of allocation sequence Blinding: participants, researchers, outcomes assessors, data analysts Data analysis: appropriate ITT-analysis (i.e. including all the randomised participants in the reported statistical analysis) Setting: primary care practices, emergency departments, and TMJ clinics. RCTs should follow the CONSORT guidelines (www.consort-statement.org) with a priori calculated sample size and adequate follow-up and clearly defined interventions with standardised outcome measures are favoured. RCTs with a large sample size in order to increase the statistical power to identify the minor difference in effects between the comparative interventions on a large scale. Given the low incidence of DDwoR amongst TMD and the difficulty in recruiting patients with a DDwoR 'acute/chronic' diagnosis, a multi-centre RCT may be the most appropriate manner, by which, the researchers can examine too the effect of CL duration on the outcome of initial non-invasive simple treatments in DDwoR. The sample size of the RCTs should also be calculated beforehand to ensure that the study has adequate statistical power.

Appendix O: TDF-questionnaire from the qualitative study (Chapter 6).

Domain	Item *(specific belief question)*[16]	Yes	No
Knowledge	I am aware of the DDwoR condition		
	I know how to diagnose DDwoR making specific attention to its pathognomonic signs and symptoms		
	I am aware about other conditions causing limited mouth opening symptom and I know how to differentiate DDwoR from these conditions		
	I know how to manage DDwoR		
	I know the content and objectives of specific DDwoR treatment options		
	I am familiar with the DDwoR management evidence		
Skills	I am familiar with the DDwoR and I have experience to manage it		
	I have the skills to diagnose and manage DDwoR		
	I have been trained how to provide specific DDwoR treatment options		
	I have practiced mandibular manipulation in DDwoR		
Social/ Professional role and identity	Managing patients with DDwoR is part of my work as a [profession: GP, A&E….etc.]		
	As a [profession], it is my job to diagnose patients with DDwoR		
	It is my responsibility as a [profession] to manage patients with DDwoR		
	Referral patients with DDwoR is consistent with my [profession]		
Beliefs about capabilities	I am confident that I can diagnose patients with DDwoR even when there is little time		
	I am confident that I can manage patients with DDwoR		
	I am confident that I can manage patients with DDwoR if I have training		
	I am confident that I can manage DDwoR even if I have never been confronted with it previously		
Optimism	With regard to managing patients with conservative management, I usually expect the best		
	With regard to managing patients, I'm always optimistic about the future		
Beliefs about consequences	If I misdiagnose the DDwoR patient in primary care, it will harm the patient		
	If I manage the DDwoR patient in primary care, it will benefit the patient		
	If I didn't manage and refer the patient with DDwoR to secondary care, it will have more disadvantages for the patient		
	If I didn't manage and refer the patient with DDwoR to secondary care, it will have more advantages for the patient		
Reinforcement	If I manage the DDwoR patient, I feel like I am making a difference		
	If I manage the DDwoR patient, I get financial reimbursement		

[16] DDwoR items for measuring TDF are based on TDF domains' questionnaire (Huijg *et al.*, 2014a; Huijg *et al.*, 2014b).

Domain	Item *(specific belief question)*[16]	Yes	No
Intentions	I will definitely want to manage DDwoR in the future if I am confronted with it frequently		
	I will definitely want to receive feedback about referred DDwoR patients in the future		
	I intend to improve my knowledge and skills regarding the DDwoR management		
	I have strong intention to manage DDwoR in the future if I get training		
Goals	I have management goals		
	It is very important to treat patients with DDwoR in primary care		
	I have a clear plan of how I will diagnose, treat, and/or refer patients with DDwoR		
Memory, attention and decision processes	I will often forget how to diagnose patients with DDwoR if I am not confronted with them regularly		
	If there is evidence about DDwoR management, I will often forget to use it if I am not confronted with DDwoR patients regularly		
	When I need to concentrate to diagnose patients with DDwoR, I have no trouble focusing my attention on pathognomonic signs and symptoms		
	I have a clear plan of when to take a decision to treat or to refer patients with DDwoR		
Environmental context and resources	Within the environmental context there is sufficient financial support for diagnosing and managing patients with DDwoR		
	Within the environmental context there is sufficient time for diagnosing and managing patients with DDwoR		
	Within the environmental context there are good resources available for diagnosing and managing patients with DDwoR		
	I can usually get professional advice over the phone if I am confronted with DDwoR		
Social influences	Within the practice, there is good team work and colleague social support for diagnosing and managing patients with DDwoR		
	Within the practice, I can usually get social support from colleague if I am confronted with the critical incident of DDwoR		
	Discussion with the patients always facilitates the DDwoR management		
Emotion	The patients' emotion/stress/distress has no effect on my decision/treatment plan for DDwoR management		
	My own emotion or work-stress/load has no effect on my decision/treatment plan for DDwoR management		
Behavioural regulation	I keep track of my overall progress towards patients' management		
	I always self-monitor my knowledge/skills to manage patients		
	If there is DDwoR management evidence, it will help me to manage patients with DDwoR		
	If there is a DDwoR e-tool, it will help me to diagnose and manage patients with DDwoR		
Nature of behaviour	Managing patients with DDwoR, as managing patients with TMD, is something I do automatically		

Appendix P: Peer-reviewed publications and international conferences presentations.

P-1: Peer-reviewed publications.

1. Systematic review of locking duration (Al-Baghdadi *et al.*, 2014b)[17]

Journal of Oral Rehabilitation

Journal of Oral Rehabilitation 2014 **41**; 24–58

Review Article

Timing interventions in relation to temporomandibular joint closed lock duration: a systematic review of 'locking duration'

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ABSTRACT **Temporomandibular joint (TMJ) 'closed lock' (CL) is a clinical condition causing TMJ pain and limited mouth opening (painful locking) that is mostly attributed to disc displacement without reduction (DDwoR), or less commonly to anchored disc phenomenon (ADP). Both conditions are described clinically as CL that can be 'acute' or 'chronic' depending on the duration of locking. There is, however, no consensus about the duration of locking that defines the acute state and its effect on the success of interventions. This review paper, therefore, aims to provide: (i) a narrative review of the pathophysiological need for early intervention in DDwoR and the clinical implications of acute/chronic CL stages on the management pathway; (ii) a systematic review investigating the effects of locking duration on the success of interventions for CL management. Electronic and manual searches until mid-August 2013 were conducted for English-language studies of any design investigating the effects of non-surgical and surgical interventions for acute or chronic CL (DDwoR or ADP). A total of 626 records were identified, and 113 studies were included. Data extraction and quality assessment were completed for all included studies. Included studies were, however, heterogeneous and mostly of poor-quality leading to contradictory and inconsistent evidence on the effect of the duration of locking on treatment outcomes. Future high-quality trials investigating the effect of CL duration on treatment outcome are needed. At present, early intervention by 'unlock' mandibular manipulation seems to be the most practical and realistic approach that can be attempted first in every CL patient as an initial diagnostic/therapeutic approach.**

KEYWORDS: **acute closed lock, chronic closed lock, disc displacement without reduction, jaw locking, locking duration, temporomandibular joint**

Accepted for publication 29 November 2013

Introduction

Temporomandibular joint (TMJ) disc displacement without reduction (DDwoR) is a specific subgroup of temporomandibular disorders (TMDs) where the disc is permanently displaced, most frequently anteriorly or anteromedially, to the condyle resulting in a 'painful locking' (1–4). This condition of TMJ pain and locking is known clinically as 'closed lock' (CL) (5–8). The 'TMJ closed lock' term does not, however, always exclusively, refer to TMJ DDwoR because another condition suggested in the literature to have the same 'hypomobility' symptoms (i.e. anchored disc phenomenon 'ADP') (9). In this review, the 'closed lock' term has only been used to describe the clinical symptoms of the 'two' conditions (DDwoR and ADP).

Depending on duration of locking, CL can be acute or chronic (7, 10–13). The definition of acute and

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[17] First page of the published paper is attached. The full-text paper and its appendices are available at the Journal of Oral Rehabilitation, year 2014, volume 41, issue 1, pages 24-58.

2. Systematic review of therapeutic interventions (Al-Baghdadi *et al.*, 2014a)[18]

vol. 93 • issue 7 • suppl no. 1 JDR Clinical Research Supplement

CLINICAL REVIEW

TMJ Disc Displacement without Reduction Management: A Systematic Review

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ABSTRACT: *Various interventions have been used for the management of patients with temporomandibular joint (TMJ) disc displacement without reduction (DDwoR), but their clinical effectiveness remains unclear. This systematic review investigated the effects of these interventions and is reported in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Electronic and manual searches up to November 1, 2013, were conducted for English-language, peer-reviewed, publications of randomized clinical trials comparing any form of conservative or surgical interventions for patients with clinical and/or radiologic diagnosis of acute or chronic DDwoR. Two primary outcomes (TMJ pain intensity and maximum mouth opening) and a number of secondary outcomes were examined. Two reviewers performed data extraction and risk of bias assessment. Data collection and analysis were performed according to Cochrane recommendations. Twenty studies involving 1,305 patients were included. Data analysis involved 21 comparisons between a variety of interventions, either between interventions, or between intervention and placebo or no intervention. Meta-analysis on homogenous groups was conducted in 4 comparisons. In most comparisons made, there were no statistically significant differences between interventions relative to primary outcomes at short- or long-term follow-up ($p > .05$). In a separate analysis, however, the majority of reviewed interventions reported significantly improved primary outcome measures from their baseline levels over time ($p < .05$). Evidence levels, however, are currently insufficient for definitive conclusions, because the included studies were too heterogeneous and at an unclear to high risk of bias. In view of the comparable therapeutic effects, paucity of high-quality evidence, and the greater risks and costs associated with more complex interventions, patients with symptomatic DDwoR should be initially treated by the simplest and least invasive intervention.*

Key Words: temporomandibular joint surgery, internal derangement, closed lock, meta-analysis, disc disorder, TMD.

Introduction

Temporomandibular joint (TMJ) disc displacement without reduction (DDwoR) is a specific temporomandibular disorder (TMD) that can cause TMJ pain and limited mouth opening (painful locking), sometimes called a "closed lock" (Okeson, 2007). DDwoR can be acute or chronic depending on the duration of locking (Sembronio *et al.*, 2008; Saitoa *et al.*, 2010). Its incidence among TMD patients is estimated at 2% to 8% (Manfredini *et al.*, 2011; Poveda-Roda *et al.*, 2012).

Various interventions have been suggested for DDwoR, but to date, the most efficacious/effective approach is still unclear, which may result in management being based more on experience than evidence (Durham *et al.*, 2007). The aim of this systematic review, therefore, was to investigate the effects of different conservative and surgical interventions used in the management of TMJ DDwoR.

Methods

Protocol and Registration

This systematic review was conducted in accordance with the Cochrane Collaboration (Higgins and Green, 2011) and the Centre for Reviews and Dissemination (Akers *et al.*, 2009) guidance, and is reported according to the Preferred Reporting Items for

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Protocol Registration Number: PROSPERO 2012, CRD42012003153. Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42012003153.

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P-2: International conferences presentations.

1. International Conference of Orofacial Pain and Temporomandibular Disorders (ICOT) and AAOP 38th scientific meeting, 2014 USA.

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Effect of 'Locking Duration' on the Outcome of Management of TMJ Closed Lock: A Systematic Review

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Introduction

Temporomandibular joint (TMJ) closed lock (CL) is a clinical condition causing pain and limited mouth opening (painful locking) that is mostly attributed to Disc Displacement without Reduction (DDwoR)[1], or less commonly to Anchored Disc Phenomenon (ADP)[2].

Both conditions are described clinically as CL which can be 'acute' or 'chronic' depending on the duration of locking[3]. There is, however, no consensus about the duration of locking that defines the acute-chronic CL states. This lack of consensus is mainly related to the unproven effect of duration of locking on CL management outcomes. A systematic review of the effect of locking duration on the success of interventions was, therefore, conducted.

Aim

To investigate the effect of locking duration on the success of different surgical and non-surgical therapeutic interventions used for the management of patients with TMJ CL.

Methods

- **Inclusion criteria:** English-language studies of any design investigating the effects of any form of non-surgical or surgical interventions on patients with clinical and/or radiological diagnosis of acute or chronic CL (DDwoR or ADP) were considered as long as the duration of symptoms were reported.
- **Search strategy:** electronic (Medline) and manual searches (up to September 2013).
- **Data extraction and quality assessment:** two reviewers
- **Quality assessment:** study design evidence level[4] (I highest - IV lowest).

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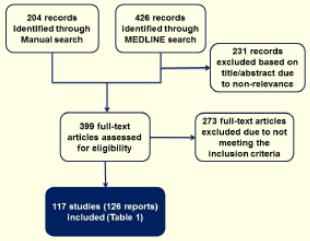
Results

Total of 630 records were identified (Figure 1).

Figure 1: PRISMA flow diagram.



In the 117 studies included, a variety of non-surgical and surgical interventions were used on CL patients with variable locking durations (one day-several years) resulting in mean success rates of 60%-86%. (Table 1).

Table 1: Summary of findings for the effect of locking duration on the success of interventions used for TMJ CL management.

Treatment Modality	No. of studies*	Locking duration (months) Mean (Range)	Overall success rate % Mean (Range)	Overall evidence quality
'Unlock' manipulation	20	9 (0.03-180)	68% (9%-100%)	III-IV
Pumping manipulation	8	7 (0.07-120)	66% (45%-100%)	III-IV
Self-management	7	- (0.5-25)	66% (60%-72%)	III-IV
Physiotherapy	2	-	-	II-III
Splint therapy	12	16 (0.25-192)	60% (13%-100%)	III-IV
Combination therapy of splint plus conservative	11	10 (-)	84% (71%-100%)	III-IV
Arthrocentesis	34	10 (0.03-109)	73% (22%-100%)	III-IV
Arthroscopy	32	19 (0.25-163)	79% (50%-100%)	III-IV
Open joint surgery	8	22 (0.5-150)	86% (70%-100%)	III-IV

* Some studies compared between different treatment modalities, and therefore, included more than once.

Discussion

Studies included were heterogeneous and most were uncontrolled studies of poor quality therefore leading to inconsistent contradictory findings.

The interventions' success rates provided in the table are based on the success criteria used by each included study. The definition of success was, therefore, highly variable involving both objective and subjective factors with the most frequent measures being mouth opening and pain levels. These may be the predominant complaints in CL, but may not be the only biopsychosocial impacts on the individual.

Conclusion

- The evidence for the effect of the duration of locking on the outcome of management of TMJ closed lock is contradictory. It may seem that the degree of intra-articular pathological changes is more important than the locking duration but this, currently, could not be proven.
- Given the poor quality of most included studies, future high quality trials investigating the effect of locking duration on CL management outcomes are needed.

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TMJ Disc Displacement without Reduction Management: A Systematic Review

#1641

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Aim

To investigate the effects of different surgical and non-surgical therapeutic interventions used for the management of patients with temporomandibular joint (TMJ) disc displacement without reduction (DDwoR).

Introduction

TMJ DDwoR is a specific temporomandibular disorder that can cause TMJ pain and limited mouth opening[1], a condition sometimes called a "closed lock" which can be acute or chronic depending on the duration of locking[2].

Different non-surgical (conservative) and surgical interventions of various degree of invasiveness have been used for the management of patients with TMJ DDwoR, but their clinical effectiveness remains unclear.

This lack of evidence on the most effective treatment may lead the management to be based more on experience than evidence with possible unnecessary or harmful interventions being applied.

Methods

- Conducted in accordance with PROSPERO-CRD[3] and Cochrane[4] guidance.

Inclusion criteria for studies (PICOS):

- **P:** any age, gender, clinical and/or radiological diagnosis of acute or chronic DDwoR.
- **I:** any form of non-surgical or surgical interventions.
- **C:** any alternative intervention, placebo, or no treatment.
- **O:** primary outcomes: TMJ pain intensity and unassisted maximum mouth opening (MMO) over short-term (ST ≤ 3 months) and long-term (LT > 3 months) follow-up.
- **S:** randomised and quasi-randomised clinical trials (RCTs & qRCTs).

- **Search strategy:** electronic and manual searches (to 1st Nov. 2013).
- **Limits:** English-language, Peer-reviewed, publications.
- **Data extraction & bias assessment:** two independent reviewers.
- **Data Analysis:** Review Manager Software (RevMan version 5.2).

Results

- **Search results:** 20 studies involving 1,305 patients included (Figure 1).
- **Risk of bias:** unclear – high risk (Figure 2).
- **Data analysis:** 21 comparisons between a variety of interventions (Table 1).
- **Meta-analysis:** 4 comparisons (Table 1, comparisons 9, 10, 20, & 21).

Figure 1: PRISMA flow diagram

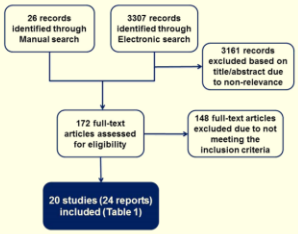

Figure 2: Summary assessment for the overall risk of bias

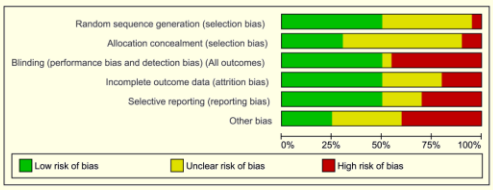

Table 1: Summary of findings for the Primary Outcomes

Comparison	Primary outcome (ST or LT)	Number of patients (studies)	Relative effect 'Risk Ratio or Mean Difference' (95% CI)	*p*-value
1. Manipulation* vs. No treatment	MMO (ST)	148 (1 RCT)	RR 16.7 (5.4, 51.1)	< .0001
2. Jaw exercises vs. Education	Pain (LT)	42 (1 RCT)	MD 0.6 (–5.5, 6.7)	NS
	MMO (LT)	42 (1 RCT)	MD -3.8 (–7.7, 0.1)	NS
3. Self-management vs. Education	Pain (ST)	44 (1 RCT)	MD -4.4 (–19.5, 10.7)	NS
	MMO (ST)	44 (1 RCT)	MD -1.4 (–6.9, 4.1)	NS
4. Self-management vs. No treatment	Pain & MMO (ST)	60 (1 RCT)	RR 1.8 (1.0, 3.2)	NS
5. Self-management* vs. Splint	Pain (ST)	44 (1 RCT)	MD -15.2 (–31.6, 1.2)	NS
	MMO (ST)	44 (1 RCT)	MD 6.0 (2.7, 9.3)	< .001
6. Splint vs. No treatment*	Pain (LT)	51 (1 RCT)	RR 0.5 (0.3, 0.9)	< .05
7. Splint* vs. Transcutaneous electric nerve stimulation (TENS)	Pain (ST)	31 (1 RCT)	RR 8.5 (1.2, 60.3)	< .05
	MMO (ST)	31 (1 RCT)	MD -0.2 (–4.1, 3.8)	NS
8. Combination therapy† vs. Education	Pain (ST)	46 (1 RCT)	MD -2.8 (–16.1, 10.5)	NS
	MMO (ST)	46 (1 RCT)	MD 1.4 (–3.9, 6.7)	NS
9. Combination therapy vs. Self-management (meta-analysis)	**Pain (ST)**	**97 (2 RCTs)**	**SMD 0.22 (–0.19, 0.62)**	**NS**
	MMO (ST)	48 (1 RCT)	MD 2.8 (–2.9, 8.6)	NS
10. Jaw exercises plus splint* vs. Splint (meta-analysis)	**Pain (ST)**	**50 (2 RCTs)**	**MD 0.9 (–12.3, 14.1)**	**NS**
	MMO (ST)	**50 (2 RCTs)**	**MD 4.7 (1.8, 7.6)**	**< .01**
11. Active vs. Placebo* Pulsed electromagnetic fields (PEMF)	Pain (LT)	30 (1 RCT)	MD 19.5 (1.0, 38.0)	< .05
	MMO (LT)	30 (1 RCT)	MD -1.0 (–6.1, 4.1)	NS
12. Active vs. Placebo Iontophoresis	Pain (ST)	18 (1 RCT)	MD -0.03 (–0.21, 0.15)	NS
	MMO (ST)	18 (1 RCT)	MD 1.9 (–5.7, 9.5)	NS
13. Arthrocentesis vs. Arthrography	Pain (ST)	33 (1 RCT)	MD -16.0 (–34.8, 2.8)	NS
	MMO (ST)	33 (1 RCT)	MD -3.0 (–9.5, 3.5)	NS
14. Arthrocentesis vs. Local anaesthesia*	Pain (ST)	37 (1 RCT)	MD 24.6 (6.1, 43.1)	< .01
	MMO (ST)	37 (1 RCT)	MD -4.9 (–10.0, 0.2)	NS
15. Arthrocentesis* vs. Combination therapy	Pain (LT)	110 (1 qRCT)	MD -28.8 (–36.6, –21.0)	< .0001
	MMO (LT)	110 (1 qRCT)	MD 2.4 (–0.1, 4.8)	NS
16. Arthroscopy vs. Self-management	Pain (LT)	51 (1 RCT)	MD 0.03 (–0.09, 0.15)	NS
17. Arthroscopy vs. Combination therapy	Pain (LT)	47 (1 RCT)	MD 0.03 (–0.09, 0.15)	NS
18. Open surgery vs. Self-management	Pain (LT)	50 (1 RCT)	MD 0.05 (–0.09, 0.19)	NS
19. Open surgery vs. Combination therapy	Pain (LT)	46 (1 RCT)	MD 0.05 (–0.09, 0.19)	NS
20. Arthroscopy* vs. Arthrocentesis (meta-analysis)	Pain (LT)	62 (1 RCT)	MD 10.0 (–1.2, 21.2)	NS
	MMO (LT)	**81 (2 RCTs)**	**MD 5.1 (3.2, 7.1)**	**< .0001**
21. Open surgery* vs. Arthroscopy (meta-analysis)	**Pain (LT)**	**81 (3 RCTs)**	**SMD -0.50 (–0.95, –0.06)**	**< .05**
	MMO (LT)	**40 (2 RCTs)**	**RR 1.1 (0.8, 1.5)**	**NS**

* Intervention showing a statistically significant benefit ($p < .05$).
† Combination therapy of splints + jaw exercises ± (self-care/medication/education ± cognitive behavioural therapy 'CBT').

Discussion

In most comparisons made, there were no statistically significant differences between non-invasive conservative interventions and minimally invasive or invasive surgical interventions relative to primary outcomes at short- or long-term follow-up ($p > .05$).

In a separate analysis, however, the majority of reviewed interventions reported significantly improved primary outcome measures from their baseline levels over time ($p < .05$).

Evidence levels, however, are currently insufficient for definitive conclusions, because the included studies were too heterogeneous and at an unclear to high risk of bias.

Conclusion

In view of the comparable therapeutic effects, paucity of high-quality evidence, and the greater risks and costs associated with more complex interventions, patients with symptomatic DDwoR should be initially managed with the most minimal and least invasive intervention.

- **Implications for practice:** The comparable therapeutic effects of reviewed interventions suggest using the simplest, least costly, and least invasive interventions for the initial management of DDwoR, in particular: patient education, self-management, and early mandibular manipulation.
- **Implications for research**: Future research needs to examine the least invasive interventions specifically with high-quality pragmatic RCTs.

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CHR Centre for Oral Health Research

2. International Association for Dental Research (IADR) 93rd General Session, 2015 USA.

#0748

Understanding Clinicians' Decisions in Managing Disc Displacement without Reduction (Closed Lock)

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Introduction

Patients with temporomandibular joint (TMJ) disc displacement without reduction (DDwoR) may suffer from sudden-onset painful/limited mouth opening and may, understandably, immediately seek care from clinicians at the frontline in emergency or non-specialist community services.

The evidence suggests that those patients should be managed initially by the simplest, least costly, and least invasive interventions[1]. Currently, however, there is a lack of understanding of frontline, and specialist, clinicians' decision-making processes when confronted with an acute DDwoR.

Understanding these processes is an essential first step towards the future development of an evidence-informed behavioural intervention to improve DDwoR management at the first point of contact.

Aims

To understand the clinicians' decision-making processes in managing patients with DDwoR and to examine the influences on clinicians' decisions.

Methods

Study design: Qualitative research.

Sampling strategy: Purposive maximum variation sampling.

Sample inclusion criteria: Differing experiences, gender, training, and qualifications of the following specialties across Northeast of England:

- General dental practitioners (GDPs)
- General medical practitioners (GMPs)
- Accident and emergency (A&E) clinicians
- Oral and maxillofacial surgery (OMFS) clinicians

Data collection: Semi-structured interviews utilising a topic guide structured around the theoretical domains framework (TDF) of behaviour change[2,3]. The 15 theoretical domains are demonstrated in Figure 2 indicated by asterisks.

Data Analysis: TDF used as a coding framework and framework approach[4] used to organise the data and the analysis. Data collection and analysis occurred until saturation (n=21).

Data & Discussion

A total of 21 participants were interviewed: 16 frontline clinicians (10 GDPs, 3 GMPs, 3 A&E) and 5 OMFS clinicians.

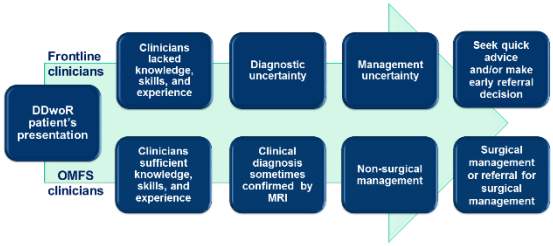
There was a clear disparity in decision-making processes between clinicians at the frontline and those working within the specialist OMFS service with the latter appearing able to diagnose and treat DDwoR.

"For the patients with…the closed lock…essentially I'd reassure them, I'd encourage them to continue with soft diet…use an Ibuleve or a topical non-steroidal gel on the joints and the muscles on the affected side…because there may well be spontaneous resolution just with…the time"
(OMFS clinician, ≥5 years of experience)

In contrast, all frontline clinicians appeared to be unfamiliar with DDwoR. Unsurprisingly, therefore, they seemed unable to diagnose and treat DDwoR, preferring to seek direct advice and/or refer early in the presentation of DDwoR (Figure 1).

"It was just I was quite lost when she was locked. I was quite lost exactly what to do because she was in so much pain and…that's why I rang up the SHO Maxfax [OMFS Senior House Officer] because… I couldn't physically do anything for her…I did feel a bit lost that I couldn't take her pain away"
(Emergency GDP, ≥5 years of experience)

Figure 1: Comparison of decision-making processes between frontline and OMFS clinicians.



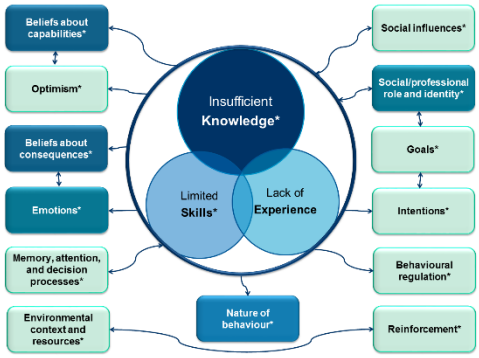
The TDF-based analysis illustrated the varying level of influence, and strength, of all 15 domains on the frontline clinicians' decision to refer early. The core influencing domains on clinicians' decisions at the first point of contact with a patient with DDwoR were the lack of condition-specific knowledge and skills.

"Certainly I don't know the difference between the subgroups of TMD so maybe that would be something and maybe how to treat each one slightly differently" (GDP, <5 years of experience)

"I just feel we haven't really – I haven't been to any training that would, you know, that instantly tells me what to do if a patient had that [DDwoR]" (GDP, ≥5 years of experience)

These two domains and the lack of condition-specific experience shaped frontline clinicians' decision-making processes by impacting on the other behavioural domains in an inter-related manner as depicted in Figure 2.

Figure 2: Model representing the inter-relationships between the theoretical domains influencing clinicians' decisions in DDwoR management.



Conclusions

The TDF-based analysis highlighted the complexity of clinical decision-making processes of healthcare professionals for DDwoR management. All theoretical domains emerged as influences on clinical practice. Of these, however, the most frequent and clearly apparent were clinical knowledge and skills.

Implications for future intervention design: All the factors identified represent theoretically-based targets for an intervention to support, and thereby improve, the clinicians' decisions around DDwoR management.

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