# Development of Patient-Centric Eating Advice and Intervention that Consider the Impact of Wearing

## **Complete Dentures on Eating Related Quality of Life**

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## Abstract

Conventional complete dentures have adverse effects on social and emotional issues around eating or Eating Related Quality of Life (ERQoL). No study has documented the impact of denture replacement on changes in ERQoL. Similarly, there is little patient-centred research regarding eating with complete dentures. Therefore, the aims of this project are to determine the effect of optimising dentures on ERQoL, and to develop a prototype of a patient-centred eating advice or intervention for complete denture wearers.

This project included four consecutive studies. The first study tested the psychometric properties of the Emotional and Social Issues Related to Eating (ESIRE) questionnaire against the denture satisfaction scale (McGill questionnaire). The second study used the ESIRE questionnaire to conduct a cohort study on edentulous patients requiring replacement dentures. The third study was a qualitative study exploring opinions of denture wearers, dentists and Dental Care Professionals (DCPs) about advice on eating with dentures. The fourth study adopted an iterative co-design process to develop a prototype of a patient-centred eating advice and intervention for complete denture wearers.

Findings showed that the ESIRE questionnaire has adequate acceptability, high internal consistency reliability and a satisfactory preliminary construct validity. Following intervention with new conventional complete dentures, a highly statistically significant improvement in the total ESIRE scores was found. Equally, all domains of the ESIRE questionnaire showed significant improvements. However, the new dentures still had a negative impact on enjoyment of food/eating, social interaction, self-consciousness, interruption to meals and food choice highlighting the importance of developing dietary advice or intervention for denture wearers. Findings of the qualitative study showed that peer delivered advice might be useful in a leaflet format and linked website, where patients can share information. The iterative co-design process engaging both patients and dental professionals produced a patient-centred leaflet on overcoming eating problems with complete dentures, developed initial ideas for the future website or web-based intervention on eating with dentures, and identified several Core Concepts for future development.

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## Declaration

I declare that the content of this PhD thesis is my own work and has not previously been submitted for any other assessment. The thesis was written in my own words according to the regulations of Newcastle University.

Hassan Faleeh Farhan Al-Sultani

## **Certificate of approval**

I confirm that, to the best of my knowledge, this thesis represents an original research carried out by Hassan Faleeh Farhan Al-sultani in fulfilment of the requirements for the degree of Doctor of Philosophy according to the regulations of Newcastle University.

Professor Paula Moynihan

Supervisor

# Dedication

This thesis is dedicated to my supervisors, parents, my wife, my daughters (Fatima and Maryam), and my country (Iraq).

## Acknowledgment

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I would like to thank my sponsor (Iraqi Ministry of Higher Education and Scientific Research) for giving me this opportunity to study a PhD. I would like to thank my whole family, especially my father and mother for their unlimited support and prayers for me to achieve my goal. I also cannot thank enough my marvellous and beloved wife Najran for her perseverance, sacrifice, patience, commitment, support and reassurance.

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## List of Abbreviations

ERQoL: Eating Related Quality of Life Social	VAS: Visual Analogue Scale		
ESIRE: Issues Related to Eating with dentures	OHIP: Oral Health Impact Profile		
DCPs: Dental Care Professionals	OHIP-EDENT: Oral Health Impact Profile-		
HRQoL: Health Related Quality of Life	Edemulousness		
OHRQoL: Oral Health Related Quality of Life	MTMM: Multi-Trait Multi-Method		
ISODs: Implant Supported Over Dentures	SDM Standard Data D		
CDs: Complete Dentures	SRM: Standardised Response Mean		
ISDP: Implant Supported Dental Prostheses	EDCD: Emerical Domains Framework		
NCDs: Non-Communicable Diseases	EBCD: Experience-Based Co-Design		
BCTs: Behaviour Change Techniques	LEAP: Living, Eating, Activity, and Planning in retirement		
ADHS: UK Adult Dental Health Survey	NE: North East England.		
QoL: Quality of life	NRES: National Research Ethics Services		
NHS: National Health Services	R&D: Research and Development		
RDA: Recommended Dietary Allowance	TMDs: Temporomandibular Disorders		
BMI: Body Mass Index	SAS: Statistical Analysis Software		
COM-B: Capability, Opportunity, and Motivation	SPSS: Statistical Package for the Social Sciences		
TRA: Theory of Reasoned Action	SD: Standard Deviation		
TPR: Theory of Planned Behaviour	SE: Standard Error		
SoC/ TTM: Stages of Change/Trans Theoretical	H <sub>0</sub> : Null hypothesis		
Model	H <sub>1</sub> : Alternative hypothesis		
HBM: Health Belief Model	CLT: Central Limit Theorem		
SCT: Social Cognitive Theory	ES: Effect Size		
CT: Control Theory	GDPs: General Dental Practitioners		
NSP: Non-Starch Poly Saccharide	NICE: National Institute for Health and Care		
DRV: Dietary Reference Value	Excellence		
NMES: Non-Milk Extrinsic Sugar	CDD: Continuing Desfaniant Development		
CONSORT: Consolidated Standards of Reporting Trials	RD: Restorative Dentistry		
TIDieR: Template for Intervention Description and Replication	SRRDG: Specialty Registrar Restorative Dentistry Group		
MRC: Medical Research Council	CBT: Cognitive Behavioural Therapy		
BCW: Behaviour Change Wheel			

## **Chapter 1. Introduction and Outline of the Thesis**

## 1.1 Introduction

Edentulism is the final consequence of loss of teeth, and is still prevalent worldwide (Felton et al. 2011; Vos et al. 2013). It is considered as a type of impairment and disability (Locker 1988), which might ultimately affect Health Related Quality of Life (HRQoL), and Oral Health Related Quality of Life (OHRQoL) (Gerritsen et al. 2010b; Viola et al. 2013). It is often associated with structural and functional changes, and has adverse psychosocial effects, which might negatively affect oral and general health (Davis et al. 2000; Roessler 2003; El-Feky 2007; Basker et al. 2011). To overcome these consequences, missing teeth have been replaced with different types of prosthesis such as Implant Supported Over Dentures (ISODs), Complete Dentures (CDs), and Implant Supported Dental Prostheses (ISDP) (Kawai et al. 2005; Harris et al. 2013; Tajbakhsh et al. 2013). Complete dentures are widely used to replace missing natural teeth, improve facial appearance, and provide assistance with chewing and speaking for millions of people (Feine and Carlsson 2003; Heydecke et al. 2003b; Kawai et al. 2005). Whilst clinical and technical excellence of complete denture construction are important (Fenlon et al. 1999; Deora et al. 2011), the ability of the patient to succeed in the complex task of denture wearing is likely to be of a prime importance (Muller et al. 1995; Roumanas 2009; Dable et al. 2014). For most patients, wearing a conventional complete denture is a complex issue in terms of eating, food selection, and social and emotional perspectives (Forgie et al. 2005; Hyland et al. 2009; Moynihan et al. 2009; Müller 2014). Much research has been conducted regarding the impact of prosthetic rehabilitation on eating. Most of these studies have tended to focus on clinical outcomes (e.g., techniques of prosthetic rehabilitation) (Scott et al. 2006; Ellis et al. 2011; AlHelal et al. 2017), and overcoming functional problems (e.g., chewing difficulties and inadequate eating of a diet with a good nutritional value) (Moynihan et al. 2000; Walls and Steele 2004a; Feine and Lund 2006; Makwana et al. 2014). Other factors such as feelings, enjoyment and experiences of patients during eating with dentures is also vital in terms of successfulness of prosthetic rehabilitation (Locker 1997; Hyland et al. 2009; Kelly et al. 2012). However, there is a lack of information regarding the impact of rehabilitation with conventional complete dentures on social and emotional issues around eating or ERQoL. Moreover, little is known about the consequence of conventional complete denture replacement on feelings and experiences of patients when eating with their dentures, enjoyment of certain types of foods, and social interaction with others, especially when denture wearers are in the accompany of their families or friends.

Therefore, exploring these issues is possibly useful for two reasons. First, to know how to increase enjoyment of food/eating among denture wearers, and secondly, to find what needs to be done to change the dietary health behaviour of those patients to provide better patientcentred care. In other words, there is a need to know about eating issues in order to provide patient-centred advice around eating that helps patients eat well with dentures. In order to fully understand the actual impact of wearing complete dentures on ERQoL, researchers at Newcastle University, UK have designed the ESIRE questionnaire to collect data on ERQoL. The authors assessed the face validity, content validity, and reliability of the ESIRE questionnaire (Kelly et al. 2012). As psychometric properties (e.g., content validity, reliability, construct validity, and responsiveness) are essential for any health status measure (Lohr 2002; Terwee et al. 2007). Therefore, the work in this thesis tested the acceptability, internal consistency reliability and construct validity of the scores of the quantitative part of the ESIRE questionnaire against the scores of the McGill questionnaire (patient satisfaction scale) (Emmell et al. 1991). The results showed good psychometric properties (good acceptability, high internal consistency reliability and satisfactory construct validity) of the ESIRE scores. The study was done as a part of the cohort study (reported in this thesis) and on a sub-sample of the same cohort patients, who visited Newcastle Dental Hospital, Newcastle upon Tyne, UK to have conventional complete denture replacement. The main aims of the cohort study were to determine any change in ERQoL, before and after conventional complete dentures replacement, collect in-depth information on social and emotional issues related to eating with complete dentures, and obtain the first evidence of the responsiveness of the ESIRE to change in ERQoL. Despite the significant improvement in ERQoL after denture replacement, qualitative data from this study uncovered some eating related problems among the denture wearers highlighting the importance of delivering advice on eating with dentures. Most, if not all of any dietary advice given would have been delivered from the clinicians perspectives; therefore, a qualitative study (focus groups with denture wearers, dentists and DCPs) was held to explore their views and opinions on the potential advice on eating with complete dentures. The qualitative study formed part of ongoing co-development approach to inform development of patient-centric dietary intervention for denture wearers. During this co-development approach, the research team, worked with patients (denture wearers), and health providers (some dental students, dentists and DCPs) as a co-design team to inform eating advice or intervention for denture wearers to help them enjoy what they eat with dentures. In addition to developing several Core Concepts for future development of dietary intervention, producing the first prototype of the patientcentred leaflet on eating with complete dentures was the main outcome of this co-

development approach. As tertiary prevention emphasises on the importance of employing necessary measures to replace lost tissues and to rehabilitate edentulous patients physically and psychologically (Harris and Garcia-Godoy 2004). This PhD study provided an epitome of rehabilitation of edentulous patients physically through treatment with new CDs and psychologically by determining the influence of denture replacement on social and emotional issues around eating with dentures. In addition, primary prevention involves providing useful information about bad health behaviour (e.g., poor diet), decrease risk factors of diseases and improve HRQoL (Brocklehurst et al. 2016). Therefore, developing patient-centred dietary advice (i.e., a patient leaflet) and intervention could help denture wearers overcome functional problems during eating with dentures, eat well and enjoy what they eat with their dentures. Delivering such dietary information might improve the diet of denture wearers and reduce the risk of diet related Non Communicable Diseases (NCDs), undernutrition and depression, which are known to be common in edentulous patients.

#### 1.2 Thesis layout

The outline of this PhD thesis includes nine chapters. After this opening or introductory first chapter, a second chapter reviews the contemporary existing literature around edentulism and the impact of edentulousness and wearing conventional complete denture on ERQoL, and the importance of implementing appropriate and effective Behaviour Change Techniques (BCTs) during designing a patient-centred advice or intervention around eating with complete dentures. It also involved sections on development of dietary advice or intervention and review of methodologies used in this PhD study. The third chapter highlights main aims and objectives of the whole project. The following four result chapters explain the main findings from the validation of the ESIRE questionnaire to using it in the cohort study, conducting qualitative study with users (i.e., denture wearers) and dental healthcare providers (dentists and DCPs), and co-designing a patient-centred eating advice and informing intervention development about eating with complete dentures. Following these result chapters, the eighth chapter deals with the general discussion in interpretative and discursive ways, and outlines recommendations for future research. Finally, chapter nine summarises the conclusions of the main findings.

## **Chapter 2. Literature Review**

This chapter provides a secondary source of evidence-based information summarised from the literature that is related to the studied subject. It comprises four sections as illustrated below:

Section 1 Edentulism and subsequent prosthetic rehabilitation: This section provides information on the definition of edentulism, its prevalence both globally and in the United Kingdom, its management and the impact of edentulism and subsequent prosthetic rehabilitation on different aspects of live including social and emotional issues around eating.
Section 2 Health behaviour change: This section discusses the concept of health behaviour change, theories or models of health behaviour change, the importance of linking behaviour change techniques to their theoretical basis and effective behaviour change techniques used in

different dietary behaviour change interventions.

**Section 3 Development of dietary advice or intervention:** This section includes information about dietary advice or intervention, issues around intervening, the mode of delivery, designing and applying, and specifying behaviour change interventions; in addition to reporting some dietary intervention studies of edentulous patients.

Section 4 Review of methodologies: This section describes the methodologies (i.e., questionnaires, qualitative study, and co-development) used in this PhD.Section 5: The final section provides an overall summary conclusion.

#### 2.1 Section 1: Edentulism and subsequent prosthetic rehabilitation

#### 2.1.1 Introduction

Edentulism is a commonly occurring health condition because of absence or loss of all teeth. Complete loss of all permanent teeth is due to the more prevalent oral diseases such as dental caries and periodontal diseases (Petersen et al. 2010), and to a lesser extent, other oral conditions such as trauma and orofacial pathology (e.g., cyst and tumours) is not uncommon (Jahangiri et al. 2015). Edentulism can be defined as "the physical state of the jaw (s) following removal of all erupted permanent teeth and the condition of the supporting structures available for reconstructive or replacement therapies" (McGarry et al. 1999). Edentulism is an outcome, which reflects multiple aspects such as an individuals' history of dental diseases, attitude and behaviour of both; patients and dentists, in addition to the availability and accessibility of dental services (Baelum et al. 2007; Fejerskov et al. 2013). It is considered as an important indicator of population oral health; thus, it has been monitored globally (Bernabé and Sheiham 2014). From a health aspect, an impairment is any loss or abnormality of psychological, physiological and anatomical structure or function (WHO 1980; WHO 2001). Based on this concept, Locker (1988) stated that edentulism or the lack of all teeth is a type of impairment. Edentulous people could exhibit the impairment as chewing difficulties or discomfort. Similarly, it is regarded as a type of disability 'the dental equivalent of mortality', and handicapping (Weintraub and Burt 1985; Fiske et al. 1998). The disability is possibly related to inability to eat some foods, particularly hard and sticky foods. The handicapping is potentially linked to inability to eat outside in public places resulting in feeling of social isolation. Thus, edentulism and subsequent prosthetic rehabilitation can adversely affect general health (Felton et al. 2011), OHRQoL (Viola et al. 2013), and social and emotional issues around eating with dentures or ERQoL (Hyland et al. 2009) of edentulous people. It seems to be the case that edentulism is the final consequence of different oral diseases, and possibly result in deteriorating effects on oral and general health.

### 2.1.2 International prevalence of edentulism

Edentulism is a global phenomenon (prevalent worldwide), and dilemma (imposes various consequences on edentulous individual). Internationally, the rates of edentulism of the adult population have been estimated to be between 7% and 69% (Felton et al. 2011). The prevalence varies between different countries and within the same country (Millar and Locker 2005; Jahangiri et al. 2015), and as illustrated in (Table 2.1). Edentulism is still high not only in developing countries, but in developed countries as well (Felton 2009). For example,

Suominen et al. (2011), found that the prevalence of edentulism among older adults aged 75 and above living in Finland was 47% for women and 29% for men. Heterogeneity in the prevalence of edentulism among different populations, and in different countries may be attributed to different factors such as age, gender, level of education, socio-economic condition, and insurance coverage, culture and life style, knowledge about oral health, access to the fluoride, smoking, sugars intake, dentist/population ratios, and beliefs and attitudes towards dental treatment (Tuominen et al. 1984; Brodeur et al. 1996; Müller et al. 2007; Elani et al. 2012; Peltzer et al. 2014). Studies reported that women are more affected by tooth loss than men (Muller et al. 2007; Musacchio et al. 2007; Hessari et al. 2008; Starr and Hall 2010a; Gaio et al. 2012a; Wennström et al. 2013). For example, according to data of Scottish Health Survey (2015), the prevalence of edentulism among women, 9%, was higher than that among men, 6%. A similar trend was found in a recent study (Abbood et al. 2017) in which the prevalence of edentulism among women, 14.3%, was higher than that among men, 12.2%. Such gender difference in the prevalence of edentulism is attributed to the high rate of tooth loss among women than men (Felton 2009) due to higher prevalence of dental caries and periodontal diseases among females than males, which possibly attributed to many factors such as composition and flow rate of the saliva and hormonal and genetic variations (Ferraro and Vieira 2010). The hormonal disturbances associated with menstruation and pregnancy (parity) could negatively affect the composition and the anti-caries activity of the saliva resulting in tooth loss (Lukacs and Largaespada 2006; Russell et al. 2008). Moreover, dietary habits (e.g., high intake of snacks), behavioural and cultural (e.g., 'son preference/daughter neglect') factors could indirectly responsible for this gender difference in the prevalence of dental caries and tooth loss (Lukacs 2011). The prevalence of edentulism is high in rural areas (Mitchell et al. 2013), and among people with lower socio-economic status (Dolan et al. 2001; Starr and Hall 2010a; Gaio et al. 2012a; Wennström et al. 2013; Bernabé and Sheiham 2014), suggesting a lack of dental facilities or those group of people are possibly unable to pay for dental services or lack of the dental knowledge to keep teeth as healthy as possible. Many studies have concluded that the prevalence of edentulism increases with age (Doğan and Gökalp 2012; Gaio et al. 2012a; Khazaei et al. 2012; Northridge et al. 2012b). For example, Medina-Solis et al. (2014) found that the prevalence of edentulism among Mexican adults aged 35-44 year was 2%, which increased to 26% among those aged 65-74 year. As the population is getting older, the prevalence of edentulism decreases and the proportion of partially edentulous patients increases (Steele et al. 2000) imposing more prosthodontic challenge on the dental team due to over eruption or drifting of the remaining teeth (Murray Thomson 2014a). According to the findings of the UK Adult Dental Health Survey, in 1998,

87% of all adults in England, Wales and Northern Ireland had at least one natural tooth. This figure increased to 94% in 2009. By 2028, it is anticipated it will be about 96% (Steele et al. 2000; Steele et al. 2012). Projecting forwards from these data, around 90% of 16-74 year olds should have a natural dentition of 21 or more teeth by 2018, but the figure will be lower for older people (Steele et al. 2000). According to the Scottish Adult Oral Health Survey (SAOHS 2016), out of 1867 adults aged 45 years and over, 515 (27.6%) were partially edentate. From those partially edentate individuals, 356 (19.1%) were age 65 years and over. It appears that edentulism is still prevalent globally, and its distribution depends on various factors, mainly the gender, age, and the socioeconomic level of the individual, in addition to the demographical factors; therefore, it is possibly difficult to directly, compare the prevalence of edentulism between different national samples.

Country	Author/ year	Country	Age group (year)	Prevalence
classification*				of
				edentulism
Developing	Khadem et al. (2009)	Iran	50-80 years	47%
economies	(Da'Ameh and Al-	Jordan	60 years and over	26.7%
	Ihyasat 2010)			
	Doğan and Gökalp	Turkey	65-74 years	47.9%
	(2012)			
	Gaio et al. (2012a)	Brazil	60 years and over	41.4%
	Khazaei et al. (2013)	Iran	50 years and over	2.2%
	Al Hamdan and Fahmy	Saudi	30 years and over	82.8%
	(2014)	Arabia		
	Peltzer et al. (2014)	Ghana	Over 50 years	3.0%
		India	Over 50 years	16.3%
		Mexico	Over 50 years	12.7%
		South	Over 50 years	8.5%
		Africa		
	Hewlett et al. (2015)	Ghana	50 years	2.8%
Economies in	(Krunić et al. 2013)	Serbia	Over 60 years	29%
transition	(Peltzer et al. 2014)	Russia	Over 50 years	18.0%
Developed	Musacchio et al. (2007)	Italy	65 years and over	44.0%
economies	(ADHS 2009)	United	45 years and over	6%
		Kingdom		
	Wu et al. (2012)	USA	Over 50 years	(24%),
			Over 50 years	(14.2%)
	(Thomson 2012)	New	65-74 years-old	29.6%
		Zealand		
	(Scottish Health Survey	Scotland	Adults 18 years and	8%
	2015)		over	
	(Northridge et al. 2012b)	USA	65 years and over	19.5%
	(Mariño et al. 2014)	Australia	65 years and over	15.3%

\* The classification is according to the United Nations report for global economic development (United Nations 2017).

 Table 2.1: Examples of the prevalence of edentulism in different countries in the world reported in the literature.

## 2.1.3 Prevalence and trends of edentulism in the United Kingdom

In general, the prevalence of edentulism in the UK is low and decreasing. Based on the 2010 Global Burden of Disease Study, it has been found that there is a significant decline in rates of edentulism in the UK, from 215 per 100,000 individuals in 1990 to 135 per 100,000 individuals in 2010 (Murray et al. 2013). Moreover, according to the UK Adult Dental Health Survey (ADHS), 37% of adults aged 16 and over had no natural teeth in England and Wales in 1968. The proportion of adults in England, Wales and Northern Ireland who were edentulous has decreased from 28% in 1978 to 6% in 2009 (Watt et al. 2013). Similarly, the UK Adult Dental Health Survey (1998) predicted future levels of total tooth loss for 2008 (8%), 2018 (5%) and 2028 (4%) (Steele et al. 2000). Furthermore, Mojon et al. (2004) predicted that the total number of edentulous adults in the UK would decrease from 15 million in 1998 to 6 million by 2028 presuming that the total population is 59 million at that time. These predictions were supported by the findings of the UK Adult Dental Health Survey in 2009, in which only 6% of the combined populations of England, Wales and Northern Ireland were edentulous, and the percentage of people who are edentate is approximately 2.7 million adults across England, Wales and Northern Ireland (Steele et al. 2012). Indeed, the proportion of edentulous people in the last study referred to might raise if the researchers considered the population of Scotland at that time; hence, these findings will be consistent with Mojan et al. (2004), especially if the effect of ageing population has been taken in consideration. According to the Scottish Health Survey (2015), the prevalence of edentulism was relatively low 8%. However, in the presence of other risk factors such as arthritis, the overall prevalence of edentulism increases to 13.4% (Abbood et al. 2017). In general, the proportion of edentulous people in the UK is decreasing dramatically, and this falling rate of edentulism is probably compatible with other western countries.

### 2.1.4 The falling rates of edentulism

Evidence from different studies show that the prevalence of edentulism is decreasing in developed countries. For example, Douglass *et al.* (2002) mentioned that the prevalence of edentulism in the US has declined by 10% every decade. This could be attributed to modern treatment modalities and widely used preventive measures (Muller et al. 2007; Müller 2014; Schimmel et al. 2015). Slade et al. (2014) investigated the data of five national health crosssectional surveys in US and concluded that the prevalence of edentulism among 15 years and over decreased from 18.9% in 1957 to 4.9% in 2012. Based on "age-cohort regression models", they predicted that the number of edentulous individuals will decrease by 30% in

2050. On the other hand, the prevalence is still high in most Asian and Middle East countries (Khadem et al. 2009; Gaio et al. 2012a; Al Hamdan and Fahmy 2014). The reason for this high prevalence is that the type of treatment that used is mostly extraction of painful teeth rather conservative type of treatments (Petersen 2003a).

Despite the decreasing prevalence of edentulism in most developed countries, the high prevalence in developing countries, in addition to the effect of aging population, and the increasing of life expectancy in most developed countries help keep the number of edentulous adults high worldwide (Mojon et al. 2004; Polzer et al. 2010). Literature reports that people aged 65 or more presently comprise 16% of the European population and are projected to increase to 27% by 2050 (Ezeh et al. 2012). According to Office for National Statistics (2017b), the percentage of population that is 65 years and over in the UK is growing. It increased between 1975 and 2015, from 14% of the population to 17.8%. It is projected to continue to grow to reach 20.2% in 2025, 23.6% in 2035 and 24.6% in 2045.

The finding of the UK Adult Dental Health Survey in 2009 apparently supports the trend of increasing in the prevalence of edentulism with age, in which one in five adults wear dentures and 6-10% of all UK adults were edentulous. The prevalence is rising to 15% for individuals aged 65 to 74, 30% for those people aged 75 to 84 and 47% for people aged 85 years and over (Gray et al. 2012). Similarly, according to the Scottish Health Survey (2015), the prevalence of edentulism increased from 3% for age 45-54 to 8% for age 55-64, followed by 19% for age 65-74, and finally, 39% for age 75 and over. Despite the fact that most of those older people retained their own teeth, the effects of ageing populations cannot be overlooked when considering the future demand for complete denture services (Carlsson and Omar 2010), particularly if we take in consideration the accumulative effect of oral diseases and tooth loss, particularly among the older population.

The dramatic decrease in the prevalence of edentulism in developed countries probably indicates a reduction in the number of people in need of complete dentures (Carlsson and Omar 2010). This claim is supported by findings from different countries such as Finland, Sweden and the United Kingdom, which show that the need for complete denture production will fall despite changing age demographics (Mojon et al. 2003). However, a study in US has argued that despite a decline in edentulism of approximately 10% per decade, the proportion of the population with one or two edentulous jaws will increase to 38 million in 2020 in comparison to 34 million in 1991. This is undoubtedly true when the effect of ageing is taken in consideration (Douglass et al. 2002).

Although the overall proportion of edentulous people may reduce a little more quickly than had previously been expected, the rehabilitation of the lost function and appearance with dental prosthesis such as conventional complete dentures is still an inevitable treatment for a large proportion of the population in the world, particularly older people (Carlsson and Omar 2010; Marchini 2014). The unstable global economic conditions, as well as poverty may even lead to a growing need for such dental prosthesis; therefore, the need for complete denture will not disappear in the next three or four decades (Felton 2009). To sum up, the prevalence of edentulism declined over the last decades in most developed countries. However, if the influence of ageing population is taken into account, there will be a considerable number of older people that still need to wear a complete denture despite its limitations.

#### 2.1.5 Consequences of Edentulism

#### 1. Structural changes

Studies have concluded that edentulism exerts some structural changes such as craniofacial changes, and lower facial height (Tallgren 1972; Williams and Slice 2014). Resorption process of alveolar bone starts after tooth loss and continues throughout life. Intraorally, this process leads to a decrease in the width and height of the alveolar ridge (ridge resorption or atrophy) (Cawood and Howell 1988). Extraorally, the process of resorption results in a decrease in facial height. Consequently, prognathism; "forward position of the chin in relation to upper part of the face" will occur and this will alter facial appearance (Tallgren 1972; Araújo et al. 2005). The degree of residual ridge resorption among edentulous patients (mean age is 74 years), which had been assessed through analysis of panoramic radiograms found to be greater in mandibular than maxillary jaw, and correlated to the duration of edentulism (Zmysłowska et al. 2007). For this reason, most patients wearing lower conventional complete dentures are possibly suffered from poor denture stability and, subsequently poor denture retention (Jahangiri et al. 2015). Residual ridge resorption is an unavoidable consequence of tooth loss and subsequent rehabilitation with dentures. It is enhanced by different factors such as gender, ageing, duration of edentulousness, denture wearing habits, absence of physiological stimuli, occlusal load and forces from cheek and tongue, an inadequate blood supply to the bone (ischemia), composition of the bone (mineral density), and type of jaw (upper or lower). However, no one of these factors was found to be more influential (Carlsson 1998; Eiseman et al. 2005). It seems that ridge resorption is the result of the contribution of different factors. When upper and/or lower ridge resorption continue, the prognosis of having successful complete dentures in place become poor resulting in deteriorating effects from aesthetic, functional and psychological perspectives.

#### 2. Functional impairment

It is a known fact that teeth are essential in cutting of food and preparing it for digestion. The number of functioning teeth in each jaw is considered a key determinant of oral health status (Hashimoto et al. 2006; Gotfredsen and Walls 2007) and masticatory ability, performance and efficiency (Fontijn-Tekamp et al. 2000; Sheiham and Steele 2001). Therefore, a lack of all teeth results in chewing difficulty, consequently, alteration of the process of digestion of some foods occur (Farrell 1955). Edentulous people are regarded as functionally disabled persons in comparison with dentate people, and even those wearing complete dentures suffer from lower chewing efficiency in comparison with those who have natural dentition (Haraldson et al. 1979). This disability is arguably attributed to the reduced chewing cycles, bite force, and muscle activity (Piancino et al. 2005). Although a structural change in chewing muscles is induced by aging, a reduced chewing function due to edentulousness is also pivotal (Newton et al. 1993). For example, computed tomography for edentulous people showed a decrease activity or bite force, decreased density and subsequent atrophy of masseter and medial pterygoid muscles (Newton et al. 1993; Raustia et al. 1996). This atrophy could be partly responsible for inability of edentulous people to chew hard food (Emami et al. 2013). A recent study to measure the thickness of masseter muscle using ultrasonography found that the thickness was reduced before wearing complete denture; however, three months after insertion of complete dentures, the thickness was increased, but it remained small in comparison with dentate individuals (Bhoyar et al. 2012). Chewing disability of denture wearers is often enhanced by several factors such as low physical retention of the dentures, unstable dentures, and if there is pain in the denture bearing tissues due to denture displacement during eating (Müller 2014). The negative effect of these factors are more obvious in lower dentures due to small denture bearing area (Müller et al. 2001b). Because of chewing difficulty, most denture wearers try to modify the process of eating, which could alter the process of food selection and limit food intake and, potentially nutritional intakes (Millwood and Heath 2000; Feine and Lund 2006). Apparently, the reduced masticatory performance and chewing ability associated with edentulousness are the main factors, which responsible for the functional impairment among edentulous people.

### 3. Psychosocial aspects

It is generally accepted that edentulism has an impact on an individual's life psychologically and socially (Smith and Sheiham 1979; de Baat et al. 1997; Carlsson 1998). Likewise, most

patients feel unprepared for tooth loss and its consequences, in which sadness, depression, feeling of losing body part, feeling of aging were the most emotional effects following tooth loss (Okoje et al. 2012). Personality of edentulous individuals may have an influence on the psychological response to tooth loss and denture wearing (Allen and McMillan 2003a). Though most patients are adapted to edentulism and subsequent wearing complete dentures physically, they are emotionally affected (Fiske et al. 1998). Those who do not cope well with edentulism are classified as "maladaptive". Three classes of maladaptive responses to edentulism and subsequent wearing denture and subsequent et al. 1988):

- "Class 1: patients who can adapt physically but not emotionally".
- "Class 2: patients who cannot adapt physically or emotionally".
- "Class 3: patients who cannot and do not wear dentures, who are chronically depressed, and who isolate themselves from society".

Various themes as a reaction to the tooth loss were identified among edentulous patients. These are 'feeling of bereavement', 'loss of self-confidence', 'concerns about appearance', and 'self-image', 'keeping tooth loss a secret', 'seeing it as a taboo subject that could not be discussed with people', 'concern about dignity', 'altered behaviour in socializing and forming close relationships', and 'premature aging' (Fiske et al. 1998; Okoje et al. 2012). Unsurprisingly, these feelings and reactions also exist in denture wearers (Davis et al. 2000), and could have a negative effect on the psychosocial well-being of patients, and the social interaction with other people (Fiske et al. 1998). Edentulism can restricts certain activities such as food choice, enjoyment of food, laughing and eating in public, and social interaction (Davis et al. 2000). Moreover, most edentulous patients, who believed that instructions about the importance of natural teeth were not explicitly explained by dental professions, expressed feelings of sadness, depression and anger. They might receive advice from their dentists, and they did not listen or they might have been anxious due to teeth extraction process, and finally and simply, they might not want to believe about the adverse effect of tooth loss (Newton and Fiske 1999; Davis et al. 2000). Therefore, dental professions should pay attention to an appropriate psychological preparation of the patient for the consequences of tooth loss prior to its extraction (Fiske et al. 1998) through explaining the importance of maintaining teeth, complications associated with edentulousness, and ways of overcoming these problems, particularly eating related difficulties. This could be achieved through establishing a good relationship between dentists and patients (Carlsson 2006). Establishing a rapport between patients and dental healthcare providers in addition to adopting a holistic approach could help

decrease the psychological consequences of edentulism and subsequent prosthetic rehabilitation, particularly with conventional complete dentures.

Evidence shows that social interaction among older people could improve physical and mental health, and establish friendships, which make the person able to face the crises and conflict in general (Rodrigues et al. 2012; Sarris et al. 2015). Moreover, social experiences have an impact on 'self-awareness', 'self-esteem', 'personal change', 'learning and satisfaction with life.' Furthermore, social participation could have a positive impact on older people's lives because it supports them socially, hence, the feeling of loneliness and abandonment is decreased (del Pino 2003; Rodrigues et al. 2012). Similarly, social support makes older people feel loved, have a high 'self-esteem', and be able to deal with health problems (del Pino 2003). Evidence also shows that edentulism possibly leads to social isolation and preventing edentulous people from participating in social events in which food is likely offered (Karuza et al. 1992; Rodrigues et al. 2012). Thus, the social behaviour of edentulous people will be affected due to the lack of confidence and ability to eat with others (Jahangiri et al. 2015). In addition, edentulism has an impact on a person's capability to relate or connect to one another, and this loss of interrelation may have an effect on person's lifestyle because of a difficulty to communicate with others could lead to loneliness and isolation, depression, and sadness (Srisilapanan and Sheiham 2001; Heinonen et al. 2004). Rodrigues et al. (2012) concluded that the lack of social participation is significantly associated with edentulism, which resulted in 40% loss in the quality of life among older edentulous people aged 60 years and over. It has been suggested that the social and emotional effects of tooth loss on dentures tolerance is greater than the problems arising from the dentures themselves (Okoje et al. 2012). While it is likely to overcome the impairment and disability caused by edentulism through improvement of techniques of complete dentures construction, the issue of handicap "describes broader social effects, such as minimized contact with other people" has not been given much attention (Allen and McMillan 2003c), particularly among conventional complete dentures wearers. Therefore, it is important to focus on how edentulism and subsequent rehabilitation with complete dentures could influence these social and emotional issues among older people to help them overcome problems arising as consequence of such issues.

## 2.1.6 Edentulism and Quality of Life (QoL)

Quality of life (QoL) is a broad term which includes different concepts such as health status, function, and life conditions (Emami et al. 2013). According to the World Health Organization Quality of Life Assessment group (1995), quality of life can be defined as

"individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns". Sometimes, it refers to indirect consequences of diseases such as unemployment or financial difficulties (Fayers and Machin 2013), and is considered as a useful parameter to assess individual's physical and mental health, including oral health (Sischo and Broder 2011). QoL is partially affected by a compromised oral health (Emami et al. 2013); for example, edentulism negatively affects individual's life in different aspects such as eating, physical and mental wellbeing and pleasure in participating in an active social life (Lee et al. 2004; Hugo et al. 2007). Trulsson et al. (2002) interviewed edentulous patients aged 58-86 years and identified several themes which explain the impact of edentulism on the quality of life. These themes include 'Alterations in self-image'; 'becoming a deviating person'; becoming an uncertain person'; 'becoming the person I once was', and 'Alterations in selfimage.' Such findings highlight the importance of exploring the effect of edentulousness on the QoL of the edentulous individuals. Edentulism and subsequently, prosthodontic rehabilitation with complete denture are probably associated with functional disability, which could negatively affect the physical and psychological wellbeing of older people, which in turn may affect oral and general health (Rodrigues et al. 2012).

### 2.1.7 Edentulism and general health

Evidence has been accumulated supporting the mutual relationship between oral and general health, functioning and well-being (Kandelman et al. 2008; Felton et al. 2011; Emami et al. 2013; Kailembo et al. 2016). Studies show that socio-demographic characteristics such as increasing age, being female, living in rural areas, less education, lower social class and lower socioeconomic status along with accompanying lifestyles and health behaviours are predictors of edentulism (Vargas et al. 2003; Pallegedara and Ekanayake 2005; Starr and Hall 2010b; Dogan and Gokalp 2012; Gaio et al. 2012b; Russell et al. 2013). Moreover, studies also reported that tobacco smoking (Arora et al. 2010; Northridge et al. 2012a), alcohol consumption (Kim et al. 2014), inadequate consumption of fruit and vegetables (Petersen 2003b; Tsakos et al. 2010; De Marchi et al. 2011a) and infrequent dental visits (Dogan and Gokalp 2012) are behavioural risk factors for edentulism. Furthermore, studies also observed associations between periodontal diseases and NCDs such as type II diabetes (Kowall et al. 2015), angina pectoris (Medina-Solis et al. 2014), hypertension (Ayo-Yusuf and Ayo-Yusuf 2008) and respiratory (Scannapieco 1999) and cardiovascular diseases (Mattila et al. 2000; Petersen and Yamamoto 2005). Since periodontal diseases are the main causes of tooth loss among older people, there is an association between edentulism and NCDs. Nonetheless, all

these associations differ according to the characteristics of the populations being studied (Mattila et al. 2000; Kailembo et al. 2017). Edentulism and NCDs share several social and behavioural risk factors; for example, smoking increases the risk of periodontal diseases, tooth loss and lung cancer (Sheiham and Watt 2000; McGrath et al. 2009). Ageing and low socio-economic status are other risk factors for both edentulism and NCDs (Kailembo et al. 2016; WHO 2018). Evidence suggests that consuming an unhealthy diet is linked to multiple oral (e.g., dental caries, which is the main cause of tooth loss) and general (e.g., cardiovascular diseases, type II diabetes and cancers) conditions. For example, Felton et al. (2011) reported an association between increased risk of cardiovascular diseases and edentulism among women due to high intake of food rich in fat, trans-fat and cholesterol, and low intake of fibre, vegetables and fruits. However, the mechanisms linking poor general health and edentulism are not clear (Emami et al. 2013). It is likely that the poor lifestyle and consuming an unhealthy diet lead to increase the risk of both edentulism and NCDs. However, edentulism could be a factor but not a cause of NCDs. Such association between edentulism and NCDs is attributed to deleterious effect of edentulism on eating and nutrition, which possibly affect general health (Ritchie et al. 2002). It could be argued that edentulous people with low socio-economic status already have questionable diet before being edentulous; hence, they may not be motivated enough to eat healthy foods as they have never tried healthier food before. Edentulism is also associated with obesity (Hung et al. 2005; Osterberg et al. 2010) and obesity related diseases (e.g., insulin resistance, cardiovascular disease, and hyperlipidaemia) (Touger-Decker et al. 2014). In order to overcome functional problems or difficulties associated with edentulousness, edentulous people tend to change eating style by choosing soft foods (rich in fat and trans-fat) and avoiding hard foods (fruits and vegetables) due to many reasons mainly chewing difficulties associated with edentulousness and its consequences. This could lead to increase the risk of obesity. It seems that edentulism has a negative sequence on food intake, food selection and possibly nutritional due to the functional limitations. This could increase the risk of NCDs and obesity related chronic diseases among frail older edentulous people, who already at risk of developing systemic diseases. Other factors such as acute and chronic diseases, gastrointestinal disturbances, functional problems, psychosocial factors, and socioeconomic level are also crucial in terms of food intake and nutritional status among those people (Walls and Steele 2004b; Emamverdizadeh and Barzegar 2011).

## 2.1.8 Edentulism and Oral Health Related Quality of Life (OHRQoL)

The term OHRQoL is commonly used to describe a subgroup of health-related quality of life referring to the orofacial area (Al-Jundi et al. 2007). It is relatively a recent phenomenon which has appeared over the last four decades, and has grown in a rapid manner (Al Shamrany 2006). As patient's perceptions are important as other clinical indicators of oral health status, therefore during assessment of oral health needs and measurement of outcome of oral conditions, evaluation of such perceptions is crucial (Leao and Sheiham 1996; Slade 1997a; Bryman and Burgess 2002; Al Shamrany 2006; Al-Jundi et al. 2007; Khalifa et al. 2013). Hence, OHRQoL has been used to explore the impact of oral health disorders such as loss of natural teeth, and possible treatment options; for example, rehabilitation with dental prosthesis on different aspects of life in several clinical studies (Slade and Spencer 1994b) (Heydecke et al. 2002; Heydecke et al. 2004; Viola et al. 2013). It evaluates some factors; for example, personal ability to function, psychological state, social factors, pain and discomfort, which might be affected by oral conditions (Inglehart and Bagramian 2002). The OHRQoL for edentulous patients has been assessed by many researchers (Scott et al. 2006; Ellis et al. 2007; Emami et al. 2010; Souza et al. 2010), who highlighted a clear association between edentulism and OHRQoL. There is a correlation between tooth loss or edentulism and a decrease in OHROoL (Steele et al. 2004; Jain et al. 2012; Batista et al. 2014; Hewlett et al. 2015). This is apparently related to the functional limitation associated with edentulism and subsequent rehabilitation with complete dentures (Koshino et al. 2006). Although ISODs offer a significant improvement in functional and consequently, OHRQoL than conventional dentures (Melas et al. 2000; Pan et al. 2014; Fernandez-Estevan et al. 2015), neither prosthesis show a superiority against natural dentition in terms of OHRQoL (Allen and McMillan 2003a).

#### 2.1.9 Management of edentulism

Different treatment modalities have been used to manage complete edentulism such as Implant Supported Over Dentures (ISODs), implant supported Fixed Dental Prostheses (FDPs) and Complete Dentures (CDs) (Kawai et al. 2005; Harris et al. 2013; Tajbakhsh et al. 2013). With ISODs, retention of the prosthesis can be achieved using magnets, clips, bars and balls (Doundoulakis et al. 2003). Whilst upper dentures are often retained by 4 implants, the 2002 McGill consensus conference concluded that the standard of care for edentulous mandible is an overdenture retained by 2 osseointegrated implants (Feine et al. 2002; Thomason et al. 2009b). Implant supported Fixed Dental Prostheses are often fabricated after

implant fixtures are successfully placed and abutments are connected (Takaba et al. 2013). Countries differ in utilization of dental implants. For example, Israel has the greatest use of implants in which the number of implants each year per 10,000 people is 230 implants followed by South Korea and Italy (180) then Spain and Switzerland (140). United Kingdom has a lower proportion (20) in comparison with above mentioned countries (Misch 2014), possibly due to limited funds for this type of treatment on the NHS system. Studies mentioned that implant supported prosthesis are substantially better than conventional dentures in terms of appearance, function, oral health related quality of life and satisfaction (El-Feky 2007; Thomason et al. 2009a; Ellis et al. 2010; Johannsen et al. 2012). However, the need for conventional complete dentures will continue in the distant future (Kawai et al. 2005). This belief appears to be attributed to many reasons, mainly the lack of access to the dental care and the high cost of implant supported prostheses (Albrektsson et al. 1988; Mack et al. 2002; Kawai et al. 2005), and fear from surgical procedure associated with ISODs in addition to the fact that not all patients are suitable for implants due to resorption of the alveolar bone needed to fix the implant (Walton and MacEntee 2005; Ellis et al. 2011). Therefore, this research focuses on provision of conventional complete dentures because this is a treatment offered on National Health Services (NHS) and mostly associated with problems and challenges to the patients. Perhaps, due to poor stability and retention associated with this type of dental treatment, particularly lower denture, which may impose certain functional and chewing difficulties that have a negative effect on individual's life.

#### **Conventional complete denture**

A conventional complete denture is considered as the most common and inexpensive type of treatment used for edentulous patients (Doundoulakis et al. 2003; Anastassiadou and Robin Heath 2006). This type of dental prosthesis has been recommended as a method of rehabilitation for edentulous people to overcome the disability associated with edentulism (Heath 1982; Mojon and MacEntee 1994; Macentee et al. 1997). It can be defined as "artificial prostheses which substitute for missing natural teeth and soft tissues, and held in place by adhesion and cohesion on supporting tissues" (Jahangiri et al. 2015). The function of 'mucosa-borne dentures' is essentially based on denture retention which is dependent on various mechanisms (Müller 2014):

• Physical suction mechanism, which is gained during impression taking (through selective tissue compression) or during creation of a posterior palatal seal (tracing process).

- Muscular activity, which plays essential role in keeping the denture fit to the residual ridge during eating. The activity of mastication muscles undergo reduce with ageing or due to certain oral conditions such as edentulism, and this could negatively affect the eating with dentures.
- Occlusion, which keeps upper and lower dentitions meet in static or dynamic contact. Clinically, the issue of occlusion becomes evident when a patient cannot wear his antagonistic denture due to surgical removal of lesions (cyst or tumour), or if the patient cannot wear one of his dentures merely because of it is uncomfortable.

Usually, conventional complete dentures are often constructed by either a traditional or a simplified method (Figure 2.1), and patients requiring conventional complete dentures typically visit the dental clinic six times before getting their dentures inserted in their mouths. While the success rate of any conventional complete denture depends upon the contribution of three person; the dentist, the dental technician, and the patient (Basker et al. 2011), emphasizing on patient's contribution is of great importance. This is because conventional complete dentures may impose certain limitations (e.g., eating related problems) on edentulous patient's life which make the adaptation of the patient to the denture is difficult, consequently the patient may set the denture aside. As adopting holistic approach in clinical dentistry and establishing a rapport between dental health care providers and edentulous patients are fundamental in terms of clinical success (Carlsson 2006). It could be argued that such relationship could reduce social and emotional instability related to eating with complete dentures through addressing the psychological consequences of edentulism and subsequent denture wearing. Moreover, involving patients and their families in improving health care services has evolved to give the patients a voice about their care and treatment (Bate and Robert 2006). However, understanding the importance of patient-centred care might not be fully established among most dentists and DCPs. National Institute for Health and Care Excellence (NICE 2013) reported that 'Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. Treatment and care should take into account individual needs and preferences.' Therefore, it could be argued that involving edentulous people in any future research about eating with complete dentures will be beneficial in improving healthcare and supporting well-being of edentulous people.





## 2.1.10 Limitations of conventional complete dentures

The standard of care for most edentulous patients is to maintain adequate oral function, appearance and comfort; insure a good OHRQoL and wellbeing, and provide a convenient dental treatments (Müller 2014). Unsurprisingly, for most edentulous people, wearing complete dentures, particularly of a conventional type, is a complex issue in terms of comfort,
function, and maintaining adequate quality of life (Berg 1993; Müller 2014). For example, most edentulous patients find that their complete dentures are upsetting, and this feeling is increased with age (Basker et al. 2011). Although conventional complete denture replaces most of lost oral structures, its success rate depends on patient's adaptation or tolerance to such type of treatment (Jahangiri et al. 2015). This adaptation is mainly restricted by functional problems such as chewing difficulty (Hartsook 1974; De Souza e Silva et al. 2009), and ongoing residual ridge resorption (Atwood 1971; Bergman and Carlsson 1985; Divaris et al. 2012), particularly in mandibular arch (Tallgren 1972) followed by instability and poor retention of the denture (De Grandmont et al. 1994; De Souza e Silva et al. 2009). In addition, the mucosa underling dentures may be ulcerated and denture induced hyperplasia may develop resulting in pain and soreness (Albrektsson et al. 1987), which may lead to further dietary restrictions (Allen and McMillan 2003c).

The importance of muscular retention becomes more obvious as physical retention decreases, and this retention depends on the ability of the patient to learn skills which help keep the denture fit in place during eating (Müller et al. 2001a). With time, muscles and other structures (e.g., temporomandibular joint) are affected by wearing dentures and ageing. Loosening of the bulk of chewing muscles, and weakening of the ligaments of the temporomandibular joint are not uncommon conditions among denture wearers (Newton et al. 1993). Moreover, a reduced motor coordination along with ageing also has an impact on chewing muscles, and subsequently on the chance of denture use, especially if it is accompanied with systemic diseases such as dementia (Taji et al. 2004; Müller 2014). These alterations are often more common among those wearing conventional complete dentures rather than ISODs. For example, patients with mandibular conventional complete dentures were found to have less bite force than those with implant-retained overdentures (Van Kampen et al. 2002; Ahmad et al. 2014; Elsyad et al. 2014) highlighting the importance of stability and retention of the compete dentures, in addition to the adaptation of muscles in improving oral function. Evidence reported that the stability and retention of complete dentures are essential for improving function and reducing eating difficulties (Scott and Hunter 2008; Rehmann et al. 2016). Therefore, many denture wearers use denture fixatives to stabilise their dentures during eating. This is because the denture fixatives can improve retention of complete dentures (Neill and Roberts 1973; Munoz et al. 2012; Yegin et al. 2017), masticatory efficacy (Cheng and Zhao 2010), patient satisfaction (Gendreau et al. 2009), food (i.e., fruit and vegetables) and nutritional (i.e., Vitamin C, saturated fat and protein) intakes (Bartlett et al. 2013) and OHRQoL (Nicolas et al. 2010) among denture

wearers. Denture fixatives; however, have some disadvantages. Using denture fixatives possibly increase a time required for maintenance or cleansing of dentures (Uysal et al. 1998). Moreover, the use of denture fixatives containing zinc can cause headaches, cramps, diarrhoea, loss of appetite, nausea, and vomiting (Duqum et al. 2012). Furthermore, misuse of denture fixatives containing zinc can result in high amount of zinc or 'hyperzincinemia', which associated with 'Myelopolyneuropathy' (a progressive neurological symptoms) (Hedera et al. 2009). Finally, although *in vitro* studies showed that using some denture fixatives cause microbial contamination such as fungal infection (i.e., *Candida Albicans*) (Gates et al. 1994), potential cytotoxic effect (Al et al. 2005) and mucosal irritation (Dahl 2007), no similar findings were found by *in vivo* studies (Kim et al. 2003; Oliveira et al. 2010; Ozkan et al. 2012). Seemingly, denture fixative are, sometimes useful in fixing dentures in the mouth during eating; however, concerns could be raised about their role in improving healthy diet and nutritional status. Moreover, issues such as bad taste and the possibility of melting of these fixatives during eating or drinking are needed to be explored further.

Interestingly, the risk of asphyxiation is probably increased among denture wearers due to improper mastication (Anderson 1977). For instance, an ill-fitting denture was found to be aspirated by 90 year-old woman (Arora et al. 2005) suggesting that monitoring loose dentures should be part of comprehensive geriatric assessment. Despite the limitations of conventional complete dentures, it has been argued that dentists will continue to provide this type of removable prosthesis for large proportion in the world (Douglass et al. 2002; Marchini 2014), particularly for those over 80 years of age (Zitzmann et al. 2008) in which intervention with ISODs is difficult or contraindicated. This is possibly due to effect of physiological age-related changes in oral tissues (e.g., resorption of alveolar bone), and presence of medical conditions (e.g., diabetes mellitus, osteoporosis, etc.).

#### 2.1.11 Patient satisfaction with conventional complete dentures

It is acknowledged that the success of any prosthetic treatment depends mainly on its clinical outcomes and a patient's satisfaction (Peltola et al. 1997; Heydecke et al. 2003b). Although clinical parameters such as techniques, quality of impressions, bite force, chewing capacity are important, patient's perception is essential in determining the success of any dental prosthesis (Peltola et al. 1997; Heydecke et al. 2003b; Weyant et al. 2004; Memon et al. 2013). Malli (2014) reported that although the dental staff responsible for the treatment is satisfied with this type of treatment, patient's satisfaction is the key factor which determines if the treatment is successful or not.

It has been argued that key determinants of denture satisfaction are psychological, biological, anatomical and constructional (Memon et al. 2013); nevertheless, the psychological and interpersonal factors are arguably more important than anatomic or clinical factors (Diehl et al. 1996). Measuring such subjective perceptions is fundamental during assessing the functional outcomes of the complete denture. Actually, using patient-based instruments or tools to measure patient's satisfaction is simple and inexpensive in comparison to the functional measures or clinical assessment (Feine et al. 1994; Awad et al. 2002; AlBaker 2013), and it is a valid method to access the patient's point of view, particular after denture replacement (Garrett et al. 1996; Ellis et al. 2007; Viola et al. 2013).

Dissatisfaction with complete dentures is not uncommon phenomenon among edentulous people (Heyink et al. 1986; Kovač et al. 2012). Studies report that most patients are dissatisfied with their conventional complete dentures (De Souza e Silva et al. 2009; Kovač et al. 2012; AlBaker 2013), or their satisfaction with conventional complete denture is less in comparison with ISOD (Pan et al. 2008; Turkyilmaz et al. 2010; Zembic and Wismeijer 2014; Martín-Ares et al. 2015). As a result of this dissatisfaction with CDs, some denture wearers try to modify their eating behaviour accordingly. They have problems with eating, speaking or singing, and even smiling, yawning, and kissing. Hand covering the mouth to avoid unacceptable smile and embarrassment during eating are epitomes of such behavioural changes (Davis et al. 2000). Müller (2014) stated that "complete denture wearers may refrain from singing in a choir, reduce their sports activities and go out less often to see their family and friends". He, also, concluded that those patients with problem in adaptation their dentures often avoid eating outside their home (e.g., in restaurants or any other public places) with their friends or relatives due to eating difficulties associated with dissatisfied dentures. Hyland et al. (2009) stated that social and emotional issues around eating with dentures are a major concern for denture wearers. Heydecke et al. (2006) reported that complete denture wearers feel difficulty in yawning, uneasy kissing, and uneasy during sexual activity. Moreover, there is also gender difference regarding patent's satisfaction with dentures. For example, Pan et al. (2008) found that older women were more dissatisfied with their CDs than older men. Furthermore, patient's satisfaction may also affected by patient preference for certain type of prosthetic treatment (Allen et al. 2001). If patients being forced to choose CDs rather than ISODs for any reasons such as low income, they may feel dissatisfied with their dentures. In order to overcome different problems associated with wearing CDs (e.g., satisfaction, functional, and other eating related difficulties) mong most patients, denture replacement is often the treatment choice to help improve chewing activity and consequently selection of

food, enjoyment of eating, and speaking (Garrett et al. 1996; Kapur et al. 1998; Ellis et al. 2007; Viola et al. 2013). The denture replacement is associated with improvement of not the clinical outcome only but patient's satisfaction as indicated by the literature (Peltola et al. 1997). It appears that as with other dental prosthesis, the success of conventional complete denture depends mainly on the patient's satisfaction, which is probably, enhanced through replacement of the old dentures with new set of dentures.

#### 2.1.12 Denture replacement and oral health

Research has explored the effect of denture replacement on different oral health outcomes such as clinical outcomes, functional aspect, patient satisfaction, and OHRQoL. Denture replacement can lead to improvement in chewing ability (Ellis et al. 2008), and associated with improvement of not the clinical outcomes only, but the satisfaction among denture wearers (mean age 59 years) (Peltola et al. 1997). The authors assessed the effect of denture replacement on oral health subjectively (through evaluation of patient's satisfaction and function of dentures by a questionnaire) and clinically (through clinical examination of the condition of the mucosa, occlusion, and stability of dentures) at follow up of 30 months. Similarly, Ellis et al. (2007) concluded that oral health-related quality of life and patient satisfaction were improved when patients provided with new dentures regardless of the technique used to fabricate these dentures. Researchers, also, measured the magnitude of change in OHRQoL before and after placement of new complete dentures, and their findings were contradicted. Several studies concluded that denture replacement cannot improve OHRQoL in which patients might not have major problems in wearing dentures before treatment, so they just noticed a slight overall effect on OHRQoL after denture replacement (Forgie et al. 2005; Scott et al. 2006). Other studies showed that intervention with conventional complete dentures helped edentulous people to improve OHRQoL (Souza et al. 2007; Zani et al. 2009; Sato et al. 2012; Viola et al. 2013; Madhuri et al. 2014). This contradiction might be related to methodological (e.g., sample size, age of participants, type of oral health measures used) and cultural differences. Whether or not edentulous patients have eating difficulties or problems before treatment, in addition to their expectation levels could affect their scores after treatment with new dentures. All of the studies that mentioned above have explored the effect of denture replacement on functional aspect, clinical outcomes, patient satisfaction, and oral health related quality of life. However, no research to date has looked at to see if prosthetic rehabilitation with complete dentures (the NHS form of treatment) has any impact on ERQoL, and that one way to do this would be to use a cohort design.

#### 2.1.13 Edentulism, complete dentures, diet, and nutrition

It is common that complete tooth loss, and subsequently prosthetic rehabilitation have a direct influence on functional activities, thereby they may affect dietary intake, and potentially nutritional status (Johansson et al. 1994; Joshipura et al. 1996; Sheiham et al. 1999; Lee et al. 2004). Moreover, a correlation was found between edentulousness and both a low intake of food such as fruits, vegetables, wholemeal breads, cereals, and grains (Shinkai et al. 2002a; Nowjack-Raymer and Sheiham 2003; De Marchi et al. 2011b), and a low intake of nutrients such as dietary fibre, lipid, carbohydrate, vitamins (C and B6), and calcium (Moynihan et al. 1994; Fontijn-Tekamp et al. 1996; Marshall et al. 2002; Nowjack-Raymer and Sheiham 2003; Cousson et al. 2012). Such findings are obvious in studies that compare the impact of tooth loss on dietary intake between edentate and dentate people. For instance, a reduced chewing ability and lower fruit and vegetable consumption were found in edentulous individuals in comparison with dentate individuals (Bradbury et al. 2008). Makwana et al. (2014) reported a direct relationship between edentulousness and under nutrition in which the risk of under nutrition was eight times higher in edentulous people (aged 60-80 years) in comparison with dentate individuals in India. A 24 hour Diet Recall and Food Frequency Form were used to collect data on food consumption, then these data were analysed after conversion it to the 'calorie content of the diet' and 'the percentage of Recommended Dietary Allowance' (RDA). According to this analysis, the authors found that 34% of edentulous participants were detected at high risk of under nutrition, and for more than 50% of them, the calorie intake per day in percentage of RDA was less than 75%. The study also reported that 16% of edentulous subjects were obese, but this percentage was less than those who were undernourished. The finding of this study is with line of other studies, which concluded that edentulous individuals with no or one denture had a high risk of under nutrition due to the negative impact of edentulousness on eating different food items and a lack of energy and protein (Lamy et al. 1999; De Marchi et al. 2008; De Marchi et al. 2011b; Furuta et al. 2013). It could be argued that the majority of older people live in care homes and they might have multiple oral and systemic issues, which could affect the total food intake. It is likely that the care homes is a factor in that some could not eat the foods being provided. It is likely that the tooth loss limited the intake of all foods. Total tooth loss limiting total food intake (possibly due to chewing difficulties), which can contribute in part to undernutrition. In addition, since the cause of malnutrition is usually multifactorial, the role of other factors such as the effect of ageing and cognitive disability, the degree of muscular atrophy, dietary habits and socioeconomic factors should not be ignored.

There is no strong evidence regarding the impact of prosthetic rehabilitation of completely edentulous patients with complete dentures on nutrient intakes. Prosthetic rehabilitation of missing teeth with different prosthesis such as complete dentures could help mitigate some of eating problems, but not all of them, and the evidence that diet improves when an edentulous patient receives prosthodontic treatment had not been substantiated (Joshipura et al. 1996; Ettinger 1998; Krall et al. 1998). For instance, evidence shows that the intake of non-starch polysaccharides, protein, calcium, iron, niacin and vitamin C in complete denture wearers is less compared with dentate individuals (Sheiham et al. 2001a; Tsakos et al. 2010). Studies also showed that older complete denture wearers (mean age 70.1) were at high risk of under nutrition in comparison with dentate subjects (Cousson et al. 2012). Moreover, the intake of different food items (e.g., vegetables, fruits, and fibres), food choice, was not improved after denture replacement among edentulous patients (aged 52-77 years) (Allen 2005). A similar conclusion was reached by (Shinkai et al. 2002b; Wöstmann et al. 2008) in which dietary intake was not improved after wearing complete dentures. Madhuri et al. (2014) conducted a non-randomized intervention study among edentulous people aged 50 years and above receiving new complete dentures. Chewing ability questionnaire was used to assess the chewing ability, and a 'food intake questionnaire (eight questions) and one day diet chart' at different intervals (bassline, three, six, and twelve months), along with Body Mass Index (BMI) were used to assess the nutritional status. The study showed that insertion of conventional complete dentures were found to be helpful in improving chewing ability and food intake among those edentulous people. There was no significant difference in the nutritive value of food (protein, energy and fat) after 12 months interval indicating a possibility of developing a malnutrition in the future. However, a high level of nutrients intake (potassium, niacin and vitamin C.) found among edentulous patients (65 years and above) wearing complete dentures in comparison with edentulous individuals with no dentures (Han and Kim 2016). In this study, a 24-hour dietary recall used to collect nutrient intake data. However, data of this retrospective study was a part of national health and nutrition examination survey in South Korea. Therefore, it is unlikely that a one-day data obtained by the 24-hour dietary recall represented the whole foods and beverages intakes of participants in this survey. Moreover, it was not clear whether a person with expertise in nutrition assessment (e.g., dietician or nutritionist) did the assessment of nutrient intakes indicating that findings of this study might base on non-validated way of assessing diet. It seems that the majority of studies show that rehabilitation improves perceived chewing ability, but does not improve diet highlighting the importance of delivering dietary advice or intervention for complete denture wearers. While it is usual to find some denture wearers have

an improved oral function in comparison with edentulous people with no dentures, the decrease in the consumption of certain types of food such as vegetables and fruits could be attributed to chewing difficulties, and subsequently, eating difficulties. These eating problems could lead to avoidance of such food items by the denture wearers, who have dentures with poor stability and retention. However, researchers argued that eating difficulties or avoidance of certain types of food due to edentulism and subsequent prosthetic rehabilitation does not always mean that there is a nutritional deficiency, but it could be related to other issues (e.g., personal preference, enjoyment of certain types of food, and individual's satisfaction during eating with dentures) (Moynihan et al. 2009). It appears that edentulism has a negative impact on life of edentulous individuals in terms of food choice and but not necessarily nutrient intakes. Prosthetic rehabilitation with complete dentures will only resolve some of these problems (but is unlikely to improve the healthiness of the diet in the absence of dietary counselling using behavioural change techniques), as wearing dentures, particularly the conventional type has not only positive, but negative effects on human's life; nevertheless, wearing dentures is better than no dentures at all. The relation between edentulism and subsequent prosthetic rehabilitation, and diet is quite complicated and difficult to understand since there are many interrelated factors, which influence the process of eating such as personal choice, enjoyment of food, and satisfaction. In addition, other issues (e.g., social and emotional) related to eating with dentures need to be explored and addressed because wearing complete dentures might influence such issues.

## 2.1.14 Complete Dentures and Eating Related Quality of Life (ERQoL)

The generic term; OHRQoL has been used in many studies to show the impact of oral conditions and their treatment on individual's life (Heydecke et al. 2002; Heydecke et al. 2004; Walls and Steele 2004b; Harris et al. 2013; Viola et al. 2013). Likewise, a specific term; ERQoL seems to be more appropriate and sensitive for detecting the actual impact of oral conditions and their consequences (e.g., tooth loss and subsequent rehabilitation with complete dentures) on issues around eating (e.g., social and emotional issues). This term was firstly used in a qualitative study to explore patient's perception of how conventional and implant supported over dentures impact on eating (Hyland et al. 2009). According to the authors "the concept of ERQoL, has been identified by the patients within this study." It is related to information on eating difficulties, food choice and avoidance, enjoyment of food, and social interaction process associated with edentulousness (Moynihan et al. 2009). Although there are many factors such as social, demographic, sensory, economic, cultural, and behavioural interacting to influence the selection of food by people (Joshipura et al. 1996;

Krall et al. 1998; Sheiham et al. 1999; Marshall et al. 2002), loss of natural teeth and subsequent prosthetic rehabilitation, particularly with complete dentures, are considered to be the most important factors that associated with changes in food choice (Carlos and Wolfe 1989; Slade and Spencer 1994a; Allen 2005). Edentulous patients tend to choose softer and more easily chewed foods potentially higher in saturated fats and free sugars, and lower in fibre diet and less nutrient dense (Wayler et al. 1984; Moynihan et al. 1994; Hung et al. 2003; Allen 2005). This type of food selection behaviour could adversely affect the enjoyment of eating food, which considered to be 'one of the nicest things we do' (Macentee et al. 1997; Lee et al. 2004). Lamy et al. (1999) argued that being edentulous with or without dentures decreases eating pleasure. Likewise, the self-consciousness and embarrassment experience when eating with dentures might have a negative influence on social contact of older individuals, subsequently, this might lead to the problem of social isolation from the community (Trulsson et al. 2002; Hyland et al. 2009) or those people could avoid eating in the care situation where social dining is the norm or compulsory. Consequently, this could increase the risk of having depressive symptoms.

Data that have been obtained from qualitative studies are fundamental to explore and provide a detailed information about patient experiences and views during eating with dentures which could have a negative impact on patients' lives (Trulsson et al. 2002; Hyland et al. 2009). Perhaps, this impact or eating difficulty is greater than clinical outcomes and the expectation or judgment of clinicians (Kelly et al. 2012). However, several qualitative studies have reported on eating with dentures (Sheiham et al. 2001b; Trulsson et al. 2002; Hyland et al. 2009). The social and emotional issues around eating with dentures or ERQoL were discussed by Hyland et al. (2009), who conducted a qualitative study to explore the impact of wearing ISODs and CDs on ERQoL. The study concluded that the functional limitations of complete dentures have a negative impact on food choice, enjoyment of food/eating and social interaction with others. However, there is much less information on the impact of optimising complete dentures on ERQoL, and far too little attention has been paid to this aspect. Enjoyment of food is very important in later life since most people have to be enjoying eating to eat well. In addition, there is little point giving nutritional advice if the basic nutrition and eating is difficult. Thus, for further understanding of the actual impact of wearing complete dentures on ERQoL, and based upon the qualitative data from Hyland et al. (2009), an instrument (ESIRE questionnaire) was developed (Kelly et al. 2012). The ESIRE questionnaire was designed to collect data on issues around eating with dentures such as emotional and social, which considered as essential in relation to the health and well-being,

particularly for older people (see section 4 of the literature for further information on the ESIRE questionnaire). Therefore, using this questionnaire to conduct a cohort study to determine how denture replacement influence ERQoL can be useful. This can be important, particularly, for conventional complete dentures, which has the potential to exert more eating problems and less satisfaction in comparison with other types of dentures such as ISOD. Such a study would provide information on whether edentulous patients require, in addition to the denture replacement, advice or intervention about eating with complete dentures. Any advice or intervention to promote healthier eating would be able to consider how denture replacement influences issues around eating.

#### 2.1.15 Conclusion

As seen in this section, edentulism is still prevalent globally. Edentulism has adverse effect on general health, OHRQoL, and ERQoL. Similarly, prosthetic rehabilitation of edentulous people with different treatment modalities, particularly conventional complete denture resulted in increased patient's satisfaction and, sometimes, OHRQoL. The majority of studies show that prosthetic rehabilitation improves perceived chewing ability, but does not improve diet. Edentulism seems to be a factor that can contribute to under nutrition but the association of edentulism to a poor diet low in fruits, vegetables and fibre is highly likely not to be causal. It is just an association based on the fact that edentulous people come from a population that have a less healthy lifestyle. So far, no study measured the impact of denture replacement on ERQoL. In other words, exploring whether insertion of new dentures can have a positive impact on patient enjoyment of food or eating, preparation of meals, and social interaction with others or not. This could determine whether there is need to administrate a dietary consultation or intervention for this group of edentulous people to help them enjoy and eat well with dentures or change their dietary behaviour. In order to develop such dietary advice or intervention, it is important to understand the concept of health behaviour change. Therefore, the next section discusses the concept of health behaviour change, particularly dietary behaviour change.

#### 2.2 Section 2: Health behaviour change

#### 2.2.1 Introduction

Considerable health conditions such cancer, lung and liver diseases, diabetes, obesity, and cardiovascular diseases have been caused by different risk behaviours such as smoking, alcohol consumption, poor diet, and low physical activity (Dixon 2008). Changing these risk behaviours or life style risk factors is important to improve the health status of people on individual and community levels (Dixon and Johnston 2010), and is regarded as a key factor in public health programmes or interventions (World Health Organization 2002). Thus, changing health behaviour is a key factor in determining an individual's health. Health behaviour can be defined as "any activity undertaken for the purpose of preventing or detecting disease or for improving health and well-being''(Norman and Conner 1996). In other words, it means stopping bad behaviours, which compromise the health (e.g., high intake of foods rich in saturated fat and free sugars), and adopting and maintaining healthier behaviours (e.g., high intake of vegetables and fruits), which promote health. Changing health behaviour is not a straightaway process. Health behaviour change involves interaction of multiple factors: personal or individual (e.g., beliefs, attitude, knowledge, hereditary background, proficiency); social (e.g., how individual interacts with his or her friends, family members, and the community); and environmental factors (e.g., person's surroundings such as workplace, school, local shops etc.). Evidence showed that health behaviour change interventions rely only on the individual or personal factor, and ignore the social and environmental factors are no longer effective (EUFIC 2014); therefore, to change behaviour, it is fundamental to consider all these factors together. Although changing an individual's behaviour is important (Hobbs et al. 2013), individual's behaviour change is difficult to attain or maintain (Carpenter et al. 2013; Dombrowski et al. 2014), and this probably because most intervention studies that aim at changing health behaviour either fail to maintain long-term evaluation for individuals under study or the effect of the intervention diminishes over the time (Curioni and Lourenco 2005; Dombrowski et al. 2010). Therefore, understanding 'behaviour' is essential for designing complex interventions (e.g., dietary behaviour change interventions). Complex interventions can be described as 'interventions that contain several interacting components such as number and difficulty of behaviours required by those delivering or receiving the intervention, number of groups or organisational levels targeted by the intervention, number and variability of outcomes, degree of flexibility or tailoring of the intervention permitted' (Craig et al. 2013). According to the Medical Research Council

(2000), complex health interventions can be developed through four phases (i.e., development, feasibility and piloting, evaluation, and implementation). Therefore, adopting the MRC framework in designing a dietary behaviour change intervention for edentulous people could increase intervention effectiveness. Such intervention could help denture wearers eat well with dentures. Michie et al. (2011a) designed a COM-B system (Capability, Opportunity, and Motivation of Behaviour), (Figure 2.2), which offers a model that helps to design an intervention to change the behaviour, in which three factors; capability, opportunity, and motivation interact simultaneously to influence health behaviour change. Capability refers to "the individual's psychological and physical capacity to engage in the activity concerned". Opportunity is "all the factors that lie outside the individual that make the behaviour, not just goals and conscious decision-making". Ideally, an intervention aiming at changing health behaviour should change all components of this system. It could be argued that using this model could increase our understanding of 'behaviour' further and providing a basis for designing effective eating advice or intervention for complete denture wearers.



Figure 2.2: The COM- B system: a framework for understanding behaviour. Adopted and reproduced from Michie et al. (2011a) with permission from BioMed Central Ltd.

#### 2.2.2 Theories and models of behaviour change

It has been argued that there is no dominant or independent theory to explain what is called 'behavioural nutrition education', which describe the interrelation between food or nutritionrelated behaviour, education, and intervention. Researchers have employed theories, or parts of theories (to inform nutrition education or dietary behaviour change) from related disciplines in the field of social sciences (Achterberg and Miller 2004). Health practitioners and researchers used theoretical frameworks as a mean to inform, evaluate and develop interventions designed to change the behaviour to an increasing extent (Michie et al. 2014). Such theories or models of behaviour change are essential for providing scientific clarifications of the procedures of behaviour change, demonstrating how, when, and why change happens (Michie and Johnston 2012) and improving the effectiveness of behaviour change interventions (Michie et al. 2008). Therefore, understanding of these theories and models is essential for developing effective interventions (Darnton 2008). There is a plethora of psychological models and theories, which explain how behaviour changes during intervention. Theory of Reasoned Action (TRA); Theory of Planned Behaviour (TPB); Stages of Change (Trans Theoretical Model) (SoC/ TTM); Health Belief Model (HBM); Social Cognitive Theory (SCT), and Self-efficacy theory are examples of the major psychological models or theories, which are commonly employed to explain, predict and facilitate health behaviours. However, this literature review focuses on Self-efficacy theory, Social Cognitive theory and Stages of Change (Trans Theoretical Model) due to their uses and effectiveness in dietary behaviour change interventions (Riemsma et al. 2002; van Sluijs et al. 2004).

#### **Self-efficacy theory**

The concept of perceived self-efficacy was introduced by Bandura (1977) as a key component of behaviour change or modification. It can be defined as "people's beliefs about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives" (Bandura and Wessels 1994). It refers to how personal beliefs, feelings, thinking and motivation can facilitate behaviour change (Bandura and Wessels 1994; Baban and Craciun 2007) highlighting the importance of the people's perceived capacity to adopt the healthier behaviour (Morris et al. 2012). Individual's beliefs about his or her efficacy can be acquired through 'mastery experiences' and experiences of other people depending on physiological indicators of the efficacy (Bandura and Wessels 1994). Literature considers the self-efficacy as a concept rather than theory. The self-efficacy is the key component of many behaviour change theories or models such as Health Behaviour Model, Trans-Theoretical Model and Social Cognitive Theory (Janz and Becker 1984; Baban and Craciun 2007; Heimlich and Ardoin 2008), and formed a main construct of different behaviour change intervention studies aimed to improving nutrition and weight control (Bagozzi and Warshaw 1990; Kelley and Abraham 2004; Miller and Gutschall 2009). Evidence suggests that using specific behaviour change techniques could boost the self-efficacy, which may act as a

mediator of the dietary behaviour change (Prestwich et al. 2014a); therefore, identifying such BCTs is important.

#### Social Cognitive theory

The Social Cognitive Theory proposes that changing human behaviour depends on interaction of the behaviour (e.g., action, habit) with additional two factors; internal or personal (e.g., influence on thoughts and action), and external or environmental (physical, socio-cultural) (Bandura 1986). In other words, individuals do not learn new behaviour exclusively by attempting them and either succeeding or not, but instead, the survival of humankind is reliant upon the replication of the activities of others. SCT is usually represented by two key notions; 'Self-efficacy', and 'outcome expectancies', which ''refers to the perception of possible consequences of one's actions'' (Baban and Craciun 2007).

#### **Stages of Change (Trans Theoretical Model)**

This model was developed and applied as a cognitive model to assess an individual's readiness to do a new healthier behaviour (Prochaska and DiClemente 1982). TTM proposed that in order to change the behaviour of an individual, the change process should involves six serial stages, (Figure 2.3) (Morris et al. 2012; Prochaska 2013). These stages are:

- Precontemplation (not ready): Individual is unaware of the problem and he has no intention to change behaviour in near future (with in the 6 months). This condition comes from either underestimation of advantages or overestimation of disadvantages of this change. Encouraging individual at this stage is necessary to make him more attentive of his decision.
- Contemplation (getting ready): Individual is aware of the problem and the serious consideration of change in behaviour and intend to take action within the next 6 months. He understands the pros and cons of this change.
- 3) Preparation: Individual at this stage is ready to start taking action within the next 30 days. Encouragement and support from family members and friends are very important. To maintain and keep progressing in this stage, people are likely to be adequately prepared.
- Action: Individual changed his behaviour, and modified his experience and/or environment to overcome problem for less than 6 months. Individual at this stage is encouraged to keep up his commitments towards changing.

- 5) Maintenance: Individual changed overt behaviour for more than 6 months, and he tries to prevent relapse and strengthen achievements. At this stage, it is highly recommended that individual try to gain support from other people who behave in healthy way and participate in a healthy activates.
- 6) Termination: No tendency to relapse and 100% confidence.

Movement or transition of each individual between stages of the intervention is controlled by two specific personal key factors which are; 'self-efficacy' and 'decisional balance' (the result of individual assessment of the advantages and disadvantages of the targeted behaviour) (Armitage et al. 2004; Heimlich and Ardoin 2008).



# Figure 2.3: Stage of Change. Adapted from (Morris et al. 2012; Prochaska 2013).

Although Trans-Theoretical Model and Social Cognitive Theory have been extensively employed in different dietary interventions (Norman et al. 2007; Prestwich et al. 2014b), TTM is more popular for use in dietary change interventions such as reductions in dietary fat (Armitage 2006), assessing of fruit and vegetable intake (Steptoe et al. 2003; Horwath et al. 2013), and evaluating fibre intake (Mau et al. 2001). Bhattarai et al. (2013) conducted a systematic review on interventions to enhance a healthy diet among adult people visiting primary health care, and found that the TTM is the most model used in these interventions. The extensive use of TTM in dietary behaviour change is attributed to its well-defined multiple stages (Spencer et al. 2007). Evidence shows that stage-based interventions were more effective that non-stage-based interventions when TTM was applied in interventions to reduce the dietary fat intake (Riemsma et al. 2002; Riemsma et al. 2003; van Sluijs et al. 2004), and increase fruits and vegetables intake (Bradbury et al. 2006b).

A meta-analysis of various internet-based health behaviour change interventions including dietary behaviour has concluded that the possible effect size of interventions using Trans-Theoretical Model and Social Cognitive Theory is generally low (Webb et al. 2010). However, evidence also shows that TTM is the most popular and convincing model of health behaviour change (Whitelaw et al. 2000; Jones and Donovan 2004), and this substantial popularity has come from its uses to change health behaviour by many clinicians and health practitioners (Herzog 2005). TTM probably has the ability to combine a broad area of information, and to be used as a model to design behaviour change intervention programmes for both; individual and community or population level (Taylor et al. 2006) or it could be due to its ability to impact people's motivation. However, Taylor et al. (2006) concluded that inadequate defining of stages and behavioural change objectives might occasionally decrease the effectiveness of TTM based interventions. Indeed, there is a lots of debate, which sometimes has reached 'an impasse' between the researchers regarding the effectiveness of Trans-Theoretical Model (Brug et al. 2005). Critics of TTM have criticised it by lacking the ability to validate the (Stage of Change) construct in relation to dietary habits, focusing on transitions from one stage to another rather than behaviour per se. A recent systematic reviews of interventions targeting healthy eating have concluded that TTM is not commonly used in the designing of such interventions, and when used, it might not lead to increase the effectiveness of these interventions (Prestwich et al. 2014b). The study also concluded that interventions used TTM and SCT were not superior than interventions used other theoretical models in terms of the effectiveness of the intervention. In general, TTM and SCT are the most widely used theories or models in dietary interventions, and TTM is the most extensively used model among clinicians and health practitioners due to its efficient components or stages, which are mainly driven by the perceived self-efficacy. Despite the absence of a conclusive evidence regarding the effectiveness of TTM in dietary interventions studies, it is still the most popular and preferable behaviour change model for many clinicians and health practitioners in the absence of evidence proves that there is another model superior to it. Other issues such as optimistic bias and ambivalence are also highlighted by researchers in social psychology to be sometimes, responsible for the decrease in the effectiveness of dietary interventions.

#### 2.2.3 Optimistic bias

The phenomenon of optimistic bias (unrealistic optimism or over-optimism) was described as 'the situation where people predict that a personal future outcome will be more favourable than that suggested by a relevant, objective standard' (Shepperd et al. 2015), and 'it occurs when people unduly predict that their personal outcomes will be more favourable than the outcomes of their peers' (Shepperd et al. 2013). This phenomenon has a clear health implications involving nutritional education and dietary behaviour change interventions (Bradbury 2002), and it has been considered as a contributing factor in hazards associated with different food-consuming habit (Shepherd 1999). For example, many individuals underestimate the probability of having a diet with high fat content in comparison to others (Gatenby et al. 1995). Some people consume low fruit and vegetable and regard themselves as 'high consumers' (Cox et al. 1998; Kearney et al. 2001). If individuals believe that they are already consuming a healthy diet and do not perceive themselves at risk, they will not have enough motivation to alter their diet (Bradbury 2002), and they will not consider the nutritional or healthy eating as a fundamental determinant in selection of their food (Cox et al. 1998). The later authors also argued that such groups of people might not be motivated by simple dietary recommendations. Therefore, dietary interventions are required in order to make the general population aware that the concept of that they already have a healthy diet rich in fruits and vegetables is not always is true (Cox et al. 1996). In order to change the attitudes of people who belief that their diet healthy (but in fact it is not healthy), it is preferable to alter their beliefs about the outcomes of dietary change (Paisley et al. 1995). Thus, one of the most important requirement to start dietary change is a perceived need to undertake change (Kearney et al. 1997). The lack of enthusiasm to change to healthier diet suggests a high level of optimistic bias (EUFIC 2005). Similarly, there is evidence to suggest that older adults (mean age 66 years) are less likely have the ability to change their beliefs than younger adults (mean age 22 years), and this leads to high level of optimistic bias among those older individuals (Chowdhury et al. 2014). Therefore, during implementation of dietary intervention, it is fundamental to pay an attention to the participant's power to change their beliefs and attitudes regarding each dietary item, encourage them to change these variables positively in order to decrease the chance of optimistic bias, and give them a feedback on their current diet.

#### 2.2.4 Ambivalence

Another possible reason for failure of dietary advice or intervention is ambivalence. It can be described as 'individuals hold positive or negative views concerning an attitude object'. It occurs when the attitude of individuals towards; for example, food and healthy eating is mostly ambivalent, but not 'clear-cut attitudes'. For example, individuals have ambivalent attitude when they are eating fast food with a high calorie content that often taste nice but are relatively less healthy. In addition to the attitude, individual's beliefs are likely mediated the influence on food choice. Beliefs about the effect of food and its nutritional quality on health are probably of great importance to determine the selection of food by individuals, and they are even more significant than the actual nutritional quality and its health consequences (Shepherd 1999). Again, eating fast food is an epitome of how people exhibit mixed feelings about certain types of food. It appears that individuals carry ambivalent behaviour and mixed feelings are unlikely to change their dietary behaviour; so, these issues or factors should be considered during development of any behaviour change intervention for denture wearers.

#### 2.2.5 Behaviour Change Techniques (BCTs)

Behaviour change techniques can be defined as 'the observable, replicable components of behaviour change interventions' (Wood et al. 2015), and reported to be the 'active ingredients' that bring about behaviour change and increase intervention effectiveness (Michie et al. 2011d; Michie and Johnston 2012; Michie et al. 2013). Using particular BCTs and theories are fundamental in terms of successfulness of any intervention (Lara et al. 2014a). Abraham and Michie (2008) argued that several techniques are usually applied in various types of behaviour change interventions, and operate differently in these interventions; thus, it is likely to be replicable. Moreover, combining and modifying different techniques is probably common, and this is the reason why constantly, recent definitions need to be established by intervention designers (Abraham and Michie 2008).

#### 2.2.6 Theory-linked Taxonomies of BCTs

Researchers specified and defined the so called 'active ingredients' or BCTs of interventions through establishing the taxonomies of BCTs (Wood et al. 2015). Different taxonomies of BCTs have been developed (Abraham and Michie 2008; Dixon and Johnston 2010; Michie et al. 2011c; Michie et al. 2011b; Abraham et al. 2012; Michie et al. 2012; Michie et al. 2013). Such taxonomies provide the researchers with scientific approaches to identify the intervention content (BCTs) reliably; hence, increase the effectiveness of the intervention (Abraham and Michie 2008; Abraham et al. 2012), facilitate a correct replication and

reporting of the intervention and linking BCTs to their theories of behaviour change (Michie et al. 2013). Linking theoretical mechanisms of change to BCTs is necessary for two reasons; the first is to theoretically inform intervention development, and the second is to test theory by evaluating interventions (Michie and Johnston 2012). Moreover, basing interventions on specific theories or models and linking them to the effective BCTs can influence on the effectiveness of the intervention through selection of participants, who are likely to benefit from the intervention, selection of appropriate BCTs, and tailoring these BCTs to individuals depending on the merits of the relevant theories or models (Albarracín et al. 2005; Michie and Prestwich 2010; Michie and Johnston 2012; Taylor et al. 2012). One of the most famous taxonomies in the field of behaviour change is a 26-item taxonomy by (Abraham and Michie 2008). It is considered as a reliable taxonomy, which was based on two principles; the first one is development of theory-linked definitions of BCTs, and the second is using these definitions (on the basis of intervention descriptions) to reliably identify techniques included in interventions (Abraham and Michie 2008). The second more recent taxonomy of BCTs, which has been established according to the 'Coventry, Aberdeen & London-Refined', (CALO-RE) taxonomy (Michie et al. 2011c). Authors derived and developed this taxonomy from the 26-item taxonomy after improving the labels and definitions of BCTs, resolving the overlap between categories for all techniques and separating and adding new 14 techniques, resulting a revised taxonomy, which has 40 BCTs. The CALO-RE scientific classification built up the premise to enhance the solid and orderly enforcement of evidence and theory for interventions (focusing on physical activity and healthy eating). This taxonomy is more far reaching, and can be utilized to advance the determination of interventions in published articles; thus, replication, application, and evidence syntheses will be moved forward. Consequently, the scientific study of behaviour change and intervention development will be more fortified (Michie et al. 2011c). Recently, this taxonomy has been applied in a systematic review aiming to identify effective BCTs in increasing fruits and vegetables intake among adults of retirement age (Lara et al. 2014a) indicating that this well-established taxonomy can be applied in dietary intervention studies (to identify the definition of the most effective BCTs) aim to improve a healthier eating pattern among denture wearers. It appears that not only the use of BCTs can increase the intervention effectiveness, but also defining and linking theses BCTs to their related theory (s) is crucial. Therefore, for any potential dietary behaviour change intervention for edentulous patients, it is importance to base the intervention on specific theory (s) and linking BCTs used in this intervention to its theoretical basis to increase the intervention effectiveness.

#### 2.2.7 Effective BCTs used in different dietary intervention studies

It is accepted that effective intervention is aiming to change behaviour positively. The effectiveness of intervention is directly related to its content (Michie et al. 2009), and BCTs or combination of techniques which are used in each intervention (Abraham and Michie 2008; Lara et al. 2014a). When BCTs are used as an 'active ingredient' of the intervention, some of these BCTs are more effective than others; therefore, these have been used more repeatedly in certain health behaviour change interventions. A systematic review and meta-analysis of randomised controlled trials by Bhattarai et al. (2013) highlighted the most BCTs used in different intervention studies to promote healthy diet among adult individuals in primary health care. These BCTs are 'provide instruction on how to perform the behaviour' followed by 'goal setting-behaviour' and then equally followed by three BCTs ('provide information on consequences of the behaviour, barrier identification/ problem solving, and provide feedback on performance').

Based on the 26-item theory-linked taxonomy, Abraham and Michie (2008) concluded that the most three commonly applied BCTs in different dietary behaviour change interventions are; prompt intention formation (technique number 4), provide information about consequences (technique number 2), and prompt barrier identification (technique number 5). Based on the same taxonomy, Michie et al. (2009) conducted a meta-regression analysis and reported 11 frequently used BCTs in many intervention studies by target behaviour (health eating). These are 'provide instruction', followed by 'provide feedback on performance', 'prompt intention formation', 'provide information on consequences', 'provide information about behaviour health link', 'prompt self-monitoring of behaviour', 'prompt barrier identification', 'provide general encouragement', 'plan social support or social change', 'prompt specific goal setting', 'prompt review of behavioural goals.'

Systematic review and meta-analysis studies (Lara et al. 2014a; Lara et al. 2014b) assessed the effective BCTs in different dietary intervention studies based on CALO-RE taxonomy by Michie et al. (2011c) to define these BCTs, and highlighted the most active ingredients of dietary interventions aiming at increasing fruits and vegetables intakes in retired adults (aged 55-75 years). These BCTs are: 'Barrier identification/problem solving'; 'Plan social support/social change'; 'goal setting (outcome)'; 'use of follow-up prompts'; 'provide feedback on performance.' More specifically, the studies also found that two specific BCTs; 'barrier identification/problem solving' and 'plan for social support/social change' are associated with increasing the effectiveness of dietary interventions (improving fruits and

vegetables intakes) among retirement age. Both of these BCTs were linked to Social Cognitive theory (Bandura 1986).

Recently, (O'Brien et al. 2016) have conducted a study to design a web-based lifestyle intervention to promote healthy eating and physical activity for individuals in the retirement age. The study applied different BCTs (i.e., 'self-monitoring' and 'goal setting behaviour and outcome', 'goal review', 'action planning', 'follow-up prompts', and 'barrier identification', 'information about consequences of behaviour) across all modules of the intervention. It seems that despite the large number of BCTs, which used in different behaviour change interventions, some of them (e.g., 'self-monitoring', 'goal setting-behaviour', 'provide feedback on performance', 'follow-up prompts' and 'barrier identification/problem solving') are frequently used in different dietary behaviour change intervention studies. Therefore, such BCTs could be used during developing dietary intervention by influencing certain constructs (e.g., attitude) positively or by improving the dietary self-efficacy.

## 2.2.8 BCTs related to enhancing dietary self-efficacy

Literature has showed that self-efficacy is a fundamental construct of most behaviour health change intervention studies (Noar et al. 2007; Abraham and Michie 2008; Foster et al. 2015), and the self-regulation prompts for action control is an efficient behaviour change technique (Schwarzer and Renner 2000; Lange et al. 2013). Therefore, it is essential to know which BCTs that could positively change the self-efficacy, and increase the effectiveness of the intervention. Based on Abraham and Michie (2008) taxonomy of 26 BCTs, Prestwich et al. (2014a) conducted a systematic review and meta-analysis and highlighted different BCTs that are associated with significant positive effects on a dietary self-efficacy. These are 'selfmonitoring', 'provided feedback on performance', 'prompted review of behavioural goals', 'provided contingent rewards', and 'planned for social support/social change'. More specifically, the study pointed the 'stress management/emotional control training' technique as the most BCTs, which significantly associated with improving the dietary self-efficacy. Stress caused by social and emotional disturbances could reduce self-efficacy (Bandura 1977; Bandura 1998). Therefore, reducing social and emotional issues around eating with dentures could increase the dietary self-efficacy. Another systematic review (Michie et al. 2009) reported that five self-regulation techniques derived mainly from Control Theory (CT) were found to be the most strongly associated with effectiveness of interventions designed to promote healthy eating among individuals aged 18 years and over. These techniques are

'Prompt intention formation'; 'prompt specific goal setting'; 'prompt self-monitoring of behaviour'; 'provide feedback on performance'; 'prompt review of behavioural goals.' It could be argued that enhancing the self-efficacy is a fundamental factor to increasing the effectiveness of any dietary behaviour change intervention; therefore, it could be recommended to apply BCTs that enhance dietary self-efficacy and change behaviour via other components (e.g., attitude, behavioural intention, etc.). Dietary interventions that apply self-monitoring and peer support components are possibly essential to self-manage and sustain healthy eating pattern among edentulous people wearing complete dentures. In addition, informing denture wearers on how to overcome problems (e.g., functional difficulties with eating) could also increase self-efficacy.

#### 2.2.9 Conclusions

It seems that it is important to positively change the dietary behaviour to reduce the chance of eating-related conditions such as obesity, undernutrition and other NCDs. To do this change, any intervention aiming at changing dietary behaviour has to be based on appropriate theoretical models of behaviour change that linked to effective BCTs. BCTs that enhance dietary self-efficacy (e.g., ' Stress management/emotional control training' and 'barrier identification/problem solving') could be the 'active ingredients' for any potential dietary behavioural change intervention for denture wearers. Such BCTs were associated with high effectiveness of dietary interventions, possibly due to the dual action through enhancing selfefficacy or changing the attitude of the target people positively. Changing the attitude and enhancing dietary self-efficacy could reduce social and emotional instability associated with eating with dentures and deceases depressive symptoms among edentulous people (see section 2.1.5: Psychosocial aspects). Self-regulatory BCTs (e.g., 'goal setting' and 'self-monitoring'), and goals and planning BCTs (e.g., 'goal setting', 'action planning') could be useful in helping edentulous people to set goals for their behaviour (e.g., healthier eating) and plan how these goals will be met. Feedback and monitoring BCTs (e.g., 'provide feedback on performance', 'goal review', 'provide information about consequences of behaviour') might be beneficial for edentulous patients in recording the behaviour or outcomes via completing; for example, a questionnaire about their behaviour. Social support BCTs such as 'plan social support/social changes' could offer social and emotional support for edentulous people, particularly those with cognitive impairment. Friends, relatives, colleagues or even other denture wearers could provide this social and emotional support. Incorporating numbers of BCTs could increase the effectiveness of the potential dietary intervention for edentulous people. It could be argued that the key idea for using BCTs is to establish a way that

edentulous people can plan and set goals, track or monitor their actions and assess how they are doing. In addition, establishing a way that they can get some feedback or practical information on their current diet. Providing people feedback about their current behaviour could help them find solutions to change it. Therefore, the potential intervention could have a mean to assess, track and plan (make it tailored) the dietary behaviour.

#### 2.3 Section 3: Development of dietary advice or intervention

The aims of this section are to discuss the importance of implementing dietary advice or intervention, mode of delivery and some other issues around intervention with particular emphasis on possible approaches, which can increase our understanding about any potential dietary advice or intervention for the group of denture wearers. This could help changing their dietary behaviour towards a healthier style. Changing the unhealthy dietary behaviour for individuals requires understanding the determinants or factors influencing food choice and analyse their interactions.

#### 2.3.1 Determinants of food choice:

Eating is 'conceptualized' as food choice in general. However, food choice is a complicated activity involving various aspects (Sobal et al. 2014). Food selection is defined as ''a dynamic and complicated process that implies choices from a set of available options in which people choose one food in preference to another or restrict their food basket by rejecting specific items'' (Lau 2008). The process of food selection sometimes needs to be modified or changed if individual's energy and nutrients become unbalanced. Besides, the process of food change requires identification of factors that influence the whole food selection process and understanding their interactions in relation to food use in order to achieve nutritional wellbeing; thus, improve general health and quality of life, particularly among older people (Lau 2008).

Many interrelated factors act together to influence the individual's food choice such as physical, physiological, nutritional, social, cultural, economic factors and attitude (Shepherd 1999). Kamphuis et al. (2015) concluded that healthiness, taste, price, and travel time to the grocery shop are important determinants of meal choice among older adults (mean age 63.3 years). Understanding these determinants of food choice and its interrelationship in older individuals is crucial to identify the key points for development of useful and valid dietary interventions to change behaviour towards healthiness (Lau 2008). The factors of food selection are varied with different stages of life, and the power of each determinant is diversified from one individual or group to another; therefore, during designing dietary interventions, it is recommended to consider the different factors influencing the decisions on food choice, which will be made by each individual or group (EUFIC 2005). The psychological determinant of food choice probably has the strongest influence over the eating behaviour of many individuals. Lau (2008) concluded that the distinct food selection determinants for the older people are the perception of taste and healthfulness. Taste

perception diminishes with age due to olfactory changes (Ship 1999). Taste perception is likely affected by denture wearing, possibly due to change of food texture due to insufficient mastication. However, Ghaffari et al. (2009) concluded that wearing dentures has no significant effect on 'gustatory and olfactory senses'. The reason for focusing on the taste perception is that if the people, who participate in the intervention or nutritional program do not accept the food which is recommended, they will never consume it (Coulston et al. 2003). Perhaps, more efforts are needed to encourage food industries to improve its products to become more healthful, tasty, and nutrient-dense (Lau 2008). Thus, it is fundamental to pay attention to all these factors during designing interventions aiming at changing dietary behaviour.

Edentulism is regarded as important factor, which influences food selection. Loss of all teeth can result in decline in masticatory efficiency (Wayler and Chauncey 1983), hence edentulous individuals tend to change dietary intake according to the food consistency or type, which is appropriate for their new situation (Wayler et al. 1984). Makwana et al. (2014) concluded that edentulous people (aged 60-80 years) wearing upper and lower dentures consumed less hard or coarse food such as raw fruits, vegetable, meat, nuts and oilseeds, which are usually rich in vitamins, minerals and proteins and fibre, in comparison with dentate people. Consequently, such people tend to favour soft diet such as processed foods, which are typically rich in fat and sugar, and have lower fibre, minerals and vitamins; hence, obesity and under nutrition were common health problems among those people. Therefore, there is a higher risk of diet related diseases. Similarly, weight gain was found among edentulous individuals (aged 70-79 years) regardless of whether they are were wearing dentures or not (Lee et al. 2004).

It appears that the process of food choice is a complex and involves interaction of different factors mainly physiological, cultural, and existence of oral conditions such as presence or absence all teeth, which could change the dietary preference of individual ending up with under nutrition or obesity. Therefore, it is recommended to encourage a healthier eating via using a dietary consultation because consumption of balanced diet is considered as a key factor of healthy ageing.

#### 2.3.2 Dietary advice and intervention

The National Diet and Nutrition Survey showed that the diet of older adults (those aged 65+) in the UK is apparently unhealthy in which the mean intake of Non-Starch Poly Saccharide (NSP) was below Dietary Reference Value (DRVs), and the mean intake of Non-Milk Extrinsic Sugar (NMES), total fat, and saturated fat was above the DRVs. In addition, those

people consumed 4.4 portions of vegetable and fruits, which is below the level recommended by WHO (equivalent to 400 grams for adults) (Steele et al. 1998; World Health Organization 2003; Bates et al. 2014). Some may not able to cook their own meals or they use traditional and often less healthy methods to prepare their food; for example, they use a saturated fats for roasting and baking, and overcook vegetables, which may destroy nutrients in these foods (Moynihan et al. 2006). Similarly, high intakes of saturated fat and low intakes of vegetables and fruits among older people are probably associated with "chronic diet-related diseases" such cardiovascular diseases, various cancers or malignancies and diabetes (WHO 1991; Lock et al. 2005; Feigin et al. ; Hjartåker et al. 2015). Preventing nutritional deficiencies, and adopting a healthier diet for this group of people are crucial in terms of health (e.g., optimizing the health-related quality of life), and economic (e.g., cost-effectiveness) perspectives (Moynihan et al. 2006). In order to promote healthier lifestyles (e.g., consumption of healthy diet), and increase the effectiveness of health services, behaviour change interventions are frequently adopted in health practices (Michie et al. 2011a; Murray et al. 2013). Behaviour change intervention is commonly defined as "coordinated sets of activities designed to change specified behaviour patterns" (Michie et al. 2011a). These behaviour change interventions are important in measuring the behavioural outcomes (Michie and Abraham 2004; Morris et al. 2012), and thus, they are essential for improving HRQoL (Kaplan 1990). Generally, it has been found that intervention to enhance a balanced diet have led to increase the consumption of vegetables and fruits, fibre, and decrease the intake of fat among adult individuals (Bhattarai et al. 2013). Moreover, dietary interventions or consuming a healthy balanced diet are probably vital in preventing the physiological and biological degenerative process associated with ageing, particularly among young adults (55-65 years), stopping weight loss among already undernourished older people or those who are at risk to become malnourished, improving quality of life, and decreasing the burden of providing health care (Makwana et al. 2014).

There is a convincing evidence that edentulism is associated with unhealthy diet. It is often has a negative effect on eating different food items and other elements such as fruits, vegetables, calcium, vitamins, and fibre (Krall et al. 1998; Moynihan et al. 2000; Marshall et al. 2002), and this deteriorating effect continues in many occasions despite of wearing different types of prosthodontic treatment (Allen and McMillan 2002). Furthermore, instructions given by the dentists to the denture wearer may lack information to make them adequately prepared for edentulism and its consequences (Obrez and Grussing 1999a). Usually, dentists make dentures and provide them to the patients, but most of them do not

think about how these dentures have impacts on eating and on social and emotional issues associated with eating with dentures. Such influence is important, particularly when those people go outside with their relative and friends, and how these dentures affect their enjoyment of certain types of food, social interaction with others, and other aspects of quality of life. There is also a lack of knowledge on whether those dentists give an eating advice to their patients or not, and whether this advice is advice on the functional problems of eating or on eating more healthy diet. Dietary advice or intervention for edentulous patients has not been widely explained, and most studies have focused on nutritional quality of diet (Moynihan et al. 2000; Sheiham et al. 2002; Ellis et al. 2008). Moreover, a limited number of studies reported that the dietary advice or intervention can lead to increase the consumption of a healthier diet (Bradbury et al. 2006b; Ellis et al. 2010; Moynihan et al. 2012). Although these interventions showed some success, existing interventions were researcher-led in that they were not patient-centred. Moreover, these interventions were designed to promote healthier eating; however, the approaches were not sustainable (as used skilled people), transferable, or scalable. Furthermore, none of the previous interventions had explored largely the eating issues faced by patients; for example, functional problems related to eating with dentures. Therefore, informing the development of advice or intervention that deals with the real issues around eating is essential to identify and remove an important barrier to healthier eating to ensure self-efficacy.

#### 2.3.3 Issues around intervening

<sup>c</sup>Wider contextual issues' such as ethical issues, equity issues and side effects should be taken in consideration during designing behaviour change interventions (Darnton 2008). Ethically, it will be almost impossible to convince people to eat recommended foods if these are not accepted as part of their daily diet (Coulston et al. 2003). During implementation of the intervention, equity can be achieved by decreasing harmful effects of the intervention and increasing choice or opportunity of the target population (Darnton 2008). Similarly, for any intervention to successfully change the behaviour, it should be effective and have a considerable effect size (it's impact at an individual or population level) (Michie and Abraham 2004). Three methods were recommended by Prestwich et al. (2014b) to maximize the effectiveness of an intervention; first of all, selection of effective BCTs or combination of techniques for each intervention; secondly, linking these BCTs to its relating theoretical frameworks; and finally, using individuals tailored interventions. Moreover, it is important to understand the definition of the active components or BCTs of the dietary behavioural change interventions (Lara et al. 2014a), their mechanisms of action and how to apply them into

practice (Glanz et al. 2008; Wood et al. 2015). Other factors such as audience characteristics, mode of delivery, type of materials, fidelity of implementation in relation to manual specifications are all important determinants of effectiveness (Davidson et al. 2003; Albarracín et al. 2005; Durantini et al. 2006). For example, during designing a dietary intervention to change a dietary behaviour, it is recommended to explicitly mention the 'dietary methodology' utilised in the intervention in order to become clear for the reader to decide whether the approach employed is robust or not (Moynihan et al. 2009). Additional variables are also important to be reported for any intervention aiming at behaviour change (Davidson et al. 2003; Michie et al. 2009), and these include:

- The content and the 'active ingredients' of the intervention.
- The target population (e.g., deprived/low income, inactive/overweight/at risk for cardiovascular diseases, and males/females).
- Delivery source (e.g., medically trained health professional, non-medically trained health professional, non-health professional).
- The setting (e.g., community, primary care, workplace).
- The format of delivery (e.g., individual, group, mixed, tailored, computerized).
- The intensity (e.g., contact time), time of outcome assessment (e.g., immediate, follow up), the duration (e.g., number of sessions over a given period), and adherence to delivery protocols.

The number of contacts with participants are important in terms of successfulness of any intervention (Lara et al. 2014a). For example, fruits and vegetables intake is increased when the number of participant intervention contacts are increased among older people at retirement stage (Lara et al. 2014b).

Reporting interventions with a clarity and detail is also important (Wood et al. 2015). Reporting of interventions is essential for three groups of people. For researchers, it is important in constructing accounts of their interventions. For reviewers and editors, it is important in assessing the descriptions of the interventions. For readers, it is important for explaining how to use the information in the interventions (Hoffmann et al. 2016). When intervention's designers publish the description of the interventions completely, participants (e.g., patients) can reliably implement them in useful ways. In addition, other researchers can structure on research findings and replicate the interventions (Hoffmann et al. 2014). Although providing information about the active ingredients or contents of the intervention is important, explicit mentioning of duration, dose or intensity, mode of delivering of the intervention are possibly key features, which affect the efficacy and replicability of any

intervention (Craig et al. 2008; Hoffmann et al. 2014). To address the issues of lack of consistency and consensus in reporting of complex interventions, the Consolidated Standards of Reporting Trials (CONSORT) group argued that ''authors should report on the interventions for each group with sufficient details to allow replication, including how and when they were actually administered" (Schulz et al. 2010). Therefore, researchers produced different guides to accurately report the intervention in published researches. Hoffmann et al. (2014) have issued 12 item (Table 2.2), 'Template for Intervention Description and Replication (TIDieR)' guide to improve methods of reporting or specifying of complex interventions; consequently their replicability by other researchers. Apparently, different issues should be taken in consideration when the researcher wants to develop dietary intervention. Reporting dietary behaviour change interventions is crucial to increase its effectiveness and make it replicable by other researchers. Therefore, the 'TIDieR guide' could be used to report any future dietary intervention targeting denture wearers.

Item	Description		
Item 1	Brief name: Provide the name or a phrase that describes the intervention.		
Item 2	Why: Describe any rationale, theory, or goal of the elements essential to the		
	Intervention.		
Item 3	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 (for example, online		
	appendix, URL).		
Item 4	What (procedures): Describe each of the procedures, activities, and/or processes		
	used in the intervention, including any enabling or support activities.		
Item 5	Who provided: For each category of intervention provider (for example,		
	psychologist, nursing assistant), describe their expertise, background and any		
	specific training given.		
Item 6	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.		
Item 7	Where: Describe the type (s) of location (s) where the intervention occurred,		
	including any necessary infrastructure or relevant features.		
Item 8	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.		
Item 9	Tailoring: If the intervention was planned to be personalised, titrated or adapted,		
	then describe what, why, when, and how.		
Item 10	Modifications: If the intervention was modified during the course of the study,		
	describe the changes (what, why, when, and how).		
Item 11	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.		
Item 12	How well (actual): If intervention adherence or fidelity was assessed, describe		
	the extent to which the intervention was delivered as planned		

 Table 2.2: Items of the Template for Intervention Description and Replication (TIDieR) checklist.

 About 1 from the formation (2014)

Adapted from Hoffmann et al. (2014).

#### 2.3.4 Designing and applying behaviour change interventions

As the aim of any dietary intervention or advice is "to extend the expectancy of health and wellness rather than just extend the expectancy of life and longevity" (Lau 2008), professional and individually tailored dietary advice from a trained dietitians or nutritionists for edentulous patients to improve their food choice is recommended (Moynihan et al. 1994; Allen and McMillan 2002; Moynihan 2002; Bradbury et al. 2006b; Bradbury et al. 2008). Nevertheless, the implementation or giving such dietary intervention by those experts is probably not feasible from practical and economic perspectives. In addition, during providing or applying an eating advice or intervention, it is also recommended to consider the effective approaches and strategies for implementing such advice or intervention. The dietary advice or intervention for edentulous patients need to be positive, possibly individualized, and matching with the dietary requirements to improve general health (El-Feky 2007). Lau (2008) suggested specific criteria for nutritional interventions for older people; for example, the intervention must be tailored in order to meet individual needs; the intervention must be 'gender specific', 'culturally sensitive', and 'economically accessible'; it should be related to the stages of desire to change. Similarly, O'Brien et al. (2016) argued that the intervention targeting older people at a retirement transition has to be tailored, scalable, sustainable, interactive, digital, and visually and functionally engaging. However, the effectiveness of interventions to change health-related behaviours such as healthier eating are often complicated due to interaction of different components (Craig et al. 2013), and this interaction determine whether this intervention is effective in changing the behaviour and subsequent health outcomes or not Michie et al. (2011c). The UK Medical Research Council's (MRC) (Medical Research Council 2000) issued a framework for developing and evaluating complex interventions. This guidance emphasises applying systematic and rigorous approaches for identifying and evaluating the evidence base and the theoretical basis for a novel intervention. It involves four inter-related phases, which may not follow a linear sequence. These are development, feasibility and piloting, evaluation, and implementation (Figure 2.4) (Craig et al. 2008). Although the guidance stressed the use of theory to develop complex health intervention, it did not provide detailed information about methods of using theory in intervention development (Craig et al. 2013).



# Figure 2.4: Key elements of the development and evaluation process of complex intervention. Reproduced from Craig et al. (2008) with permission from BMJ Publishing Group Ltd.

Another guidance is Behaviour Change Wheel (BCW) (Figure 2.5), which was developed and used to characterise and design behaviour change interventions. The circular-format of the framework consists of three layers: at the centre is a 'sources of behaviour' (it includes three components of behaviour change; capability, opportunity, and motivation), surrounded by the second layer, which represents intervention functions, and the third layer policy, which refers to 'policy categories'. This framework has addressed the entire field of intervention in terms of functions or policies, and met all criteria of 'coherence' or link to 'a model of behaviour'. It is considered as an appropriate guidance for behaviour change at individual, community, and population levels. The reliability of this formwork has been tested in several areas of behaviour change; control of tobacco use, and reduction of obesity. Nonetheless, more studies are required to test how this framework can result in increasing the effectiveness of dietary behaviour change interventions (Michie et al. 2011a). This framework could provide a more efficient method of developing an intervention that are likely to be appropriate for changing the dietary behaviour among denture wearers.



# Figure 2.5: Behaviour Change Wheel. Reproduced from Michie et al. (2011a) with permission from BioMed Central Ltd.

It seems that designing an effective dietary behaviour change intervention is not straightforward process and entails substantial effort from intervention designers. During designing of the intervention, addressing and answering certain questions by the intervention designers are crucial. Example of these questions are; what is the target behaviour needs to be changed, how it will be change, by whom it will be change, and in which settings this will be change. Moreover, identifying interpersonal and environmental factors, which could enable or delay the desired behaviour, are essential. Furthermore, selection of potential approaches, which produce change in the behaviour, is important. This could be achieved through selection an appropriate audience that informs intervention design.

# 2.3.5 Mode of delivery

As with other health behaviour interventions, different methods and strategies have been used to deliver the dietary advice or intervention. Some people try to change their own health behaviour themselves (e.g., using prompt self-monitoring of behaviour), others seek to offer support and help for other people in need (e.g., using provide normative information about others' behaviour) ( (EUFIC 2014). The traditional approach (print materials such as booklet or leaflet), which (mainly based on the presumptions that the target individuals lack of information or knowledge about what they should do to initiate a healthier behaviour) is sometimes used in various health consultation expeditions. This approach presume that improving knowledge can lead to the change the attitude of the individual, and hence, making a willingness to change (Speller 2007). For instance, providing feedback on current diet in

either printed tailored or iterative forms has been shown to be effective in improving the fruit intake in the short term in comparison with providing small group nutrition education (Wright et al. 2011). More specifically, the intake of food (vegetables and fruits) and nutrients (fat, protein and vitamin C) increased after rehabilitation of edentulous subjects (mean age 73.9) with complete dentures accompanied with dietary advice in a form of pamphlet (Bartlett et al. 2013). These 'eat well' and the 'good life' pamphlets include a practical information on eating well and feeling healthy. Findings of this study could imply that providing information in form of a leaflet is an effective method to change the dietary behaviour among denture wearers. However, it has been argued that giving such information may only help those people that have desire to read the information or instructions, and perhaps, not got the educational background and the motivation to change their behaviour. For other people, whose behaviour framed by their social or environment may not get the benefit of this advice or intervention, and this may affect the intervention's equity, and promote health inequality (Christmas et al. 2009). It could be argued that most problems associated with eating with dentures are related to chewing difficulties; therefore, providing printed information (in form of a patient leaflet) pertaining to functional problems associated with eating with dentures may be useful in overcoming such problems. Changing behaviour is different from overcoming known barriers. Still, such eating information or advice could change the dietary behaviour, particularly if such information is basing on experience of patients and including healthier piece of advice.

Direct face-to-face approach (by either individual or group sessions or both of them) has been used to implement health behaviour change interventions (e.g., dietary behaviour change interventions) in many intervention studies (Coates et al. 1999; Gann et al. 2003; Sacerdote et al. 2006). Other dietary intervention studies have used other means in conjunction with face to face sessions such as sending postal newsletters or mail to participants (Kristal et al. 2000; Takahashi et al. 2006), and using phone calls (Stevens et al. 2003). For example, Moynihan et al. (2012) implemented a customised dietary advice or intervention for denture wearers in form of one to one counselling sessions plus a tailored written dietary package. However, holding face to face sessions are possibly impractical in terms of time and cost-effectiveness perspectives (Erbe et al. 2017). A successful intervention needs to be sustainable, scalable and transferable (O'Brien et al. 2016), which are likely achievable with web-based intervention. The internet is, increasingly, used to deliver interventions and programs, which promoting health behaviour changes (Murray et al. 2009; Ritterband and Tate 2009). Interventions can be delivered on smart mobile and on a desktop computer screen or a tablet (Webb et al. 2010;

Hoffmann et al. 2016). It has been argued that the internet-based program or intervention is more effective in improving diet and nutrition than printed material among a staff of 'a human resources company' (Cook et al. 2007). This is because the web-based interventions or programs could be delivered electronically by various methods (Table 2.3) to large proportion of people in which wide range of characteristics and components can be performed in such interventions or programs, including education information, 'social interaction/support tools', 'self-monitoring', 'and goal-setting features' (Duncan et al. 2014). Moreover, technology based methods are convenient to the participants because they are often interactive, costeffective and stressing on keeping the identity of the users as confidential and anonymous as possible (Moore et al. 2013). Furthermore, studies reported that web-based interventions were comparable face-to-face interventions in terms of results (Williams 2011; Lara et al. 2016). Using such mode of delivering dietary advice or interventions could be supported by increasing figures of access to the internet globally. For example, in 2016 an estimated 49.2% of the world's population have access to the Internet, with estimates in United State, 88.6% and United Kingdom, 93.5% (Internet World Stats 2016). The UK data is distributed to 98.8% for age 16-44 years, 94.9% for age 45-54 years, 88.3% for age 55-64 years, 74.1% for age 65-74 years, and 38.7% for age 75 and over (Office for National Statistics 2016). For those aged 75 and over, the percentage increased to 41% in 2017 (Office for National Statistics 2017a) and 44% in 2018 (Office for National Statistics 2018). However, further research is needed to be conducted to explore the perception of edentulous patients (e.g., denture wearers), particularly those over 70 years old regarding the practicality of using web-based information as a method of providing advice on eating with dentures. Integrating face-to-face and internet as mode of delivering interventions was used by several researchers (Wentzel et al. 2016; Erbe et al. 2017). Therefore, it could be useful to use such blended technique in delivering eating advice or intervention for denture wearers. It seems that there are different modes for delivering the dietary advice or intervention. Selection one of these methods may depend on the research aims and objectives, the intervention designers, and the target population.

Mode of delivery	Approach	Example
Automated functions	A) The use of an enriched	1. Supplementary content and links.
	information environment.	2. Testimonials.
		3. Videos.
		4. Games.
	B) Automated tailored	1. Comparison to norms or
	feedback based on	Goals.
	individual progress	2. Reinforcing messages.
	monitoring	3. Coping messages.
	C) Automated follow-up	1. Reminders.
	messages	2. Tips.
		3. Newsletters.
		4. Encouragement.
Communicative	A) Access	1. Ask the expert facility.
functions	to an advisor to request	2. Expert-led discussion board.
	advice	3. Chat sessions.
	B) Scheduled	Emails.
	contact with advisor	
	C) Peer-to-peer access	1. Buddy systems.
		2. Peer-to-peer discussions boards.
		3. Forums or live chat.
Use of	Other means of	1. Email.
supplementary	communications	2. Telephone.
modes		3. Short Messaging Service (SMS)
		4. CD-ROM.
		5. Videoconferencing.

# Table 2.3 Mode of delivery of different internet-based interventions.Adapted from Webb et al. (2010).

# 2.3.6 Dietary intervention studies of edentulous patients.

It has been found that adopting healthier eating patterns is one of the key factors to prevent non-communicable chronic diseases and promote healthy ageing (Sofi et al. 2008; Sofi et al. 2010a; Murray et al. 2013), and this can be achieved by implementation of dietary advice and dietary intervention. Despite many intervention studies, which have aimed to change the dietary behaviour (Kreuter et al. 2000; Anderson et al. 2001; Oenema et al. 2005; Bowen et al. 2009; Panunzio et al. 2010; Wright et al. 2011; O'Brien et al. 2016), few intervention studies have specifically targeted edentulous patients (Bradbury 2002; Bradbury et al. 2006b; El-Feky 2007; Ellis et al. 2010) and these did not consider the social and emotional issues around eating with complete dentures or ERQoL.

Bradbury et al. (2006a) carried out a randomized controlled trial aiming to increase fruits and vegetables intake among edentulous patients (aged 45-80 years) attending Newcastle Dental Hospital for replacement conventional complete dentures. Stages of Change (Prochaska et al. 1992), and Optimistic Bias (Weinstein 1980) were the theoretical frameworks that used to underpin the intervention. The implementation of the intervention was done through 'individual counselling sessions with the nutritionist, and the provision of an individually tailored nutrition education package'. The study assessed 'the readiness to change diet' before and six weeks after intervention, and showed that a tailored dietary intervention in conjunction with replacement dentures can positively change dietary behaviour. The study also concluded that dental setting is an appropriate site for receiving dietary advice among those people.

Hyland et al. (2007) implemented a 'food-club programme' for older people aged between 65-85 years living in 'sheltered accommodation schemes'. This programme was implemented with the help of peer educators trained as Community Nutrition Assistants. The study concluded that peer educators made the programme more effective and accessible to older people, particularly in deprived community. This study does not mention if the participants in this program were dentate or edentate; however, the age and sociodemographic of the participants suggest a substantial proportion of the study population were likely to be edentulous or have compromised oral function.

Ellis et al. (2010) conducted an intervention study to measure the effect of customised dietary advice on patient's satisfaction with their dentures implant-supported mandibular overdentures or conventional dentures 6 months after dietary intervention. In this study, optimistic bias (Weinstein 1980) and stages of behavioural change (Prochaska and Velicer 1997) were the theoretical frameworks which used to underpin the dietary intervention, whereas, motivational interviewing techniques (Miller and Rollnick 2003) was the BCT which applied to change the dietary behaviour. The authors found that depending on the nature of their prosthesis, the delivery of customised dietary advice to the edentulous patient's impacts differently on their denture satisfaction. It is likely that patients subjected to this type of dietary intervention are encouraged and supported to try new foods or food preparation
methods. However, patient's satisfaction and their chewing ability were better among patients wearing implant-supported overdentures than those wearing conventional dentures. This could be explained by the fact that implant-supported overdentures may be better in terms of stability and comfort than conventional dentures. Moynihan et al. (2012) presented what happened to the diet of these participants following the intervention and showed improved dietary intake of the two groups, particularly those with implant-supported mandibular overdentures. In this study, a 'community nutrition assistant' implemented individual counselling sessions and provided 'an individually tailored nutrition education package' to all participants.

It seems that dietary interventions might be effective in improving healthier eating pattern among denture wearers and the effectiveness of these interventions is greater among edentulous individuals, who wear implant-supported mandibular overdentures than conventional dentures. However, the above-mentioned dietary interventions were not developed with input from users (patients) and or dental practitioners. Literature has shown examples of health intervention studies through which patient-centred services have been improved in which patients and staff were working together in a co-design approaches or methods (Bate and Robert 2006; Rozenblum et al. 2012; Lord and Gale 2014). For example, O'Brien et al. (2016) integrated evidence from qualitative research with individuals at retirement age, and expert knowledge (e.g., stakeholders) to develop a web-based intervention for those people in the retirement transition. No such approach has been adopted to develop an eating intervention for denture wearers. Therefore, a similar approach may be useful to develop dietary advice and intervention for edentulous patients, particularly those having eating difficulties or problems.

## 2.3.7 Conclusions

Evidence shows that in addition to the denture replacement, delivering dietary intervention is, also, required to improve dietary intake among edentulous people. This suggests that rehabilitation of edentulism with different types of prosthodontic treatments may affect the individual's life positively especially if accompanied with dietary advice or intervention. However, the effect of providing an eating advice (e.g., a patient leaflet) or intervention (e.g., web-based information) for edentulous people (wearing complete dentures) to improve ERQoL has not been explored yet. Therefore, further studies are required to discuss the impact of wearing complete dentures, denture replacement and the effect of providing eating advice or intervention on social and emotional issues around eating with dentures or ERQoL.

For example, increasing the enjoyment of the eating, reducing any self-consciousness associated with wearing complete dentures, and promoting social interaction among denture wearers. It is clear that it is important to understand the effect of wearing complete denture on social and emotional issues around eating with dentures from denture wearers to get in depth information on ERQoL. In addition, it is also necessary to discuss these issues with denture wearers themselves in terms of potential eating advice or intervention, but before that, it is essential to review the potential methodologies that could be used to achieve these goals. The next section of this literature review will consider the potential methodologies that could be used to explore this as part of this PhD study.

#### 2.4 Section 4: Review of methodologies employed in this PhD research

This section includes information on subjective health measures (i.e., the ESIRE and McGill questionnaires) and their psychometric properties, and methodologies (i.e., qualitative research and co-development approaches), which were used in the research studies that comprise the PhD.

#### 2.4.1 Assessment of patient's satisfaction (The McGill questionnaire)

It is generally acknowledged that a significant increase in the interest of developing patientsbased assessment of oral health outcomes over the last decades has highlighted the emergence of a new area of research in the field of dentistry (Sischo and Broder 2011). A number of instruments have been developed to assess the functional, social, and psychological outcomes of oral conditions, and these tools are different in terms of length, content, sub-scale structure, response formats, and methods of obtaining OHRQoL scores (Locker et al. 2001). The majority of measures have been shown to have adequate reliability and validity (Kushnir et al. 2004; Bae et al. 2007; Montero-Martín et al. 2009; Khalifa et al. 2013), and some have been evaluated for their ability to detect clinically meaningful change in the context of clinical trials (Thomason et al. 2002; Scott et al. 2006; Montero-Martín et al. 2009; Al Habashneh et al. 2012; da Mata et al. 2015). Internationally, the most popular and comprehensive instruments that measure the impact of oral disorders on oral health related quality of life is Oral Health Impact Profile (OHIP-49) (Slade and Spencer 1994b), and its short forms OHIP-14 (Slade 1997b) and OHIP-EDENT (Allen and Locker 2001). These instruments include different questions, in which seven conceptually formulated dimensions were captured based on Locker's theoretical model of oral health (Locker 1988). The seven domains include: functional limitations; physical discomfort; psychological discomfort; physical disability; psychological disability; social disability; and handicap (Slade and Spencer 1994b). Despite the fact that these instruments are mainly designed to measure OHRQoL, they are also used to indirectly measure the general satisfaction with prosthetic treatment or they include few questions related to the satisfaction with dentures. For example, OHIP-EDENT instrument was used to measure patient's satisfaction before and three months after insertion of new CDs (Viola et al. 2013). This questionnaire includes two questions related to the patient's satisfaction, and responses were made on a five-grade Likert-type scale and as follows: 1 = mostly satisfied, 2 = satisfied, 3 = not satisfied, 4 = mostly not satisfied, and 5 = no answer. However, there are other instruments that were mainly designed to measure patient's

satisfaction with different dental prosthesis. For example, a self-administrated questionnaire designed at Guy's Dental Hospital was used to measure patient's satisfaction with their complete dentures three months after the first review visit. Responses were made on a fourgrade Likert-type scale and as follows: 1 = very satisfied, 2 = satisfied, 3 = dissatisfied, and 4 = very dissatisfied (Fenlon and Sherriff 2008). One of the most frequently used tools which measure patient's satisfaction with lower complete prostheses is the McGill questionnaire or denture satisfaction scale (Appendix A). It was designed based on a pilot study on chewing efficiency with dentate people (Emmell et al. 1991). Many researchers have successfully used this validated instrument to measure satisfaction of the patients with several aspects of their lower dentures. These parameters include general satisfaction, ability to clean, ability to speak and ability to chew certain index food items such as fresh white bread, hard cheese, raw carrots, dry salami, sliced steak, raw apple and lettuce, as well as their ratings of comfort, aesthetics and stability (De Grandmont et al. 1994; Thomason et al. 2002; Heydecke et al. 2003a; Ellis et al. 2010; Rashid et al. 2011). This multi-items scale or questionnaire has nine conceptual domains; ease of cleaning, general satisfaction, ability to speak, comfort, aesthetics, stability, ability to chew, function, and oral condition. Each domain has one item except for the three domains: ability to chew (which has eight items or questions), function (which has eight items or questions), and oral function (which has two items or questions); hence, the McGill questionnaire contains 23 items in total to be answered using a VAS response. The VAS comprising a 100-mm line anchored by two words used to answer the questions of this validated questionnaire, which was specifically, designed to collect information on lower prosthesis among edentulous individuals. The VAS of the McGill questionnaire extends between specified limits; zero (relates to a lowest patient's satisfaction), and 100 (relates to a highest patient's satisfaction.

### 2.4.2 Assessment of ERQoL (The ESIRE questionnaire)

Although most instruments that assess OHRQoL include items relating to eating, they only cover eating as a broad issue and lack specificity; therefore, there has been a perceived need for an instrument that can explore issues around eating (e.g., emotional and social issues) or ERQoL. In order to fully understand the actual impact of wearing complete dentures on ERQoL, researchers at Newcastle University, UK designed the multi-items ESIRE questionnaire (Appendix B) (Kelly et al. 2012). This questionnaire was developed based on a qualitative study on patient point of views of how wearing conventional and implant-supported dentures affect eating and the social context of eating (Hyland et al. 2009). It is a patient-based instrument designed with VAS questions (the quantitative part, which includes

33 VAS questions) to be answered using a VAS response. The VAS of the ESIRE questionnaire ranges from zero (relates to a more negative eating outcome) to 100 (relates to a more positive eating outcome). In addition to these quantitative questions, there are open questions (a qualitative part, which includes 31 free text questions) to be answered using free text to further understand differences in responses on the VAS scale (Kelly et al. 2012). The ESIRE questionnaire has six domains: enjoyment of food/eating (has eight questions); selfconsciousness/embarrassment (has 10 questions); interruption to meals (has one question); confidence when eating (has four questions); time for eating or preparation of meals (has four questions), and finally functional ability to eat (has six questions). Face validity, content validity, and reliability have been tested and reported (Kelly et al. 2012). The content validity was tested by individual discussion with a small sample of 10 patients recruited during their visits to the Newcastle Dental Hospital. A researcher independent of the clinical care team conducted semi-structured interviews with the participants. These interviews informed whether the questionnaire accurately reflected their experience of eating with dentures. After that, an independent panel of five clinical staff from the School of Dental Sciences at Newcastle University assessed the comprehensiveness and relevance of the questions in relation to the interview transcripts. They also commented on the structure, phrasing and assessment scale for both the VAS scale questions and the qualitative questions. At the same time, the face validity was also tested with the same group of 10 patients as for the content validity as part of the semi-structured interviews in terms of clarity, comprehension, style and relevance for both the VAS scale and the qualitative questions. In addition, the independent panel of five clinical staff from the School of Dental Sciences also reviewed the face validity, so the questionnaire was modified adequately. Reliability testing on the questions answered using the VAS scale was conducted using a further group of 30 patients comprising 15 conventional dentures and 15 implant-supported denture patients. Cronbach's alpha was used to test the internal consistency reliability for each domain, and it was high and ranged from 0.86 to 0.95. Intra-class correlation coefficient was used for test-retest reliability for each domain and the result of this test ranged from 0.87 to 0.92. Known-groups comparison were also done by comparing the ESIRE scores ('mean VAS score by question and by domain') for patients, who had implant-supported over dentures with those who had conventional complete dentures. For each of the 33 single items or questions in the ESIRE questionnaire, patients with conventional denture patients reported lower scores (more negative eating-related outcomes) than those with implant-supported dentures (Kelly et al. 2012).

Literature shows that preliminary field test (item reduction) is often conducted to identifying items with poor psychometric performance; hence, they could be deleted or eliminated. This can be done through evaluation of the acceptability criteria of an instrument or questionnaire (e.g., missing data, minimum and maximum scores, floor/ceiling effects, item-total correlations and item scaling success). Moreover, exploratory factor analysis is frequently performed as an additional item reduction procedure on adequate (usually large) sample size (Lamping et al. 2002; Smith et al. 2005). It is often used to eliminate items, which load (correlate) more highly on other factors than the factor it should belong to (Streiner et al. 2008). In other words, items of each subscale (factor) should be highly correlated to each other than items of other subscales (factors). Items that cross-load on many factors or that do not load on any factor could be excluded or eliminated. However, it was not clear if item reduction analysis was done for the ESIRE questionnaire when it was developed. Psychometric properties (e.g., content validity, reliability, construct validity, and responsiveness) are essential for any health status questionnaire (Lohr 2002; Terwee et al. 2007). To date, the ESIRE questionnaire did undergo face validity, content validity, and reliability, but it has not undergone construct validity or responsiveness assessment. Therefore, it is recommended to validate the ESIRE questionnaire by testing its psychometric properties against a relatively similar instrument or tool (e.g., McGill questionnaire) to decide if it meets standard quality criteria for measurement properties of health status measures recommended by several researchers (Lamping et al. 2002; Terwee et al. 2007). However, in order to do that, it is essential to understand what the psychometric properties of health measures are.

## 2.4.3 Psychometric properties of health measures

#### Acceptability

Psychometrics can be defined as "a well-established scientific field concerned with the measurement of subjective judgements using numerical scales and the evaluation of the measurement properties of scales (e.g. reliability, validity, responsiveness)." (Smith et al. 2005). In psychology, a scientifically robust measure or scale should be assessed or evaluated for its psychometric properties to determine whether it meets standard criteria (Lamping et al. 2002). Despite of considering the acceptability of a measure as non-pivotal psychometric property, it is essential as it refers to how practical the instrument is. This, in turn, has significant implications clinically (Brazier et al. 1999). Acceptability is often evidenced by response rate, missing data of 5% or less, and the likely capacity to pick up differences

between patients at either of extreme positions and over time, as evidenced by item distributions and floor and ceiling effects (i.e. the percentage of respondents reporting the minimum and maximum values) (Smith et al. 2005). If the majority of patients display the minimum or maximum scores, the possibility of determining meaningful differences between them at these highest or lowest values is affected (Lim et al. 2015). Acceptability of the scores of the ESIRE questionnaire needs to be tested to see if any item of the ESIRE questionnaire fits poorly and needs to be deleted or eliminated.

#### **Internal consistency reliability**

Measuring the internal consistency for an instrument in a population other than that for which it was planned is important (Terwee et al. 2007; Mokkink et al. 2010). Internal consistency reliability is the degree of Inter-item correlations in a subscale or domain that measures the same construct (Terwee et al. 2007). It represents the 'homogeneity' of elements of the measure and is often measured by Cronbach's alpha coefficient (Cronbach 1951), which has to reach a value between 0.70 and 0.95 (Streiner et al. 2008). Cronbach's alpha coefficient more than 0.95 is an indication of redundancy rather than homogeneity. Inconsistent items are usually excluded from the study based on their values of Corrected Item-Total Correlation. Item-total correlations  $\geq 0.25$  is the level, which is taken as indicative of adequate internal consistency (Streiner et al. 2008, p.97; Field 2013).

## **Construct validity**

Construct validity is considered as one of the most important features of any instrument or tool that measuring what is so called unobservable variables (e.g., 'intelligence', and 'aggression') (Westen and Rosenthal 2003). For example, enjoyment of food or eating, self-consciousness or embarrassment, and confidence when eating domains of the ESIRE questionnaire are examples of such unobservable variables. Hence, there is a need to assess the psychometric properties of the ESIRE questionnaire against a relatively similar instrument or tool (e.g., McGill questionnaire) to assess whether the scores of the two questionnaires support the convergent or discriminant validity. Construct validity can be defined as ''an overarching term, which seen by most to encompass all forms of validity, which refers to the extent to which a measure adequately assesses the construct it purports to assess.'' (Westen and Rosenthal 2003). Two aspects of construct validity are convergent and discriminant validity (McColl 2005). Convergent validity refers to ''the degree to which the construct is similar to (converges on) other constructs that it theoretically should be similar to''; while discriminant validity refers to ''the degree to which the construct is not similar to (diverges

from) other constructs that it theoretically should be not be similar to" (William 2008). Convergent validity is measured by assessing correlations between two instruments or subscales within those instruments that should, theoretically, be associated or related. Discriminant validity is measured by assessing correlations between two instruments or subscales within those instruments that should, theoretically, not be associated or related to each other (Campbell and Fiske 1959; Westen and Rosenthal 2003). Lack of construct validity of a given instrument may mean that the results obtained from this instrument are likely to be difficult to interpret. However, measuring the extent to which an instrument or tool can be characterized as having adequate construct validity is complicated because there is no standard tool to measure the construct validity (William 2008). Instead, it is often tested either by using a correlational approach of Multi-Trait Multi-Method (MTMM) analysis (Campbell and Fiske 1959) or more recently, by a model-based method or approach (e.g., confirmatory factor analysis of MTMM data), which is often requires large sample size. The correlational MTMM approach is often adopted for measuring different constructs or concepts (called traits by Campbell and Fiske) by different assessment methods (e.g., different questionnaires) (Campbell and Fiske 1959). This method has the advantages of testing the convergent and discriminant validity simultaneously using correlation matrices (Streiner et al. 2008). It was argued that there is no golden rule of how high and how low these correlations; however, correlations of the convergent validity should be as high as possible; while correlations of discriminant validity should be as small as possible (William 2008). In other words, it is preferable that the correlations of the convergent validity are greater than correlations of the discriminant validity. Correlations should be stronger between domains/subscales across instruments (i.e. methods) that purport to measure the same/similar constructs, than between domains/subscales either within or between instruments that purport to measure different constructs. However, this method has a disadvantage in which the more measures the study use, the more correlations result, consequently, this makes the process of getting all correlations in an ideal pattern that supports the construct validity is hard or difficult.

#### Responsiveness

In addition to aforementioned psychometric properties, responsiveness of any measure or questionnaire developed principally for measuring changes over time is also essential (Guyatt et al. 1987a). Responsiveness means "the ability of an instrument to detect small but important changes (e.g., improvements or deteriorations)" (De Boer et al. 2004). Guyatt et al. (1987b) argued that an oral health measure is considered as responsive to change in the oral

condition that measured if it distinguishes clinically meaningful alteration using reasonable sample size. Paired-t test, effect size for the change scores, Minimal Importance Difference (MID), Standardised Response Mean (SRM) and Guyatt's responsiveness index are often used to assess the responsiveness to change of oral health measures (Deyo et al. 1991; Locker et al. 2004). No strict rules applied with regard to the sample size required in which most studies of responsiveness utilised small samples, generally less than 50 subjects (Beaton et al. 1997; Locker et al. 2004). However, using other measures of responsiveness (e.g., minimal importance difference, Guyatt's responsiveness index) requires a large sample size (usually more than 50 subjects) (Locker et al. 2004). As the ESIRE questionnaire was originally designed to evaluate the effectiveness of the treatment (e.g., denture replacement) on ERQoL, it is recommended to assess the responsiveness of the ESIRE questionnaire by using one of the above-mentioned responsiveness tests.

## 2.4.4 Conclusions

Different instruments exist to measure the impact of oral conditions and subsequent complications on human's quality of life, particularly among older individuals. Some of these tools were designed to be answered by Likert-type scale such as OHIP, which is mostly used to collect information on oral health related quality of life. Others measures were designed to be answered by VAS scales such as Denture Satisfaction Scale and the ESIRE questionnaires, which are widely used to collect data on patient satisfaction and eating related quality of life respectively. Therefore, evaluating the psychometric properties (e.g., acceptability, reliability, validity and responsiveness) of the ESIRE questionnaire is or prime importance to assess if this tool is reliable and valid form of measurement of the ERQoL.

In addition to these instruments, which mostly generate quantitative data, qualitative methods and co-design approaches are also useful in exploring patient's perception and views regarding issues around eating or ERQoL and informing the development of dietary advice or intervention. Mixing quantitative and qualitative methods is fundamental to ensure rigour in conduction of research, and often based on the researcher's philosophy to approach certain topic. The next sections of this review will discuss the role of qualitative research and of codesign or co-development in informing eating advice or intervention development.

#### 2.4.5 Qualitative research and Co-design in intervention development

Qualitative research and, recently, participatory methods or co-design are widely used to collect data that inform intervention development (Lewin et al. 2009; Yardley et al. 2012; O'Brien et al. 2016). This is, ideally, achieved through collaboration with potential stakeholders (e.g., patients, health care providers...etc.), who are possibly the potential beneficiaries of any health intervention, or responsible for implementing it (Jagosh et al. 2012; Janamian et al. 2014; Goodyear-Smith et al. 2015). "Iterative procedures of reflection and action, carried out with and by people rather than on them" (Cornwall and Jewkes 1995) can help tailoring and modification of the intervention to suit the participant's settings and circumstances (Goodyear-Smith et al. 2015). Similarly, exploring the needs, attitudes, behaviour, and contextual factors of a particular group of people, in addition to the studied topic can be achieved by using qualitative methods such as interviews, focus groups, and observational methods (Pope and Mays 1995). The findings of such qualitative studies can help intervention developers design and developed an acceptable and effective intervention (O'Brien et al. 2016).

#### 2.4.6 Qualitative research in healthcare

Over the past three decades, researchers have shown an increase interest in conducting qualitative research targeting the health care system to understand its complexity from the patient and health care provider's perspectives (Nicholls 2009a). Developing or evolving of concepts helping researchers to grasp social phenomena in naturalistic but not experimental settings is the substantial goal of qualitative research (Pope and Mays 1995). In general, qualitative research focuses on individual experiences, values, attitudes, behaviours, and interactions and attempts to answer mysterious questions (Nicholls 2009a). Ormston et al. (2013) described qualitative research as 'naturalistic, interpretative approach concerned with exploring phenomena from the interior and taking the perspectives and accounts of research participants as a starting point'. In qualitative studies, systematic and self-conscious research design, data collection, interpretation, and communication are required as basic strategies to ensure accuracy and precision of the qualitative studies. In addition, researcher's philosophical assumptions, skill and experience in conducting and employing research methodologies to answer specific questions are fundamental (Pope and Mays 1995). Therefore, before understanding the various approaches adopted by the qualitative research, it is possibly essential to have an idea about the philosophical suppositions underpinning the qualitative studies.

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## 2.4.7 Philosophical assumptions of qualitative methodologies

In order to produce rigorous and meaningful research, it is important for any researcher to explicit the larger philosophical ideas being adopted while conducting any research, and this information is necessary to justify the choice of quantitative, qualitative or mixed method approaches for the research (Creswell 2013). Researchers in quantitative studies focus on variables that can be measured and analyse the causal relationships between them (Denzin and Lincoln 2011). The socially constructed nature of reality, the firm connection between the researcher and what is studied, and the circumstantial constraints that constitute inquiry are often stressed by a qualitative researcher, who searches answers to questions that emphasize on how social experience is gained and given meaning. Qualitative research is different from quantitative research in terms of philosophical principles. Linking between qualitative methodology (a theory of how research will proceed), the searcher's philosophical assumptions (the ideas and beliefs that inform research), and methods (the way the research study is conducted) of data collection in qualitative research is not uncommon (Murphy et al. 1998; Murphy et al. 1999; Nicholls 2009b; Nicholls 2009a). In fact, the researcher's philosophical assumptions of qualitative methodologies depend mainly on how the researcher view reality (ontology) and truth (epistemology).

Ontology is the nature of reality and what there is to know about the world, and it has two ontological positions or stances; realism and idealism. Realism states that there is an outside reality (e.g., patient's reality) independence of a researcher's perception and the research process. Idealism states that the reality depends on the researcher' belief and understanding (there is interconnection between reality, the researcher's perception and the research process). In between these two broad stances, a number of more nuanced perspectives can be specified. One of these is subtle realism, which tries to represent reality rather than to reproduce or admit the existence of outside reality (e.g., patient's reality), but that this reality is interdependent with, and occurs through the researcher's interpretation (Mays and Pope 2000; Ormston et al. 2013).

Epistemology is dealing with how can we learn about the social world and what is the basis of our knowledge, and it has two extreme stances; positivism and interpretivism (Ormston et al. 2013). Positivism is the belief in single objective reality. In other words, the researchers has no influence on the world fact; for example, any disease has its own real 'essence or entity' regardless of individual experience or social conventions. This concept forms the philosophical basis of the quantitative research. Interpretivism, on the other hand, is the belief

in multiple realities (each individual has own 'unique experience'), and the researcher has an influence on the social world (social facts and values). This concept forms the philosophical bases of the qualitative research (Nicholls 2009b). An example of multiple realities is that each complete dentures wearer has its own experience and perceptions regarding eating difficulties with dentures and more specifically, the potential advice on eating with complete dentures, so exploring such issues rather than knowing factors interacting to cause eating problems is arguably important and needed to be studied and clarified.

#### 2.4.8 Methods of data collection in qualitative research

There is no ideal method for conducting qualitative study, and factors such as the purpose (s) and the objective (s) of the research, participant's characteristics, the audience for the research, the funders, and the position and the environment of the researchers themselves are necessary during conduction of qualitative research (Ormston et al. 2013). However, there are three main methods, which are widely used to collect or gather qualitative data in healthcare research. These are observation, focus groups, and interviews (Britten 1995; Kitzinger 1995; Pope and Mays 1995).

## Observation

Observational method is the systematic watching of people and events for the purpose of finding out about behaviours and interactions in natural settings (Mays and Pope 1995b). In this type of methodology, the researcher is 'going into the field' to describe and analyse what has been seen, so the researcher is absolutely regarded as the research instrument.

#### **Qualitative interviews**

Qualitative interviews are approaches or methods that are widely used to explore patient perceptions and beliefs, attitudes and experiences (Murphy et al. 1998; Durham et al. 2011; Alhamdani 2012). Qualitative interviews are commonly used to generate in-depth information about a certain topics in healthcare (Fitzpatrick and Boulton 1994). For instance, Hyland et al. (2009) conducted one to one interviews with patients who had received replacement conventional dentures or ISODs at Newcastle Dental Hospital in order to explore their views and opinions on social and emotional issues around eating with dentures. There are three main types of interview, which are: Structured, semi structured, and in depth interviews (Britten 1995). Structured interviews includes the administration of structured questionnaires in which the trained interviewers can ask the interviewees several questions in a standardised pattern.

Semi structured interviews are most common in qualitative research and based on 'a predefined set' of open-ended questions which define the area to be studied. These broad questions are probably allow the interviewers and the interviewees to digress for the purpose of gaining more details about emerging ideas. In-depth interviews are often like a monologue and tend to be less structured in which less issues is covered but in more details. Qualitative interview requires a trained interviewer, who should be able to prompt (to prevent the divergence of the topic) and probe (to explore the each issue in appropriate manner) (Britten 1995; Nicholls 2009c).

#### Focus groups

Focus groups or 'group depth interviews' are considered as one of the most widely used research tools in the social sciences (Stewart and Shamdasani 2014). They are frequently used in health research to understand and explain meanings, beliefs and cultures, which affect individual's believes, feelings, experiences, and behaviour regarding certain issues such as food choice and dietary behaviour change (Rabiee 2004; Wong 2008). Focus groups can be defined as 'a technique involving the use of in-depth group interviews in which participants are selected because they are a purposive, although not necessarily representative, sampling of a specific population, this group being 'focused' on a given topic' (Thomas et al. 1995). Participants in focus group discussion are always encouraged to speak to each other, ask questions if it is necessary, and exchange ideas and points of view (Kitzinger 1995). Therefore, it is likely that the idea behind using focus group discussion is to collect a breadth and if needed, in-depth information in a way, which cannot be achieved by other qualitative methods through direct interaction and communication between the participants. In this type of research methodology, participants are selected based on certain criteria such as having similar socio-characteristics, gender group, age-range, ethnic and social class background, particularly when the researcher tries to explore sensitive issue (Krueger 1994). However, many researchers do not recommend the concept of homogeneity as it results in setting the participant's behaviours according to their pre-existing relationships and leadership's pattern in the group. It is preferable that the participants should not know each other to ensure honest interaction and response (Rabiee 2004). Heterogeneity in the focus groups could help providing evidence about important different perspectives to apprise the future intervention design (Ayala and Elder 2011). Another criterion is that participants must be familiar with topic and having the ability to positively engaged in the discussion and feel comfortable to talk to the moderator and to each other (Richardson and Rabiee 2001). Selection of the participants based on their knowledge on the subject or topic to be discussed is probably

related to the concept of 'Applicability' (Rabiee 2004). It has been argued that the role of the moderator (this term is often accurately describes the researcher's function in a group discussion rather than the term 'interviewer') and the assistant moderator should not be underestimated during conduction of focus groups (Krueger 1994). Capturing the non-verbal communication expressed by the participants in a group discussion, noting which utterance is made by which particular participant, indicating the impact of the group dynamic, and documenting point of views are the duties of facilitator or moderator (Kitzinger 1994; Kitzinger 1995). However, the assistant moderator can also observe non-verbal interactions, keep a reflective diary, and write observational notes (during interview), and summary notes (promptly after each focus-group interview) (Krueger 1994; Rabiee 2004). These actions are probably essential in terms of complementing the oral text and completing the data analysis.

The moderator should have adequate skills and training to run the group discussion and have the ability to create an environment that attracts the participants (who do not know each other) and make them feel relaxed and positively encouraged to engage in the group discussion; hence, they are able to exchange feelings, point of views regarding certain issue (Kitzinger 1994; Kitzinger 2003). The moderator should have the ability to elicit the information from all participants and prevent the domination of few participants on the group discussion.

#### Uses of focus groups

The use of focus groups as a mean of generating qualitative data has become popular (Doody et al. 2013a). Their use in the exploratory phase of quantitative (to develop and refine research instruments) and qualitative (to define or explore certain topic, which can be subsequently used in other research approaches) studies are not uncommon (Barbour 2013). Breen (2006) mentioned that "focus-group discussions are far more appropriate for the generation of new ideas formed within a social context." They are regarded as a useful mean to involve users in healthcare system and development of its strategies, assess the needs and participatory planning, and evaluate the health promotion and nutrition intervention programmes (Duke et al. 1994; Kitzinger 1995; Richardson and Rabiee 2001). Likewise, focus groups are widely applied in health studies such as health promotion studies, health services research (e.g., exploring service user's opinions, and in assessing the needs of patients in developed countries) (Ritchie et al. 2013). More specifically, focus groups have been frequently used in dental research (Chestnutt and Robson 2001) in exploring the views of service-users (Robinson et al. 2005), and in recording the perceived barriers for accessing dental care among older people (Borreani et al. 2008; Barbour 2013). Literature reported that focus

groups are often used in initial stages of intervention development to inform intervention design (Freimuth and Mettger 1990; Yardley et al. 2012; Moore et al. 2013), and assess the acceptability of the intervention (Freimuth and Mettger 1990; Ayala and Elder 2011). Interaction between participants in the focus groups and the moderator and assistant moderator can lead to a deeper understanding of factors that may prevent or enable development of effective interventions (Ayala and Elder 2011). Moreover, insufficient understanding of how the intervention will be delivered by the users can lead to reduce the intervention effectiveness, and hinder the target population to participate in any future research (Abelson 1997; Boote et al. 2002). As focus groups are often a better choice than one to one interview when the researcher needs to encourage reluctant older people to speak about their perception and generate new ideas about the studied subject (Barbour 2013), it could be argued that using such method of data collection is likely to be advantageous in designing and development of dietary advice or intervention targeted edentulous people.

#### Advantages and disadvantages of focus groups

One of the important features of focus group interviews is the group dynamics, so the data that are generated from focus group discussion are much deeper and richer than those generated from one to one interviews (Krueger 1994; Thomas et al. 1995). Synergism and interaction (the unique features of focus group discussions) between the group members is possibly contributed to such large amount of data (Green et al. 2003). This kind of interaction between the participants is not achievable by other qualitative methods and probably enables the researcher to observe how people talk to each other about certain issue (Casey and Krueger 1994; Doody et al. 2013b). It, also, allows the participants to engage in generating ideas and solutions, which could be useful in developing an intervention for people under the studied problem. The richness of data obtained by qualitative research can be strengthen by using other participatory methods, which are, recently, used in intervention development (Ayala and Elder 2011). The second advantage of a focus group interview is that the researcher can increase the number of participants without increasing the time required to conduct such session (Casey and Krueger 1994). Subsequently, a large amount of data can be generated in a short time and less use of resources in comparison with one to one interviews (Rabiee 2004). Finally, focus group interviews have a high face validity in which understanding the technique and finding the credibility of the result are easily achievable by the participants (Casey and Krueger 1994). However, participant's recruitment in focus group discussions is sometimes problematical, especially when those participants come from low income or minority ethnic groups. This may be attributed to lack of confidence and low self-

esteem among such groups of the population, therefore a systematic process with sufficient incentives is possibly required to identify and recruit the participants in focus group discussions. Another possible disadvantage of focus groups is the number of non-attenders. Most informants may not attend a session for different reasons and circumstances, so it is recommended to over-recruit by 10-25% depending on the topic and the type of participant. Obtaining an agreed date from the participants (perhaps in advance of the session), and reminding them a few days before the start of the session are crucial to maximise participation in the discussion group (Rabiee 2004). Another limitation of focus group discussions is that analysis and interpretation of the data generated by focus group interviews is much more difficult and requires more time, thought and effort (Casey and Krueger 1994; Doody et al. 2013a).

#### Number of participants in focus groups

It has been argued that there is no 'magic formula' with regard to the number of focus groups, and the number of participants depends mainly on aims of the study, nature of the participants, nature of the data the researcher needs and the analysis method (Barbour 2013). The number of focus groups depends mostly on achieving data saturation (theoretical saturation) in which no new themes emerge during data analysis. In other words, subsequent groups only produce repetitive information in relation to the subject under study (Krueger 1994). The ideal number in each group differs and it probably varies from six to eight participants (Finch and Lewis 2003). This range is adequate to ensure variety of perspectives and limited enough to assure conduction of a well-organised focus group. Sometimes, a smaller group is desirable in certain issues (Finch and Lewis 2003), for example:

a) When the participants are highly interested in the topic under study; for instance, discussing an aspect of practice among professionals.

b) When the study is discussing sensitive issues.

c) When the depth, but not the breadth or of data is required.

d) When the population group involves children and older people or those with communication difficulties.

Four participants are acceptable for conducting a group discussion, but the researcher has to be active and stimulate the discussion. In the case of when the group is very small (there are less than four participants in the each group), it is regarded as paired (two participants) or tried (three participants) interviews rather than a group discussion, but this situation is still suitable to collect in-depth information on the topic under study. Large groups (above eight) are not recommended because the active participation will be uneven, which probably affects

group dynamics, gains superficial rather than in-depth information, and makes the identification of individual speakers' voices on the recording tape is difficult (Finch and Lewis 2003). Finally, each focus group should last for approximately 1-2 hours depending on the topic under study, the number of the participants and the number of the questions; thus, it is preferable from ethical point of view to inform the participants about the length of the session (Rabiee 2004).

#### 2.4.9 Qualitative sampling

Qualitative studies are generally not tended to enumerate, they aim to answer exploratory questions starting with 'what', 'how', and 'why' rather than 'how many' question, which is often quantifiable in nature (Ormston et al. 2013). Therefore, they mostly use purposive non-probabilistic sample to fulfil their aims or goals. In practice, researchers use this type of qualitative sampling to minimise the cost and time of qualitative data collection (Mays and Pope 1995a). A statistical representativeness or probability sampling method of quantitative research is not required in qualitative research, which supposes that each individual has a unique experience (Nicholls 2009c). This could help the researcher to select wide range of participants, who have characteristics or live in situations related to a studied phenomenon, and can add both depth and breadth to understand the studied phenomenon (Nicholls 2009c).

#### 2.4.10 Methods of data analysis in qualitative research

There is a variation in data analysis between qualitative and quantitative studies. This is possibly attributed to a difference in the philosophy underpinning each one, methodology, and method of data collection and analysis (Nicholls 2009b). In qualitative research, data collection and analysis occur concurrently; while, in quantitative research, data analysis start after finishing data collection. Hence, the main goal of the process of analysis of the qualitative data is exploring the meaning of the studied situation rather than searching the fact as in quantitative research (Rabiee 2004). Qualitative research is often identified with realism and followed a process of inductive reasoning (theory developing); while, quantitative research is identified with idealism and it favours deductive reasoning (theory testing) (Pope and Mays 1995; Nicholls 2009b). Inductive reasoning is an iterative process of detailed readings and re-examining of the raw data to generate themes (Thomas 2006), develop a hypothesis (Bloor 1978), and possibly building a theory for the studied phenomenon (Nicholls 2009b). An iterative approach means that the researcher tries to do early data analysis while collecting data. This helps to inform the subsequent data collection via theoretical sampling

technique or other methods that ensure the generation of emerging themes (Pope et al. 2000; Endacott 2008).

Analysis of qualitative data has been described as 'an interplay between researchers and data (Corbin and Strauss 2014), so the extent of subjective selection and interpretation of the generated data is often accepted (Rabiee 2004). No method is absolutely superior for analysing data generated by the qualitative research (Nicholls 2009c) in which the method of analysis depends on the research type and the researcher philosophy to approach the studied phenomenon (Denzin and Lincoln 2011). Therefore, different analysis techniques have been adopted to suit various methodological approaches (Spencer et al. 2003). As qualitative research is thriving in the world, new methods of data analysis are being identified. However, most methods of analysis include some basic principles such as text generation from raw data, initial reading of the text, scrutinizing of the text, linking the text to the pre-existing theory, further data collection and recognition of any emergent theme (s), and finally, identification of negative cases (Nicholls 2009c).

Different methods have been used been used by researchers for the purpose of analysing qualitative data. Thematic analysis has been widely used as a qualitative analytic method (Boyatzis 1998; Braun and Clarke 2006). Thematic analysis flexible and can be used with multiple theories; however, it does not allow comparisons between themes and cases (Braun and Clarke 2006). The 'constant comparative method' (Glaser 1965) or 'grounded theory' (Punch 1998) has been used by many researchers for the purpose of data collection and analysis. For example, Trulsson et al. (2002) used the constant comparative method for grounded theory (Glaser and Strauss 1967) to collect and analyse qualitative data about the effect of edentulousness on the quality of life of patients aged from 58-86 years. This approach includes four stages: a) Comparison of incidents within each category; b) Integrating categories and their properties; c) Delimiting the theory; d) Writing the theory, which is the final stage. To summarise and display the coded data, framework analysis is also used. The framework analysis of Bryman and Burgess (Bryman and Burgess 1994), Krueger (Krueger 1994), Ritchie and Spencer (Ritchie and Spencer 1994), and Ritchie framework analysis (Ritchie et al. 2013) are examples of framework matrices, which have been used to analyse the coded data. Combining two approaches in the analysis of qualitative data is not uncommon (Rabiee 2004; Green and Thorogood 2013). For instance, Alhamdani (2012) used line by line coding (Strauss and Corbin 1990) in qualitative research to understand patients' experience of orbital blow-out fractures. The author also adopted a framework approach (case by case and theme by theme) by Ritchie et al. (2003) for the purpose of data organisation, and the principles of constant comparative method (Glaser 1965) for producing an inductive and iterative analysis of the data. Similarly, Al-Baghdadi (2015) used framework analysis (Ritchie and Spencer 1994), and Theoretical Domains Framework (TDF) of behaviour change (Michie et al. 2005) to analysis qualitative data that explore the process of professionals' clinical decision-making in the management of temporomandibular disorder, (disc displacement without reduction). Few qualitative research studies on eating with dentures (ISODs and/or CDs) (Obrez and Grussing 1999a; Hyland et al. 2009) in which no enough information on the approaches of data analysis was provided. Most of methods and approaches of data analysis mentioned above have been widely used in analysing the data generated by one to one semistructured interviews and some of them have been used to analyse the data generated by focus groups. Doody et al. (2013a) reported that 'Constant comparative analysis' (Glaser 1965) and the Ritchie and Spencer framework analysis (Ritchie and Spencer 1994) are the most appropriate techniques that can be used to analyse the data generated by focus group interviews. However, the use of any method or approach of analysis depends mostly on the researcher's philosophical assumption. Analysis of the qualitative data generated by focusgroups often requires experienced researchers due to the bulk of data generated which tends to overwhelm the less experienced researchers (Rabiee 2004). A 1-hour interview requires approximately 5-6 hours generating a transcript. For this reason, reducing the data is the main goal in analysis process (Robson 1993; Krueger and Casey 2009). Hence, returning to the aim or the purpose of the study is crucial to exclude irrelevant information. This goal could be achievable through the process of indexing and charting, in which the main aspect of this task is minimizing the data. Ultimately, analysis of focus group interviews must be systematic, sequential, verifiable, and continuous (through the use of either a long table or a computerbased approach) in order to minimise the potential bias introduced in analysis and interpretation of the data (Krueger and Casey 2002b). As with other qualitative research methods, analysis of the transcripts or data generated from focus group interviews can be done by using specialised software such as NVivo software (QSR), Excel software, Microsoft Word, or even 'by hand'.

## 2.4.11 Conclusions

Conduction of qualitative research is largely determined by the researcher's philosophical assumption and the research aims and objectives. Methods of qualitative dada collection such focus groups and interviews are commonly used in to explore individual's perception regarding specific problems, and inform behaviour change intervention design and development. The synergistic effect and dynamic characteristic of focus groups make them

superior compared to one to one interviews in highlighting barriers, proposing solutions for the studied problem, and generating ideas, which can praise intervention design and development. Therefore, it is recommended to use such method of data collection to inform eating advice or intervention for complete denture wearers. The next section explores the role of Co-design approach in in health care service design including intervention development.

#### 2.4.12 Co-design of Health Delivered Intervention

In the health care sector, co-design or what so called co-production or co-development has been applied to involve patients in health care design or intervention for the last decade (Ruland et al. 2008; Macdonald et al. 2012; Bowen et al. 2013; Springham and Robert 2015). It firstly innovated and was piloted in the 'Head and Neck Cancer Service in Luton and Dunstable, UK' (Bate and Robert 2007, pp.1-13) as a project named 'Experience-Based Co-Design (EBCD)', which is a six stage process (Figure 2.6). The online EBCD toolkit describes this technique or approach as 'an approach that enables staff and patients (or other service users) to co-design services and/or care pathways, together in partnership. The approach is different to other service improvement techniques' (The King's Fund 2016). This approach is often focusing on the role of patients in developing and improving health services around patients' experiences through using multiple techniques of service design such as prototyping and storyboards, instead of using material and supplier-centred processes (Rogers et al. 2008; Bjögvinsson et al. 2012). It typically takes approximately 6 to 12 months to accomplish (Donetto et al. 2014) indicating that it could need much time, effort and resources. However, according to the international survey of EBCD projects in healthcare services, during the period from 2005 to 2013, approximately 59 co-design projects were implemented in Australia, Canada, England, the Netherlands, New Zealand, and Sweden. Additional 27 projects were in the planning stage (Donetto et al. 2015) highlighting the importance of applying design thinking to improve public services. Co-design is considered as an innovative way of actively involving patients, healthcare staff and stakeholders to explore the care pathway, capture patient's experience and work collaboratively for the purpose of understanding these experiences and improving them (Boyd et al. 2012). It is now adopted by many health organisations in the world; for example, the 'National Health Service Institute for Innovation and Improvement' has advocated using certain procedures (e.g., theory, tools and techniques) to design interventions to help improve the quality of the services provided by NHS organizations (Carr et al. 2012). Co-design can be defined as 'a process in which targeted end users and other relevant stakeholders form a partnership with researchers and work together on all aspects of intervention development, from needs assessment to content

development, pilot testing and dissemination.' (Eyles et al. 2016). Co-design has been applied in different health contexts such as head and neck cancer (Bate and Robert 2007) and dementia (Tan and Szebeko 2009), and more recently used to design web-based health care services for various purposes and target communities (Bartlett et al. 2012; Antypas and Wangberg 2014; Revenäs et al. 2015). For instance, O'Brien et al. (2016) have used co-design techniques to develop an evidence-based Web-Based lifestyle intervention for people in the retirement transition in which stakeholders have been placed at the heart of developing solutions and designing the 'final Web-based intervention prototype of LEAP (Living, Eating, Activity, and Planning in retirement).' The iterative nature of co-design be more convenient or acceptable when collaborating with patients, dental care staff, and other relevant stakeholders because such methodology could allow for tool re-development and refining based on the experiences and interactive discussion of partnership groups. As such, implementation of web-based interventions is potentially better than traditional approaches (interventions are predominately designed by researchers) in terms of effectiveness of the interventions. It could be concluded that user-centred design possibly contributes to service improvements in the healthcare sector by creating two opportunities; the first is thinking about approaches to improving of healthcare around patient experiences, and the second is innovating new methods, tools and techniques such as (e.g. co-design), which are largely used in healthcare improvement work in recent years.



Figure 2.6: The Experience-based Co-design cycle. Adapted from (Donetto et al. 2015) with permission from Taylor and Francis Group.

#### 2.4.13 Advantages and disadvantages of implementing co-design

Co-design allows participants to discuss different topics in supportive environments, prioritise their work and change the way they do things around them. It also allows the healthcare team and stakeholders to hear the patient voice and experience and increase their knowledge (Donetto et al. 2014). Despite the assumption that there are incremental quality improvements delivered by co-design projects, these slight changes could lead to major behavioural changes due to the interactive partnership between healthcare workers and patients (Robert et al. 2015). The co-design process is participatory and depends on the cooperation between partners, who exchange information and make a shared decision across all aspects; hence, interventions are possibly implemented based on the result of discussions between the partners (Eyles et al. 2016). However, implementation of co-design in the healthcare environment is probably challenging because working within healthcare organisations is likely frustrating to the professional service designers due to potential conflict and tension, which could emerge between patients and healthcare staff in various situation related to poor health services (Bowen et al. 2013; Robert et al. 2015). Researchers, who conduct co-design studies require additional training courses about methodology of such approaches for the purpose of transferring knowledge and skills; hence, being able to facilitate or conduct projects within healthcare systems. Sometimes, implementing of co-design is impractical in terms of time (take long time to conduct), efforts (a complicated process, which requires at least three days of working per week), budget or resources (cost-effective as it involves different participants, researchers and facilitators). For instance, 9 to 12 months are required to finish the six stage process of the EBCD (Bate and Robert 2007). Moreover, there is a possibility that some participants (particularly healthcare staff members) being not fully engaged with co-design project due to time limitation and unfamiliarity with the approach (Donetto et al. 2014).

#### 2.4.14 Methods and Phases of Co-design

Different methods or techniques have been used in intervention-design research and these are: obtaining evidence mainly from qualitative studies (e.g., focus groups/group discussions); survey; single-person formative interviews; single-person design or prototype testing sessions; advisory team discussions; review of existing resources/technology; pilot study to test user acceptability; storyboarding; persona building; mapping; generating ideas; end users providing photos and videos to inform intervention development; asking experts for who should be involved in development; classroom discussion; responding to comments on social

media; observation of interaction with intervention; phased roll out of intervention for fine tuning; half-day workshops; hand-drawing prototyping; expert review of final intervention; and sandpit testing of prototype in groups (Robert et al. 2015; Eyles et al. 2016; O'Brien et al. 2016). Like the 'community-based participatory research', the co-design process includes number of participatory research frameworks, which potentially involve similar series of consecutive phases. Researchers often used different techniques or methods and various phases or stages based on the research aims and objectives. For example, Bratteteig et al. (2013) described six phases or stages of the design process, and these were: Identify the opportunity; generate a knowledge explicitly and implicitly; identify the needs and desires, describe the requirements of delivery of the intervention; contemplate the intervention; and eventually test the prototype and the pilot, and evaluate them. Moreover, Eyles et al. (2016) reported that most participatory design frameworks involve six steps, which are:

- Evaluation of contextual understanding and evidence.
- Assessment of user needs to inform the focus of intervention.
- Assessment of user needs to inform the format of the intervention.
- Development of the intervention including content and framing.
- Pre-testing of intervention prototypes followed by changes based on feedback.
- Pilot testing of the intervention in the 'real world' providing feedback incorporated into the final version of the intervention.

Finally, O'Brien et al. (2016) described seven stages, which are: Compiling the evidence base; Co-design workshop 1; Co-design workshop 2; translating outputs into a design brief and specification; intervention build; co-design workshop 3; and iterative intervention optimization as sequential phases or stages to develop aforementioned LEAP for older people at retirement. This approach has several advantages. It followed and complemented the MRC guidance for the development of complex health interventions in which systematic, rigorous methods were used in identifying, and evaluating the evidence underpinned the theory-based intervention. One of the main strength of this approach was using different research methodologies such as systematic reviews, qualitative research and co-design techniques to draw conclusions based on skills and expertise of a multidisciplinary team. This approach described practical phases and methods of integrating the evidence with input from stakeholders such potential intervention users (older people), and health and social care professionals, who worked in partnership with the research team to inform intervention development. In practice, however, this approach was difficult in terms of conduction and resources. According to the authors, it was challenging to interpret requirements from

different viewpoints and evidence sources '(i.e., people with experience of retirement, organizations, and subject experts)' together with the scope and predefined aims of the study program; hence, such challenges called for realistic concessions based on discussion and decisions by the research team.

## 2.4.15 Conclusions

Recently, using co-design and participatory methodologies in developing health behaviour change intervention is not uncommon. Working in partnership with patients, health care providers and other relevant stakeholders in one multidisciplinary team can result in generating new intervention ideas, and maximizing the acceptability of the intervention and increasing its possible effectiveness. However, conducting such approaches in intervention development could be challenging to the research team in terms of resources, time and practical perspectives. Although the literature reports a plethora of co-design or co-production approaches, the systematic, sequential approach developed by O'Brien et al. (2016) seems to be the most thorough one because it is based on integration of a scientific evidence, expertise and working knowledge of experienced people, and contribution of stakeholders in the co-design process. Therefore, it is recommended to adopt this approach in the current research to inform a person-based dietary intervention development for other older people (e.g., edentulous people).

## 2.5 Section 5: Summary conclusions

Edentulism is commonly occurring health condition in which its prevalence is still high worldwide. A variability in the prevalence of edentulism exists both nationally and globally. Although there is evidence that the rate of edentulism is declining in most developed countries, the increasing proportion of the ageing population may contribute to keep the occurrence of edentulism high. Edentulism or the lack of all natural teeth has negative consequences on human's life such as functional impairment, psychological and social effects. It is considered as a type of impairment, which might ultimately affect both; health related quality of life, oral health related quality of life, and eating related quality of life. Complete dentures are widely used to replace the missing natural teeth, improve facial appearance, and provide assistance with chewing as well as speaking to millions of people. However, for most patients, wearing a complete denture, especially conventional complete dentures is a complex issue in terms of food selection, social and emotional perspectives. Although the impact of tooth loss and subsequent prosthetic rehabilitation on the quality of life has been studied widely, there is a lack of information regarding patients' perceptions, particularly on eating with dentures. Indeed, when there is a need for complete denture, most dentists focus on physical function of the teeth whilst denture wearers are potentially focus on social and emotional meanings of the denture inside the mouth. Exploring the difference in these two priorities could help us understand non-acquiescence in complete denture use, so further studies on the impact of wearing dentures on 'social identity' may be advantageous. Further studies are also required to explore the effect of denture replacement on social and emotional issues related to eating with conventional complete dentures. Research has shown that delivering customized dietary advice or interventions for denture wearers is helpful in terms of eating healthily, and the effectiveness of these interventions is increased if they are based on particular behaviour change theories and techniques. However, no dietary advice or interventions specifically aimed at edentulous patients have been developed with input from users (e.g., edentulous patients) and dental professionals (e.g., dentists and DCPs). Therefore, it could be useful to conduct qualitative studies with stakeholders to explore their views about eating with denture to lead to development of person-centred eating advice and a dietary intervention. It is recommended that such interventions are based on patient's experiences and opinions rather than relying on the views of experts. No specific eating advice or dietary intervention package based on the qualitative data exploring the perceptions and opinions of users (edentulous patients) themselves and dental health providers, who responsible for their

treatment; in addition to other experts; for example, nutritionists or dieticians. In addition, no eating advice or intervention reported to improve enjoyment of eating with complete dentures, reduce the self-consciousness or embarrassment associated with eating with complete dentures, and increase social interaction among denture wearers. Thus, the goals of this PhD study are to study the impact of wearing complete denture and denture replacement on social and emotional issues around eating with dentures or ERQoL. Then, discussing these issues with stakeholders (e.g., denture wearers and dental health providers) to inform development of a model or prototype of eating advice and dietary intervention for edentulous patients wearing complete dentures to help them overcome eating related problems or difficulties and eat well with denture.

## **Chapter 3. Aims and Objectives**

## 3.1 Aims

- To test the acceptability, internal consistency reliability and construct validity of the ESIRE questionnaire against the McGill questionnaire.
- 2) To determine any magnitude of change in ERQoL among edentulous patients after conventional complete denture replacement, to gain in-depth information on social and emotional issues related to the eating with dentures, and to assess the responsiveness of the ESIRE questionnaire to change in ERQoL.
- 3) To explore and analyse views of denture wearers, dentists and DCPs about advice received and given on eating with complete dentures.
- 4) To produce a prototype of patient-centred eating advice (i.e., patient leaflet) and inform intervention development for complete denture wearers.

## 3.2 Objectives

- To onduct a quantitative study on a sample of conventional complete denture wearers in NE England in order to assess psychometric properties of the ESIRE against the McGill questionnaire.
- To apply the ESIRE questionnaire in a cohort study on edentulous patients with existing dentures and who need new conventional complete dentures, to collect data on ERQoL.
- 3) To conduct a qualitative study (i.e., focus groups) with service users (i.e., denture wearers, dentists and DCPs) from Newcastle Dental Hospital to obtain qualitative data that inform appropriate eating advice and intervention for denture wearers.
- 4) To use an iterative co-design or co-development process to integrate scientific evidence from the literature, focus groups with service users (i.e., denture wearers, dentists and DCP) and a cohort study in addition to working together with stakeholders to develop eating advice and intervention for denture wearers.

# Chapter 4. Validity Study: Psychometric Properties of A questionnaire that Aims to Assess Issues around Eating with Dentures

## 4.1 Introduction

According to WHO, health can be defined as 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' (WHO 2016b). This definition puts the concept of psychological or mental welfare in the heart of healthiness. Based on this contemporary concept, oral health could be defined as physical, psychological and social well-being of an individual in terms of oral soft and hard tissues. Traditionally, measurement of oral or dental health has been based on clinical indicators, which often try to objectively assess, and quantitatively measure clinical outcomes of oral conditions with no attention to any subjective exploration of the individual's perceptions (Montes-Cruz et al. 2014). For example, conventional dental indices are indeed disease measures, rather than measures of oral health per se (Murray Thomson 2014b). Presently, conceptual models of oral health are widely used as tools to explore the individual's perception of oral health, and psycho-social perspective and welfare (Sischo and Broder 2011). A number of instruments have been developed to assess the functional, social, and psychological outcomes of oral conditions (Slade and Spencer 1994b; Slade 1997a; Allen and Locker 2001; Kelly et al. 2012). These instruments differ in terms of their length, content, sub-scale structure, response formats, and methods of calculating OHRQoL scores (Locker et al. 2001; Tubert-Jeannin et al. 2003). For example, one of these instruments has only three items (Gooch et al. 1989); while another tool has 49 items (Slade and Spencer 1994b). The majority of these measures have been shown to have adequate reliability and validity (Kushnir et al. 2004; Bae et al. 2007; Montero-Martín et al. 2009; Khalifa et al. 2013), and some have been evaluated for their ability to detect clinically meaningful change in the context of clinical trials (Scott et al. 2006; Montero-Martín et al. 2009; Al Habashneh et al. 2012). While the objectives of these instruments are varied, and multiple; either 'discriminative' (e.g., distinguishing different clinical status) or 'evaluative' (e.g., measuring within and between subject variations over time) (El Osta et al. 2012), the majority of them help us understand the relationship between general and oral health (Sischo and Broder 2011). It has been suggested that generic OHRQoL questionnaires, though useful in comparing different populations, may not be sufficiently sensitive to pick up the unique features that might be important for each disorder (Jenkins et al. 2011). Therefore, condition-specific measures of oral health related quality of life are potentially more applicable in terms of sensitivity to pick up the influence of oral conditions on human life

than generic health tools (Tubert-Jeannin et al. 2003). For examples, OHIP-EDENT was derived from OHIP-49 to collect data on the impact of edentulism on a specific group of edentulous patients (Allen and Locker 2001). A self-administrated denture satisfaction scale (McGill questionnaire) was designed to collect data on general satisfaction with lower denture (Emmell et al. 1991). A self-administrated ESIRE (Emotional and Social Issues Related to Eating) questionnaire was also developed to collect data on Eating Related Quality of Life (ERQoL) among edentulous people (Kelly et al. 2012) (see chapter 2, section 2.4.1 and 2.4.2 for more details on the McGill and ESIRE questionnaires). While the validated McGill questionnaire was used by many researchers (De Grandmont et al. 1994; Thomason et al. 2002; Heydecke et al. 2003a; Ellis et al. 2010; Rashid et al. 2011), the newly developed ESIRE questionnaire needs some psychometric evaluation before using it as an ERQoL measure. Face validity, content validity, and reliability (internal consistency reliability and test re-test reliability) have been tested and reported. Known-groups comparison were also done by comparing the ESIRE scores ('mean VAS score by question and by domain') for patients, who had implant-supported over dentures with those who had conventional complete dentures (Kelly et al. 2012). However, it was not clear if item reduction analysis was done for the ESIRE questionnaire when it was developed. Psychometric properties such as content validity, reliability, acceptability (e.g., response rate, completion rate, missing data, minimum and maximum scores, floor/ceiling effects, scaling success), construct validity (e.g., convergent and discriminant), and responsiveness are essential for any health status questionnaire (Lohr 2002; Terwee et al. 2007). This study, therefore, assessed the psychometric properties (i.e., acceptability, internal consistency reliability and construct validity) of the ESIRE questionnaire against the relatively similar McGill questionnaire on patients (conventional complete denture wearers) recruited from Newcastle Dental Hospital, Newcastle upon Tyne, UK. For all the above mentioned reasons, a psychometric evaluation study of the ESIRE questionnaire against McGill questionnaire was conducted on patients (conventional complete denture wearers) recruited from Newcastle Dental Hospital, Newcastle upon Tyne, UK.

## 4.2 Aims and Objectives

## 4.2.1 Aim

To test the acceptability, internal consistency reliability and construct validity of the ESIRE questionnaire against the McGill questionnaire.

## 4.2.2 Objective

To conduct a quantitative study on a sample of conventional complete denture wearers in NE England in order to assess psychometric properties of the ESIRE against the McGill questionnaire.

## 4.3 Method:

## 4.3.1 Study Design

This is a quantitative study (a psychometric evaluation study) to test the psychometrics properties of the ESIRE questionnaire against the McGill questionnaire. The study forms a sub-analysis of a larger cohort study (see Chapter 5).

## 4.3.2 Ethical and legal considerations

A positive ethical opinion from the National Research Ethics Services (NRES) committee London-Westminster, approval number 15/LO/1299; August 2015 (Appendix C) and a relevant Research and Development (R&D) approval from Newcastle upon Tyne Hospitals (NHS Foundation Trust, number 7515, September 2015) (Appendix D) were obtained.

## 4.3.3 Study participants

Patients, who fulfilled the inclusion/exclusion criteria (Table 4.1), were identified as denture wearers during one of their visits to the Prosthodontic clinic at the Dental Hospital, Newcastle upon Tyne, UK. Potential participants were invited to take part in the study by giving them a participant information sheet of the study (Appendix E). Participants interested in taking part in the study gave a verbal consent and signed a written informed consent form (Appendix F). After that, two self-administrated questionnaires (ESIRE and McGill) were given, at the same time, to all consented participants in a randomised order. In other words, the researcher (HA) asked half of the participants to complete the ESIRE questionnaire in the beginning and he asked the second half of participants to complete the McGill questionnaire in the beginning to ensure that there was no bias or inequality in answering questions of each questionnaire. To

avoid bias, administration of the questionnaires was undertaken by the researcher, who was not involved with treatment. Participants were informed that their contribution in the study would not affect the result of the treatment. Instructions on how to complete the questionnaires were given to all participants. In addition, the researcher was available to answer any question raised by the participants. The researcher asked participants to return the questionnaire during their subsequent visit or were provided with a sealable, stamped, and addressed envelope to send the questionnaires by post.

## **Inclusion criteria**

- Edentulous patient with existing dentures, and requiring new conventional complete dentures regardless of the complexity of the case and the technique that used.
- Undergraduate students at the Dental Hospital, Newcastle upon-Tyne, UK, have provided dentures for all participants.
- Participant able to give verbal and written consent, and be fluent in the English language to ensure adequate comprehension of the questionnaires to minimise data bias.
- Age  $\geq$  18 years.

## **Exclusion criteria**

- Participants that do not understand verbal and written English of the questionnaires.
- Patient with ISODs or tooth supported over dentures or dentate patients.
- Patient with a history of Temporomandibular Disorders (TMDs) or jaw clenching. These attributes were determined from the latest clinical examination noted in the patient's records.

## Table 4.1: Inclusion and exclusion criteria.

## 4.3.4 Sampling

The sample size estimation was carried out using a Statistical Analysis Software (SAS), version 9.2. Using Fisher's z test normalizing transformation for Pearson Correlation, thirty individuals were required in order to have 80% power to detect a positive correlation between the scores of the two questionnaires (Pearson Correlation test=0.6) at a statistical significance level of 5%.

#### 4.3.5 Data analysis

An MS Excel Database (version 2013) was used to enter the raw data (VAS scores) for the purpose of subsequent analysis using Statistical Package for the Social Sciences (SPSS) statistics 23.0 software. Appropriate descriptive statistics (mean, median, skewness, and kurtosis) were used to describe the data from the two questionnaires. A Shapiro-Wilk's test and visual inspection of histograms, normal Q-Q plots, and box plots were used to explore whether the data were normally distributed or not.

Acceptability of the ESIRE scores was assessed by evaluating overall response rate, overall item response rate (i.e., overall item completeness rate and overall item missing rate), minimum and maximum scores, percentage of respondents with minimum (zero) and maximum (100) score per item (high % of responses at either extreme, representing potential item/scale floor and ceiling effects). Floor and ceiling effects were estimated according to the criteria of Terwee et al. (2007) in which floor and ceiling effects are likely to be presented if more than 15% of respondents achieved the minimum or maximum possible score respectively. The overall response rate of people to each questionnaire was calculated by dividing the number of people, who answered questions in each questionnaire by the number of people invited to take part in the study. It requires the completeness of data (e.g., the ESIRE or McGill scores) to be 80% or above (Isaac and Michael 1971). The overall item completion and missing rates of each questionnaire was calculated by dividing the number of completed or missing items on total number of items in each questionnaire multiplied by 100. The overall scores and the scores of each domain were calculated by obtaining the mean score per items (questions) for each of the McGill and the ESIRE questionnaire. Then after, the total scores for each questionnaire were calculated by obtaining the mean of the scores for all individuals in the study. Where some questions or items were omitted by some of the respondents, the average score, across completed items was calculated (Streiner et al. 2008, p.139). In other words, the overall score for each questionnaire and the overall score for each domain were calculated by obtaining the averages of the answered questions only. Missing data were treated based on a criterion that a scale score be calculated if a respondent answered half or more of the items in each subscale or domain in a composite scale (Fairclough and Cella 1996; Ware et al. 2000). For summary scores, the acceptable level of missing data was <5%.

Cronbach's alpha (Cronbach 1951) was used to test the internal consistency reliability and homogeneity of the two questionnaires. Cronbach's alpha is a coefficient, which ranges from 0.00 (no consistency in measurement) to 1.00 (a perfect consistency in measurement)

(Streiner et al. 2008, p.8). Criteria "(Cronbach's alpha >0.9 is excellent, >0.8 is good, >0.7 is acceptable, >0.6 is questionable, >0.5 is poor, and < 0.5 considered as unacceptable)" by George and Mallery (2003) were used to describe the values of Cronbach's alpha; therefore, in excess of the convention of 0.7 indicative of adequate internal consistency (70% of the variance in the scores is a reliable variance) (Cronbach 1951; Streiner et al. 2008).

Item scaling success was calculated for each item, defined as the number of times that item correlated higher, by  $\geq 2$  standard errors (the standard error of a correlation coefficient), with its own scale (with correction for overlap) than it did with each of the other scales. Accordingly, the percentage of item scaling successes (relative to the total number of comparisons) for each scale was calculated. Item-to-own scale correlations (the correlation of each individual item with overall score of its own scale or domain) and Item-other scale correlations (the correlation of each individual item with overall score of another domain) were used to determine the item scaling success for all items of the ESIRE questionnaire to determine the scaling success of the ESIRE scores. Ideally, an item should be correlated more highly with its own scale (item convergent validity) than with other scales (item discriminant validity) (Smith et al. 2005). The item-to-own scale correlations were  $\geq 0.4$  was considered adequate (Streiner et al. 2008). Values of corrected item-total correlation (the correlation of each item with all other items combined), and Cronbach's Alpha if item deleted (it tells us what the value of alpha would be if this item is deleted) were also tested for all items of the ESIRE questionnaire. They were important to determine if any item in the set of the questionnaire is inconsistent with other items, so it can be deleted (Cronbach 1951). Corrected Item-total correlations  $\ge 0.25$ , and Cronbach's Alpha if item deleted > 0.70 were the levels that were regarded as indicative of adequate internal consistency (Cronbach 1951; Streiner et al. 2008, p.97; Field 2013).

Since the data were not normally distributed, Spearman correlation coefficient was used in all correlational analysis to test the direction and strength of relationship within the ESIRE scores and between scores of the ESIRE and the McGill questionnaires. Inter-Item Correlations (the correlation of every item in the scale with every other item) with in the ESIRE questionnaire were used to explore the convergent validity of the ESIRE scores. Correlation matrices of MTMM (Campbell and Fiske 1959) were used to test the convergent and discriminant validity (at a domain level) of the ESIRE scores in comparison to the McGill scores. Ideally, measures/subscales purporting to measure the same construct should be moderately to highly correlated to each other; whilst, measures/subscales purporting to measure different constructs should be weakly correlated to each other. In this study, it was hypothesised that there would

be high correlations between the scores of all domains of the ESIRE questionnaire to support its convergent validity. Moreover, moderate to high correlations between the scores of some domains (e.g., enjoyment of food/ eating, confidence when eating, and functional ability to eat) with the scores of all domains of the McGill questionnaire were also expected. For the discriminant validity of the ESIRE questionnaire against McGill questionnaire, it was hypothesised that there would be weak/low correlations between the scores of other domains (e.g., self-consciousness/ embarrassment, interruption to meals and time for eating or preparation of meals) of the ESIRE questionnaire with the scores of all domains of the McGill questionnaire were expected to support the discriminant validity of the ESIRE questionnaire against the McGill questionnaire. Cohen's criteria; strong or large (0.50), moderate (0.30), and weak or small (0.10) correlations were used to define and interpret the results (Cohen 1988). Spearman correlation coefficient was used to measure the correlation between the total (average) score of the two questionnaires. Finally, the probability was accepted at 5% significance level.

#### 4.4 Results

## 4.4.1 Sample characteristics

The sample size was bigger than initially anticipated, as the response rate was higher than expected. The achieved sample size was 38 participants aged 52-85 years (mean age=72.95 years), males=13 (34.21%) and females=25 (65.79%).

#### 4.4.2 Descriptive statistics

Figure 4.1 and Figure 4.2 present the distribution of scores of the ESIRE and McGill respectively. The ESIRE scores were slightly skewed, z-value=1.99, but normally distributed (Shapiro-Wilk test is 0.95 at significance levels of (p>0.05); however, McGill scores were highly skewed, z-value=3.36, and not normally distributed (Shapiro-Wilk test is 0.88 at significance levels of (p<0.05).



Figure 4.1: Distribution of the ESIRE scores.



Figure 4.2: Distribution of the McGill scores.

Figure 4.3 shows the box plots (a visual depiction) of the distribution of the total scores for the two questionnaires. The box plot of the ESIRE questionnaire was slightly asymmetrical, in which the upper quartile data 48.40 appear slightly longer (spread out) than lower quartile data 24.24 (relatively bunched together) with only one outlier. In this study, outliers were individuals with extreme values relative to the majority of the sample. For McGill questionnaire, the box plot was more asymmetrical, in which the upper quartile data 34.60 and lower quartile data 16.15 were relatively bunched together with multiple outliers. For the ESIRE scores, there was only one outlier (P18) with discrepant result in which the mean was 86.78; while, for the McGill scores, four outliers (P18, P19, P35, and P38) with discrepant results were found and their mean scores were 84.35, 76.26, 67.12, and 68.13 respectively.



Figure 4.3: Box plots of the total scores for the ESIRE and McGill questionnaires.

Table 4.2 shows the descriptive statistics of the data of the two questionnaires in which values of mean, skewness, kurtosis, and median reflect the difference in distribution of the scores of the two questionnaires, and how these data varied. The difference also was reflected by the values of mean, skewness, kurtosis, and median for each domain or subscale score of the two questionnaires. The minimum and maximum scores observed for each questionnaires were ranging from (0-100), and percentage of respondents with a score of zero was 31.58% and 23.68% and of 100 were 13.16% and 7.89% for the ESIRE and the McGill questionnaires respectively indicating the possibility of floor effect.
	Descriptive statistics											
Questionnaire/ domain	Mean	Standard	Skewness	Kurtosis	Median	Minimum	(%)*	Maximum	(%)**			
	(SD)	Error (SE)				scores		scores				
ESIRE												
Enjoyment of food/ eating	30.49 (20.50)	3.33	0.64	-0.42	27.94	0	13.16	100	5.26			
Self-consciousness/ embarrassment	43.11 (22.19)	3.60	0.40	-0.43	39.60	0	21.05	100	13.16			
Interruption to meals	49.47 (33.34)	5.41	-0.03	-1.31	51.00	0	07.89	100	5.26			
Confidence when eating	47.28 (29.75)	4.83	0.14	-1.26	43.25	0	07.89	100	2.63			
Time for eating or preparation of meals	43.99 (30.22)	5.04	0.40	-1.20	35.25	0	07.89	100	2.63			
Functional ability to eat	24.38 (19.99)	3.33	1.71	3.30	19.67	0	13.16	100	5.26			
Total scores	37.40 (19.24)	3.12	0.77	0.15	33.79	0	31.58	100	13.16			
McGill												
Ease of cleaning	69.21 (29.90)	4.85	-0.94	-0.19	78.00	0	2.63	100	2.63			
General satisfaction	16.63 (19.59)	3.18	1.81	2.94	08.50	0	7.89	83	0			
Ability to speak	56.53 (30.32)	5.05	-0.27	-1.20	65.50	0	2.63	100	05.26			
Comfort	21.61 (24.54)	3.98	1.39	0.87	09.50	0	5.26	86	0			
Aesthetics	42.34 (30.95)	5.02	0.38	-1.06	39.50	0	2.63	100	02.63			
Stability	13.79 (16.99)	2.76	1.74	2.71	06.00	0	15.97	68	0			
Ability to chew	22.10 (21.71)	3.52	1.58	2.06	15.75	0	15.79	99	0			
Function	28.86 (24.69)	4.01	1.25	0.96	21.19	0	7.89	100	02.63			
Oral condition	23.28 (22.43)	3.74	1.06	0.02	14.00	0	5.26	75	0			
Total scores	28.50 (19.90)	3.22	1.29	1.24	23.97	0	23.68	100	07.89			

\* Percentage of respondents with minimum (zero) score per domain. \*\* Percentage of respondents with maximum (100) score per domain.

Table 4.2: Descriptive statistics of scores of the ESIRE and McGill questionnaires.

### 4.4.3 Acceptability of the ESIRE

The overall response rate was 80.85% for each questionnaire. The overall item completion rate was 96.89% for the ESIRE questionnaire and 92.1% for the McGill questionnaire. The overall item-missing rate was 3.11% for the ESIRE questionnaire and 7.9% for the McGill questionnaire. Of the 38 respondents, 33 participants answered all 33 VAS questions of the ESIRE questionnaire, five respondents answered fewer than 33 questions with the percentage of missing items ranged from 3% (one item is missing) to 42% (14 items are missing) per respondent. Mean number of missing items was 1.03 and the median was zero.

Table 4.3 shows an item level analysis of the scores of the ESIRE questionnaire, reporting percentage of people, who actually answered each of the 33 VAS questions, the minimum and maximum scores reported by respondents, median, mean and Standard Deviation (SD) of the responses. In general, low score rate was found for all items and domains, and this was reflected by the low values of mean and median of the scores of each item and each domain. The percentage of respondents completed each item ranged from 92.1% to 100%. Minimum score reported was zero for all items except items (Q7c) and (Q13a) in which the minimum scores were two for each item or question and one for item (Q12a). Maximum score reported ranged from 82 for item (Q22a) to 100 for most items. Percentage of respondents with minimum (zero) score per item ranged from 2.63% to 13.16%, while the percentage of respondents with maximum (100) score per item ranged from 2.63% to 7.90%. The percentage of respondents completed each domain was 97.4% for the domain (confidence when eating); 92.1% for the domain (time for eating or preparation of meals); 94.7% for the domain (functional ability to eat), and 100% for all other domains. Minimum and maximum scores reported for all domains were zero and 100 respectively. Percentage of respondents with minimum (zero) score per domain ranged from 7.90% to 21.05%, while the percentage of respondents with maximum (100) score per domain ranged from 2.63% to 13.16%.

Domain	Item	No. (%)*	Mean VAS	Median	Min	No. (%)**	Max	No.
	number		scores (SD)					(%)***
Enjoyment of food/eating	Q1a	38 (100)	27.40 (28.06)	17.50	0	1 (2.63)	100	1 (2.63)
	Q2a	37 (97.4)	53.03 (28.68)	52.00	0	1 (2.63)	99	0
	Q3a	38 (100)	40.00 (28.45)	42.50	0	1 (2.63)	97	0
	Q3b	38 (100)	32.21 (27.60)	27.50	0	1 (2.63)	93	0
	Q3c	38 (100)	26.58 (27.17)	16.50	0	1 (2.63)	95	0
	Q3d	38 (100)	24.21 (26.26)	12.00	0	2 (5.26)	93	0
	Q4a	36 (94.7)	20.17 (24.44)	11.50	0	4 (10.53)	100	1 (2.63)
	Q5a	38 (100)	21.18 (24.09)	15.00	0	3 (7.90)	95	0
	Total	38 (100)	30.49 (20.50)	27.94	0	5 (13.16)	100	2 (5.26)
Self-consciousness/embarrassment	Q7a	38 (100)	46.13 (35.41)	42.00	0	1 (2.63)	98	0
	Q7b	38 (100)	37.32 (35.53)	25.00	0	3 (7.90)	100	2 (5.26)
	Q7c	38 (100)	33.66 (35.21)	18.00	2	0	100	2 (5.26)
	Q7d	37 (97.4)	28.54 (31.81)	16.00	0	1 (2.63)	100	1 (2.63)
	Q8a	38 (100)	17.45 (23.12)	6.50	0	5 (13.16)	86	0
	Q9a	37 (97.4)	33.11 (33.84)	17.00	0	2 (5.26)	99	0
	Q10a	37 (97.4)	54.46 (36.77)	58.00	0	2 (5.26)	100	2 (5.26)
	Q11a	37 (97.4)	43.38 (36.00)	36.00	0	2 (5.26)	100	2 (5.26)
	Q12a	37 (97.4)	65.97 (32.67)	85.00	1	0	100	3 (7.90)
	Q13a	38 (100)	72.05 (31.86)	89.50	2	0	100	3 (7.90)
	Total	38 (100)	43.11 (22.19)	39.60	0	8 (21.05)	100	5 (13.16)

Interruption to meals	Q14a	38 (100)	49.47 (33.34)	51.00	0	3 (7.90)	100	2 (5.26)
Confidence when eating	Q15a	38 (100)	67.24 (28.52)	78.00	0	1 (2.63)	100	1 (2.63)
	Q15b	37 (97.4)	48.38 (33.26)	50.00	0	2 (5.26)	100	1 (2.63)
	Q15c	36 (94.7)	36.92 (35.50)	19.00	0	3 (7.90)	100	1 (2.63)
	Q15d	36 (94.7)	31.22 (31.38)	16.50	0	3 (7.90)	98	0
	Total	37 (97.4)	47.28 (29.75)	43.25	0	3 (7.90)	100	1 (2.63)
Time for eating or preparation of meals	Q16a	36 (94.7)	56.53 (31.57)	58.50	0	1 (2.63)	100	1 (2.63)
	Q16b	35 (92.1)	43.57 (31.83)	34.00	0	1 (2.63)	100	1 (2.63)
	Q16c	35 (92.1)	37.57 (33.00)	27.00	0	3 (7.90)	100	1 (2.63)
	Q16d	35 (92.1)	43.99 (30.22)	24.00	0	3 (7.90)	98	0
	Total	35 (92.1)	43.23 (34.78)	35.25	0	3 (7.90)	100	1 (2.63)
Functional ability to eat	Q18a	36 (94.7)	20.83 (29.43)	8.00	0	4 (10.63)	100	1 (2.63)
	Q19a	36 (94.7)	18.72 (22.42)	8.50	0	3 (7.90)	100	1 (2.63)
	Q20a	35 (92.1)	25.63 (26.42)	12.00	0	3 (7.90)	100	1 (2.63)
	Q21a	35 (92.1)	18.43 (24.11)	9.00	0	2 (5.26)	100	1 (2.63)
	Q22a	36 (94.7)	20.22 (20.06)	13.50	0	2 (5.26)	82	0
	Q23a	35 (92.1)	42.66 (33.52)	38.00	0	1 (2.63)	100	1 (2.63)
	Total	36 (94.7)	24.38 (19.99)	19.67	0	5 (13.16)	100	2 (5.26)

\* Percentage of respondents completed each item. \*\* Percentage of respondents with minimum (zero) score per item. \*\*\* Percentage of respondents with maximum (100) score per item.

Table 4.3: Item and domain level analysis of the scores of the ESIRE questionnaire reporting item response rates, minimum and maximum scores, median, mean, and SD of the responses.

#### 4.4.4 Internal Consistency Reliability

The overall items (VAS questions) internal consistency reliability of the scores within each questionnaire was measured using Cronbach's alpha test, and values were 0.96 for the ESIRE questionnaire and 0.97 for McGill questionnaire indicating that both questionnaires had good reliability. More specifically, Cronbach's alpha was also used to test the internal consistency reliability within each domain within the ESIRE questionnaire for all participants (Table 4.4). All values were high, ranging from 0.86-0.95 suggesting that adequate internal consistency was achieved for each domain.

Domain	Number	Number of	Cronbach's alpha
	of items	participants	
Enjoyment of food/eating	8	36	0.90
Self-consciousness/embarrassment	10	36	0.86
Interruption to meals	1	N/A	N/A
Confidence when eating	4	37	0.93
Time for eating or preparation of meals	4	36	0.95
Functional ability to eat	6	36	0.86

 Table 4.4: Internal consistency reliability (Cronbach's alpha) for the ESIRE scores by domain.

# 4.4.5 Tests of scaling assumptions

Table 4.5 shows the percentage of item scaling successes (relative to the total number of comparisons) for each scale of the ESIRE questionnaire. The item-to-own scale correlations were  $\geq 0.4$  for all items of the ESIRE scores apart from item Q5a and Q12a in which item-to-own scale correlations were 0.36 and 0.36 respectively. Eleven items or questions (Q2a, Q4a, Q5a, Q7a, Q8a, Q9a, Q10a, Q12a, Q13a, Q22a, and Q23a) were identified as scaling failures or probable scaling failures. The percentage of item scaling success for the domain (enjoyment of food/ eating) was 63% in which most items of this domain correlated more highly with the score of this domain than with the five other domain scores except for items Q2a, Q4a, and Q5a in which the percentages of item scaling success were 20%, 20%, and 0% respectively indicating that these items correlated more highly with other domains than with their own domain. For the domain (Self-consciousness/ embarrassment), the percentage of item scaling success was 34% in which most items of this domain correlated more weakly

with the score of this domain than with the five other domain scores except for items Q7b, Q7c, Q7d, and Q11a in which the percentages of item scaling success were 100%, 100%, 60%, and 60% respectively. Regarding the domains (interruption to meals and time for eating or preparation of meals), the percentage of item scaling success was 100% in which the only one item (Q14a) of this domain is correlated more highly with the score of its own domain than with the five other domain scores. For the domain (confidence when eating), the percentage of item scaling success 80% in which most items of this domain correlated more highly with the score of this domain than with the five other domain than with the five other domain scores. Finally, the percentage of item scaling success for the domain (Functional ability to eat) was 57% in which the percentage of item scaling success was 60% for item Q18a, 80% for Q19a, 60% for Q20a, 100% for Q21a, 40% for Q22a, and 0% for Q23a.

		Item own	Number on			Correlation		Correlation	Correlation		Correlation	Correlates lower with	Correlates	Correlates	Correlates lower with	Correlates lower with	Correlates lower with			
		scale	which item		Item own-	with	Correlation	with	with		with	eniovment	lower with self-	lower with	confidence	time for	functional			
		correlation	own scale		scale	eniovment of	with self-	interruption	confidence	Correlation	functional	of food	consciousness	interuption to	with eating	eating than	ability than		Percentage	
		(corrected	correlation	SE	correlation -	food/eating	consciousness	to meals	when eating	with time for	ability to eat	than with	than with own	meals than	than with	with own	with own	Scaling	of scaling	
Item	Scale	for overlap)	based	correlation	2SEs	scale	scale	scale	scale	eating scale	scale	own scale	scale	with own scale	own scale	scale	scale	success	success	
Q1a	enjoyment of food/eating	0.824	36	0.054	0.715		0.411	0.235	0.684	0.466	0.666	5	Y	Y	Y	Y	Y	5	100%	
Q2a	enjoyment of food/eating	0.529	36	0.122	0.286		0.445	0.062	2 0.520	0.627	0.510	)	Ν	Y	Ν	Ν	Ν	1	20%	
Q3a	enjoyment of food/eating	0.741	36	0.076	0.589		0.487	0.270	0.670	0.548	0.659	)	Y	Y	Ν	Y	Ν	3	60%	
Q3b	enjoyment of food/eating	0.829	36	0.053	0.723		0.531	0.309	0.653	0.456	0.652	2	Y	Y	Y	Y	Y	5	100%	
Q3c	enjoyment of food/eating	0.885	36	0.037	0.812		0.530	0.334	0.688	0.439	0.625	5	Y	Y	Y	Y	Y	5	100%	
Q3d	enjoyment of food/eating	0.857	36	0.045	0.767		0.492	0.315	5 0.709	0.413	0.583	3	Y	Y	Y	Y	Y	5	100%	
Q4a	enjoyment of food/eating	0.440	36	0.136	0.167		0.265	-0.033	0.367	0.263	0.393	3	Ν	Y	N	N	Ν	1	20%	
Q5a	enjoyment of food/eating	0.360	36	0.147	0.066	j	0.300	0.082	0.436	0.206	0.445	5	N	N	N	N	Ν	0	0%	63%
Q7a	self-consciousness/embarassment	0.548	36	0.118	0.311	0.581		0.166	5 0.570	0.502	0.515	5 N		Y	Ν	Ν	Ν	1	20%	
Q7b	self-consciousness/embarassment	0.753	36	0.073	0.607	0.390		0.472	0.346	0.061	0.362	2 Y		Y	Y	Y	Y	5	100%	
Q7c	self-consciousness/embarassment	0.735	36	0.078	0.580	0.405		0.478	3 0.334	0.018	0.369	Y Y		Y	Y	Y	Y	5	100%	
Q7d	self-consciousness/embarassment	0.698	36	0.087	0.525	0.640		0.341	0.526	0.160	0.400	) N		Y	N	Y	Y	3	60%	
Q8a	self-consciousness/embarassment	0.587	36	0.111	0.365	0.532	2	0.457	0.581	0.384	0.566	5 N		Ν	N	N	N	0	0%	
Q9a	self-consciousness/embarassment	0.416	36	0.140	0.136	0.423		0.290	0.637	0.242	0.348	8 N		N	N	N	N	0	0%	
Q10a	self-consciousness/embarassment	0.438	36	0.137	0.165	0.290		0.476	5 0.363	0.350	0.377	N		N	N	N	N	0	0%	
Q11a	self-consciousness/embarassment	0.712	36	0.083	0.545	0.401		0.559	0.534	0.382	0.597	Y		N	Y	Y	N	3	60%	
Q12a	self-consciousness/embarassment	0.362	36	0.147	0.068	0.147		0.225	5 0.288	0.285	0.264	N		N	N	N	N	0	0%	
Q13a	self-consciousness/embarassment	0.496	36	0.127	0.241	0.261		0.382	0.318	0.356	0.422	2 N		N	N	N	N	0	0%	34%
Q14a	interruption to meals	1.000	38	0.000	1.000	0.217	0.532		0.403	0.131	0.470	) Y	Y		Y	Y	Y	5	100%	100%
Q15a	confidence when eating	0.701	37	0.085	0.531	0.490	0.431	0.368	3	0.632	0.593	8 Y	Y	Y		N	N	3	60%	
Q15b	confidence when eating	0.907	37	0.030	0.848	0.647	0.659	0.504	L.	0.615	0.789	9 Y	Y	Y		Y	Y	5	100%	
Q15c	confidence when eating	0.890	37	0.035	0.821	0.664	0.649	0.468	8	0.667	0.828	8 Y	Y	Y		Y	N	4	80%	
Q15d	confidence when eating	0.846	37	0.047	0.751	0.719	0.601	0.415	5	0.570	0.770	) Y	Y	Y		Y	N	4	80%	80%
Q16a	time for eating	0.739	36	0.077	0.586	0.314	0.148	-0.075	5 0.510		0.494	Y	Y	Y	Y		Y	5	100%	
Q16b	time for eating	0.957	36	0.014	0.929	0.503	0.409	0.152	2 0.652		0.723	8 Y	Y	Y	Y		Y	5	100%	
Q16c	time for eating	0.928	36	0.023	0.881	0.610	0.511	0.267	0.715		0.803	8 Y	Y	Y	Y		Y	5	100%	
Q16d	time for eating	0.918	36	0.027	0.865	0.623	0.536	0.283	3 0.729		0.819	) Y	Y	Y	Y		Y	5	100%	100%
Q18a	functional ability to eat	0.717	36	0.082	0.553	0.632	0.434	0.389	0.699	0.515		N	Y	Y	N	Y		3	60%	
Q19a	functional ability to eat	0.749	36	0.074	0.601	0.581	0.417	0.458	3 0.674	0.563		Y	Y	Y	N	Y		4	80%	
Q20a	functional ability to eat	0.762	36	0.071	0.620	0.505	0.322	0.256	0.656	0.628		Y	Y	Y	N	N		3	60%	
Q21a	functional ability to eat	0.810	36	0.058	0.694	0.424	0.300	0.235	0.690	0.625		Y	Y	Y	Y	Y		5	100%	
Q22a	functional ability to eat	0.606	36	0.107	0.392	0.524	0.130	0.176	0.606	0.397		N	Y	Y	N	N		2	40%	
Q23a	functional ability to eat	0.435	36	0.137	0.161	0.335	0.384	0.359	0.407	0.560		N	N	N	N	N		0	0%	57%
																		100	61%	

 Table 4.5: The percentage of item scaling successes of the ESIRE scores.

Table 4.6 shows values of the corrected item-total correlation and the Cronbach's Alpha test if item deleted for the scores of the ESIRE questionnaire. These values are important in order to inform whether the current length of the ESIRE questionnaire affects the correlation between its items or not and whether there is need to delete some items or not. In general, the corrected item-total correlation values ranged from 0.36-0.89 for the first domain (Enjoyment of food/eating), 0.36-0.75 for the second domain (Self-consciousness/embarrassment), 0.70-0.91 for the fourth domain (Confidence when eating), 0.74-0.96 for the fifth domain (Time for eating or preparation of meals), and 0.44-0.81 for the sixth domain (Functional ability to eat). This implies that the current length of the ESIRE questionnaire do not affect the correlation between its items since all Corrected Item-Total Correlation values were above the minimal accepted level of reliability for this test, which is 0.25. Regarding the Cronbach's Alpha if item deleted threshold to consider deletion of items, all values were ranging from 0.81-0.98. Most of these values were less than the overall Cronbach's Alpha values of corresponding domains pointing out that there is no need to delete any item to increase the level of reliability. However, some items in which their values of the Cronbach's Alpha if item deleted were slightly higher than the corresponding overall Cronbach's Alpha values of each domain indicating that these items could be deleted. These items were (Q4a and Q5a) of the domain; enjoyment of food/eating, (Q15a) in the domain; confidence when eating, (Q16a) in the domain; time for eating or preparation of meals, and (Q23a) in the domain; functional ability to eat.

Domain	Item	Corrected Item-Total	Cronbach's Alpha if Item
		Correlation	Deleted
Enjoyment of food/eating	Q1a	0.82	0.87
	Q2a	0.53	0.90
	Q3a	0.74	0.88
	Q3b	0.83	0.87
	Q3c	0.89	0.87
	Q3d	0.86	0.87
	Q4a	0.44	0.91
	Q5a	0.36	0.91
	Overall Cronbach's Alpha= 0.9	0	
Self-	Q7a	0.55	0.85
consciousness/embarrassment	Q7b	0.75	0.83
	Q7c	0.74	0.83
	Q7d	0.70	0.84
	Q8a	0.59	0.85
	Q9a	0.42	0.86
	Q10a	0.44	0.86
	Q11a	0.71	0.83
	Q12a	0.36	0.86
	Q13a	0.50	0.85
	Overall Cronbach's Alpha= 0.8	6	
Interruption to meals	Q14a	N/A	N/A
Confidence when eating	Q15a	0.70	0.95
	Q15b	0.91	0.88
	Q15c	0.89	0.89
	Q15d	0.85	0.90
	Overall Cronbach's Alpha= 0.9	3	
Time for eating or	Q16a	0.74	0.98
preparation of meals	Q16b	0.96	0.91
	Q16c	0.93	0.92
	Q16d	0.92	0.93
	Overall Cronbach's Alpha= 0.9	5	
Functional ability to eat	Q18a	0.72	0.83
	Q19a	0.75	0.83
	Q20a	0.76	0.82
	Q21a	0.81	0.81
	Q22a	0.61	0.85
	Q23a	0.44	0.89
	Overall Cronbach's Alpha= 0.8	6	

 Table 4.6: Values of corrected item-total correlation test and Cronbach's alpha if item

 deleted for scores of the ESIRE questionnaire.

#### 4.4.6 Construct validity of the ESIRE score

Table 4.7 shows the correlation matrices of MTMM analysis, which measured the convergent validity (with in the ESIRE scores) and discriminant validity (between scores of the ESIRE and the McGill questionnaires) on a domain level. Most correlations between domain scores of the ESIRE questionnaire were positive and ranged from 0.39 (moderate) to 0.81 (high) supporting the convergent validity of the ESIRE questionnaire. However, the correlations of the domain (interruption to meals) with other two domains (enjoyment of food/ eating and time for eating or preparation of meals) were positive, but low or weak, 0.22 and 0.13 respectively.

Regarding the correlations between the scores of the domains of the two questionnaires, there were some weak (negative or positive) correlations ranged from -0.20 to 0.30 between certain domains supporting the discriminant validity of the ESIRE scores against McGill scores. For the other domains (potentially share similar aims or objectives), large proportion of these correlations were either moderate or high and ranged from 0.32 to 0.76 respectively. Such findings support the hypotheses of discriminant validity of the ESIRE questionnaire against the McGill questionnaire.

Figure 4.4 shows scatterplot of total ESIRE scores versus total McGill scores. Because of the lack of normality in McGill scores, the, Spearman Correlation coefficient was used to test the direction and strength of relation between the total scores of the two scales. A strong, and positive correlation (r=0.78) between the total (average) scores of two questionnaires. Such correlation indicates that the scores of the two questionnaires are possibly moving in the same direction.



Figure 4.4: Scatterplot of total ESIRE scores versus total McGill scores.

	ESIRE								McGill							
	Domain	Enjoyment of food/ eating	Self- consciousness/ embarrassment	Interruption to meals	Confidence when eating	Time for eating or preparation of meals	Functional ability to eat	Ease of cleaning	General satisfaction	Ability to speak	Comfort	Aesthetics	Stability	Ability to chew	Function	Oral condition
ESIRE	Enjoyment of food/ eating	1.00														
	Self-consciousness/ embarrassment	0.56	1.00													
	Interruption to meals	0.22	0.53	1.00												
	Confidence when eating	0.68	0.59	0.40	1.00											
	Time for eating or preparation of meals	0.52	0.39	0.13	0.69	1.00										
	Functional ability to eat	0.67	0.57	0.47	0.81	0.75	1.00									
McGill	Ease of cleaning	0.25	0.02	-0.20	0.07	0.18	0.15	1.00								
	General satisfaction	0.67	0.42	0.35	0.76	0.47	0.66	0.05	1.00							
	Ability to speak	0.66	0.46	0.27	0.75	0.52	0.68	0.43	0.51	1.00						
	Comfort	0.54	0.30	0.20	0.52	0.39	0.50	0.20	0.80	0.44	1.00					
	Aesthetics	0.48	0.25	-0.08	0.51	0.42	0.34	0.38	0.50	0.51	0.60	1.00				
	Stability	0.55	0.38	0.20	0.66	0.52	0.55	-0.17	0.70	0.29	0.56	0.28	1.00			
	Ability to chew	0.75	0.50	0.43	0.75	0.52	0.75	0.14	0.77	0.66	0.57	0.35	0.64	1.00		
	Function	0.54	0.30	0.21	0.57	0.62	0.73	0.50	0.48	0.60	0.51	0.46	0.25	0.65	1.00	
	Oral condition	0.49	0.29	0.39	0.45	0.32	0.50	0.23	0.59	0.45	0.51	0.24	0.38	0.59	0.51	1.00
Correla	ations Spearman's rho:															
Perfect	correlation Hig	gh correlatio	on	Moderate	correlation		Weak of	correlation	n							

 Table 4.7: Correlation matrices of domains of the ESIRE and McGill scores according to the Multi Trait Multi Method (MTMM) analysis.

## 4.5 Discussion

So far, no study has assessed the psychometric properties of the ESIRE questionnaire by comparison with another instrument. This study is the first conducted among a group of complete denture wearers to investigate the psychometric properties of the ESIRE against McGill questionnaire. The later was selected because it is a validated and widely used instrument in research (Thomason et al. 2002; Ellis et al. 2010; Rashid et al. 2011), and includes different questions, which were designed to be answered using VAS scale. Since both measures employ a VAS, this makes comparsions more straitfowrward. Overall, most VAS scores of the ESIRE questinnire were higher than VAS scores of McGill questionnire, and this was reflected by their mean values 37.40 for the ESIRE, and 28.50 for the McGill. The result of this study also revealed that the ESIRE scores were less skewed, z-value=1.99, and normally distributed. For the ESIRE scores, there was only one outlier (P18) with discrepant result; while, for the McGill scores, four outliers (P18, P19, P35, and P38) with discrepant results were found. The outliers refer to some data points were being further away from the sample mean than what is considered reasonable. The outliers might occur due measurement errors, by chance or participants intentionally reporting incorrect data (Tukey 1977). However, in this study, outliers were due to high ESIRE and McGill scores. Therefore, it is possibly not recommended to remove such outliers from both questionnaires because they are representative and valid data, since all those participants had high scores, which relate to a more positive eating and satisfaction outcomes. The reason behind these high scores is probably that some people had more extreme experiences and, therefore, more extreme scores. All those participants had being wearing dentures for more than 25 years, and they were visiting the Dental Hospital to replace the dentures.

#### 4.5.1 Acceptability of the ESIRE

The overall response rate (80.85%) for the two questionnaires was good and within the normal acceptable level 80% or above (Isaac and Michael 1971). The overall item completeness rate (96.89%) of the ESIRE questionnaire was higher than that of the McGill questionnaire (92.1%), and the overall item missing rate (3.11%) of the ESIRE questionnaire was lower than that of the McGill questionnaire (7.90%%). The result of missing data of the ESIRE questionnaire was accepted according to the criterion of missing data for summary scores, which is preferable to be <5% (Smith et al. 2005). In the light of the expected higher than usual rate of missing data among most older people, initial consideration of these data

indicated that the rate of missing data was generally low, particularly for the ESIRE questionnaire. Five respondents answered fewer than 33 questions with the percentage of missing items per respondent ranged from 3% (one item is missing) to 42% (14 items are missing) highlighting that these items are consistently omitted (which might suggest that they are not well understood, or are not acceptable). According to (Fairclough and Cella 1996), who recommend that a scale score be calculated if a respondent answered half or more of the items in each subscale or domain, it is not recommended to delete the data of those five participants because they answered more than 50% of the items in each domain. Despite the low response rates for some items within the ESIRE questionnaire, the findings of the nonresponse rates concluded that the questionnaire has adequate comprehensibility or acceptability.

In the current study, the percentage of respondents with a score of 100 was 13.16% for the ESIRE questionnaire and 7.89% for the McGill questionnaire. Both values are lower than the normal limit, which is 15% indicating that there is no ceiling effect (the data of each questionnaire cluster at top). However, the percentage of respondents with a score of zero was 31.58% for the ESIRE questionnaire and 23.68% for the McGill questionnaire (Table 4.2). Such percentages are higher than the normal limit which is 15% indicating a potential floor effect (the data of each questionnaire cluster at bottom). Literature indicates that if floor or ceiling effects are present, this could affect the psychometric properties of the scale or measure. For example, this could compromise the content validity (extreme scores could be missed in the lower or upper end of the measure or scale). Moreover, this could reduce the reliability of the scale (respondents with the minimum possible score will not be distinguished from each other). Furthermore, this could limit the responsiveness of the scale (changes cannot be measured among the respondents, and overtime) (Terwee et al. 2007). It could be argued that pre-treatment patients, who scored at the higher (positive eating outcomes) end of the ESIRE, could exhibit slight or no improvement in their condition after treatment, while those recording the likely lowest ESIRE score may not be able to determine any additional deterioration in their condition. However, the percentage of respondents with a score of zero is still acceptable considering that most patients were older. Streiner et al. (2008, p.84) argued that some older respondents could not read some items and subsequently answer them unfairly due to difficulty in concentration and retardation. These could be the reasons why there were some respondents with high zero scores. It is possible that the high percentage of respondents with zero score was due to the fact that most denture wearers were coming to the

Dental Hospital to replace their old dentures due to problems of wearing dentures (e. g., instability, poor retention and subsequently chewing difficulties and eating problems), particularly problems related to the lower denture. Therefore, it is reasonable that they were particularly disappointed with their old dentures, and therefore, reported low scores in terms of satisfaction with denture and ERQoL. It could be argued that flooring effect of this study did not affect the responsiveness of the ESIRE questionnaire, which was responsive to change in ERQoL over time (see chapter 5, Table 5.2). Finally, although the two questionnaires were self-administrated, and most participants were of aged 70 years or over, they had no difficulties in understanding the direction of the answers, which is contrary to a previous study (Tubert-Jeannin et al. 2003), which used a Likert scale and demonstrated a high rate of misunderstanding. This could be explained by evidence that the VAS scale is much more explicit, understandable, and less confusing than discrete type scales (Appukuttan et al. 2014).

# 4.5.2 Internal Consistency Reliability

Cronbach's alpha (Cronbach 1951) was used to test the overall internal consistency reliability of the scores of each questionnaire, and both values were high (0.96 for the ESIRE questionnaire, and 0.97 for the McGill questionnaire). The internal consistency reliability for each scale/domain score was also high and ranged from 0.86-0.95. For the ESIRE questionnaire, these good internal consistency reliabilities are in agreement with the result of a previous study (Kelly et al. 2012), and supports the use of ESIRE questionnaire in variety of samples. The analysis of this current study suggests that both instruments demonstrated satisfactory psychometric properties when used with this group of denture wearers in which the overall reliability of each questionnaire was high indicating that individual items of each questionnaire produced results consistent with the overall scale.

## 4.5.3 Tests of scaling assumptions

Results of several item-other scale correlations and item scaling success (Table 4.5) were potentially not promising because there was no adequate evidence of high scaling success. A 'scaling success' refers to an item correlates significantly more highly, by at least two standard errors, with its own scale than with other scales. A 'probable scaling' success indicates that an item correlates more highly with its own scale than other scales, but not significantly (by less than two standard errors). A 'scaling failure' refers to an item correlates significantly more highly (by at least two standard errors), with another scale than with its own scale. A 'probable scaling failure' indicates that an item correlates more highly with another scale than with its own scale, but not significantly (by less than two standard errors (Smith et al. 2005). The scaling success analysis of the current study showed that multiple item (i.e., Q2a, Q4a, Q5a, Q7a, Q8a, Q9a, Q10a, Q12a, Q13a, Q22a, and Q23a) were identified as scaling failures or probable scaling failures; therefore, they are possibly candidates for exclusion or elimination before conducting further item reduction using factor analysis to remove or delete the weakest items. Such findings could highlight the importance of discussing these items with the original ESIRE developers to ensure whether they can suggest any changes to these items. As discussing items, which perform poorly with the clinicians to determine their clinical importance, is not uncommon (Smith et al. 2005). Therefore, it is recommended to have consultation with clinical experts to evaluate the importance such items or questions before doing this analysis because some items could still have a potential importance from clinical perspective. Most item-to-own scale correlations (except item Q5a and Q12a) were  $\geq 0.4$  indicating adequate items convergent validity of the ESIRE scores among this group of edentulous people. Most item-other scale correlations were lower than item-own scale correlations indicating adequate item discriminant validity of the ESIRE scores.

The findings of the corrected item-total correlation, and Cronbach's Alpha if item deleted (Table 4.6) showed that removal of any item would result in a lower Cronbach's alpha. Thus, we would not want to remove any item or question from the ESIRE questionnaire except for result of some items (i.e., Q4a, Q5a, Q15a, Q16a, and Q23a). Removal of these items would lead to small improvement of the corresponding domain alpha, but again, we would not want to remove these items or questions because of two reasons; first, the overall reliability of the questionnaire is high (Cronbach's Alpha=0.96), and removal of any of these items results in only slight improvement in the reliability. Secondly, the corresponding values of Corrected Item-Total Correlation were  $\geq 0.25$ , which is the minimal accepted level of reliability for this test as indicated by many studies (Lamping et al. 2002; Smith et al. 2005; Streiner et al. 2008; Field 2013). It could be concluded that all corresponding Corrected Item-Total Correlation were well with the questionnaire overall, and no item should therefore be discarded. Nonetheless, further item analysis using other methods on adequate sample size is possibly required.

## 4.5.4 Construct (convergent and discriminant) validity of the ESIRE score

According to Campbell and Fiske (1959), correlation matrix analysis of MTMM approach is widely used to test the construct validity (convergent and discriminant validity) by demonstrating that multiple measures of certain construct should be more related to each other than to measures of another construct, although the two measurements are similar. Thus, in this study, the correlation matrices of modified MTMM approach (William 2008) were used to provide evidence for both convergent and discriminant validity of the scores of the ESIRE questionnaire in comparison to the McGill questionnaire, all in one analysis. This method used to assess if multiple domains of the ESIRE questionnaire are more related to each other than to domain of the McGill questionnaire (Table 4.7).

Within the ESIRE questionnaire, analysis showed that most correlations between domain scores were moderate or strong supporting the convergent validity of the ESIRE questionnaire. There was a weak correlation (r=0.22) between the domain (interruption to meals) and the domain (enjoyment of food/ eating), and this was expected because when the denture wearers always interrupt meals to clean foods or liquids from the dentures, the enjoyment of food/ eating decreases, particularly when eating in public places. The domain (interruption to meals) correlated weakly (r=0.13) with the domain (time for eating or preparation of meals). Again, this result was expected because when the denture wearers always interrupt meals to clean foods or liquids from the dentures, their satisfaction with time it takes to eat a meal decrease and this may be more of an issue when eating in public places. Since the majority of the correlations between the scores of the domain of the ESIRE questionnaire were positive and high, it could be concluded that results of the present study indicate adequate convergent validity of the scores of the ESIRE questionnaire among the targeted people (conventional complete denture wearers). This was expected assuming that all questions were intentionally worded in the same way or direction during development of the ESIRE questionnaire. Such findings support the hypotheses of the convergent validity of the ESIRE questionnaire.

Between the ESIRE and McGill questionnaires; there were moderate to strong correlations between the scores of some domains of the ESIRE questionnaire (i.e., enjoyment of food/ eating, confidence when eating, time for eating or preparation of meals, and functional ability to eat) with the scores of all domains of the McGill questionnaire apart from domain; ease of cleaning in which the correlations were low or weak. This result was expected because the two questionnaires include multiple questions related to eating of different food items, chewing ability, and satisfaction with dentures. The reason why there were positive and strong correlations between these domains in the two questionnaires could be that these domains were possibly sharing similar goals, and exploring similar issues. For instance, when the scores of the domain (functional ability to eat) of the ESIRE questionnaire increase, it is expected that the scores of the domain (general satisfaction) of the McGill questionnaire increase as well. Such findings indicate that the scores of these domains move in the same direction, and support the hypothesised relationship of convergent and discriminant validity between the ESIRE and McGill scores. Despite these moderate and strong correlations, there were, also, weak to moderate correlations between certain domains of the two questionnaires indicating that the scores of these domains did not move in the same direction. For example, there were weak to moderate correlations between the scores of some domains of the ESIRE questionnaire (i.e., self-consciousness/ embarrassment and interruption to meals) with the scores of all domains of the McGill questionnaire. Such results also support the hypothesised relationship of discriminant validity between the ESIRE and McGill scores. However, there were mixed (low, moderate and high) correlations between the scores of some domains of the ESIRE questionnaire (i.e., time for eating or preparation of meals) with the scores of all domains of the McGill questionnaire, and this was apposite to the original hypotheses. It could be argued that the scores of the two questionnaires were skewed and the conceptual domains of the two questionnaires were not matched perfectly, hence, it was expected to have weak or even negative correlations between dissimilar domains and moderate or high correlations between relatively similar domains or subscales. Both questionnaires include items that address satisfaction with dentures, chewing ability, oral function, comfort, and appearance. For instance, regarding the function dimension, there were certain questions, which related to similar food items such as apple, lettuce, and steak. This means that the two questionnaires share common measurement's items or more specifically, questions. Moreover, within each similar dimension, the number and content of each question differs. For example, within the function dimension, the ESIRE has questions concerning with how satisfied respondents are with their ability to eat foods with pips or seeds, nuts, and sticky or chewy foods; whilst the McGill questionnaire includes questions related to white bread, hard cheese, and dry salami. The two questionnaires were primarily designed to measure relatively different constructs; for instance, the ESIRE questionnaire focuses on social and emotional issues around eating with dentures (e.g., enjoyment of food/ eating, self-consciousness/ embarrassment, interruption to meals etc.); while, McGill questionnaire focuses on a general

satisfaction (e.g., ability to speak, stability, ability to chew, and function). These differences in item and domain contents may mean that the ESIRE is more targeted at detecting impacts in the form of social and emotional effects, while McGill is more targeted at detecting patient satisfaction with their dentures. For these reasons, perfect correlation (r=1.00) would not be expected between the scores of the McGill and the ESIRE questionnaires. Nonetheless, the commonality of underlying constructs suggested that there should be a strong correlation between the overall scores for the two questionnaires. This was obvious in the study when Spearman Correlation coefficient was used to test the direction and strength of relation between the total scores of the two scales. The Spearman Correlation coefficient was r=0.78, indicative of a strong correlation. Such findings do support the fact that the ESIRE and the McGill questionnaires are relatively similar measures in terms of aim and objectives of their items. It could be argued that this study provided a first evidence of construct validity of the scores of the ESIRE questionnaire among a sample of complete denture wearers. Validation process of any instrument or tool is based on gathering evidence through manipulation of various statistical tests or approaches on multiple population. It is not a straightforward process because there is no gold standard for doing it due to the variety of the measurements in terms of their content, length, and their aims and objectives. Ideally, the convergent and discriminant validity of any new scale should be tested against another instrument, which is 'maximally different' (Campbell and Fiske 1959). However, it is difficult to predict to which extent 'maximally different' is (Foster and Cone 1995). It could be concluded that correlational analysis has provided preliminary evidence of adequate construct validity; however, the validity evidence for the ESIRE questionnaire must be interpreted with some caution due to the inherent difficulty in differentiating between domains of the ESIRE and McGill questionnaires. Therefore, further evidence of validation of the ESIRE questionnaire, in the form of confirmatory factor analysis, is required, using a larger sample.

#### 4.6 Strengths and limitations of the study

This study has some strengths and limitations. Important psychometric properties (i.e., acceptability, floor and ceiling effects, internal consistency reliability and construct validity) of the ESIRE questionnaire were evaluated based on quality criteria for measurement properties of health status questionnaires (Lamping et al. 2002; Terwee et al. 2007). Moreover, the overall response rate of participants for the completion of the two questionnaires were high indicating that the potential respondents were interested in taking

part in the study. Furthermore, the overall all completion rate was high, particularly for the ESIRE questionnaire highlighting that most respondent understood most of the questions. Despite the aforementioned strengths, the present study also has some weaknesses or limitations, which were:

- The sample size was too small for factor analysis. The rule of thumb is that ten cases (subjects) per variable are required. As the ESIRE appears to have 33 items or questions, 330 respondents might be required for factor analysis. However, it was not feasible to have the resource to collect data on that larger number of patients in the context of a PhD study.
- There was no opportunity to measure the test-retest reliability of ESIRE questionnaire. The ESIRE questionnaire was given to all participants on two occasions (before and after denture replacement) for determining any change in ERQoL after dentures replacement, but not for measuring the test-retest reliability. We did not give the ESIRE questionnaire on two occasions before treatment because there was no enough time to do that, particularly if we took in consideration that most participants were older (mean age=72.95) years. Giving the ESIRE questionnaire for three times is probably demanding, and impractical due to relatively long time to complete the questionnaire (mean time to complete the ESIRE questionnaire was 34 minute) (Kelly et al. 2012). We prioritised our work and did the most important things within the scope of this PhD study.
- In general, all participants in the current study were recruited from the Northeast of England. It is, therefore, unlikely that the study samples are fully representative of the population of the denture wearers, and this could make the data not completely generalizable to the whole UK. It could be speculated that drawing the participants from a dental hospital population might have led to some bias in terms of those experiencing more problems and hence being less satisfied with their dentures.

# 4.7 Clinical implications of the study

The findings of this current study are possibly providing evidence that will be 'scientifically credible' to clinicians and researchers, who will use the ESIRE questionnaire to evaluate the efficacy of new treatments for edentulism. Clinicians and researchers could use the ESIRE questionnaire to determine any change in ERQoL among edentulous people wearing

conventional dentures or ISOD. Results obtained from using the ESIRE questionnaire as an oral health measure could increase the understanding of clinicians regarding the impact of denture replacement on ERQoL, and encourage them to pay more attention to the impact of wearing conventional complete denture on social and emotional issues around eating with complete dentures.

### 4.8 Conclusions

In general, the ESIRE questionnaire was superior in comparison to the McGill questionnaire in terms of data distribution and skewness, completeness rate, internal consistency reliability and acceptability. The scores that obtained from ESIRE were less skewed, and normally distributed with one outlier, while these obtained from the McGill questionnaire were skewed, and not normally distributed with more outliers. Moreover, the overall item completeness rate of the ESIRE questionnaire was higher than that of the McGill questionnaire, and the overall item missing rate of the ESIRE questionnaire was lower than that of the McGill questionnaire. Both questionnaires demonstrated a high Cronbach's Alpha values, which are considered as an indicative of an excellent internal consistency. ESIRE questionnaire demonstrated good psychometric properties when used with this group of denture wearers in which the values of overall reliability and item-total correlation were high and adequate indicating that there was no need to delete any item from the questionnaire. Correlational analysis of MTMM approach demonstrated adequate convergent validity of the ESIRE scores and an acceptable discriminant validity of the scores of the ESIRE questionnaire in comparison with the scores of the McGill questionnaire among this sample of denture wearers. Therefore, it could be concluded that exploratory convergent and discriminant validity hypotheses concerning the relationship between scores of the ESIRE and McGill questionnaires were supported. However, construct validity of the ESIRE questionnaire needs to be further explored using confirmatory factor analysis on a larger sample. Such analysis could be useful in producing a short form of the ESIRE questionnaire. The ESIRE questionnaire could be translated to other languages and used by clinicians and researchers in other countries to collect data on ERQoL (see section 4.7). Improvements in ERQoL could be of clinical importance for the clinicians, who make the dentures.

# Chapter 5. Cohort Study: The impact of Replacement Conventional Complete Dentures on Eating Experience

## 5.1 Introduction

It is acknowledged that the transition to edentulousness, and subsequent prosthetic rehabilitation, have various influences on overall QoL, including oral and general health (Davis et al. 2000; Scott et al. 2006; Emami et al. 2013). Similarly, this transition has been shown to have a negative impact on the functional ability to consume different foods and nutrients (Moynihan et al. 2009). For the majority of edentulous patients, wearing conventional complete dentures is often the only available treatment option, predominantly due to their relatively low cost (Carlsson and Omar 2010). However, such a form of prosthetic rehabilitation could have several effects on patients' lives such as functional, structural and psycho-social influences, effects on OHRQoL and ERQoL (Davis et al. 2000; Forgie et al. 2005; Hyland et al. 2009; Basker et al. 2011; Müller 2014). Therefore, exploring patient perceptions regarding the effects of different oral conditions (e.g., edentulism), and treatment options (e.g., conventional complete dentures) on health outcomes (OHRQoL and ERQoL) using specific patient-based tools or instruments is important.

OHRQoL measurements have been widely used to assess the impact of edentulousness and prosthetic rehabilitation on the life of edentulous individuals (Ellis et al. 2010; AlBaker 2013). Some of these instruments were used to measure the changes in OHRQoL, and patient satisfaction before and after denture relining (Krunić et al. 2015) or denture replacement (Kuo et al. 2013; Viola et al. 2013), and there were differences in the findings of these studies regarding the influence of denture replacement on the OHRQoL and patient's satisfaction. For example, several studies reported that provision of new complete dentures had a positive influence on patient satisfaction; however, it did not necessarily result in a significant social impact on OHRQoL (Forgie et al. 2005; Scott et al. 2006). Other studies, however, have shown an overall improvement (Ellis et al. 2007) or a significant improvement (Viola et al. 2013) in patient's satisfaction and OHRQoL among edentulous patients after provision of new conventional complete dentures. Whilst we have some understanding therefore on the effect of denture replacement, particularly with conventional complete dentures, on social and emotional issues related to eating with dentures. For example, feelings and experiences of

the patients during eating with their dentures, enjoyment of certain types of foods, especially in public arena with families or friends or how their dentures affect their social interaction with others. These factors are important in terms of clinical success; however, there is little in the literature regarding the effect of denture replacement on ERQoL. Therefore, exploring issues around eating with complete dentures is useful for two reasons; first, to know how to increase enjoyment of food/ eating among denture wearers, and second, to determine what needs to be done to change dietary behaviour to inform patient-centred care. In other words, there is a need to know about eating issues in order to provide patient-centred advice around eating that helps patients enjoy eating with dentures and help promote healthier eating (e.g., promoting eating vegetables and fruits in suitable ways for denture wearers). In order to fully understand the actual impact of wearing conventional complete dentures on ERQoL, researchers at Newcastle University, UK, have designed and validated a 24-item instrument to collect data on Social and Emotional Issues Related to the Eating (ESIRE questionnaire) (Kelly et al. 2012). The ESIRE questionnaire is a patient-based instrument designed with questions (quantitative part) to be answered using VAS response ranging from zero (anchored to a negative eating outcome) to 100 (anchored to a positive eating outcome). In addition, open questions (qualitative part) are included to be answered using free text. The qualitative data give detailed information or explanation to the breadth of data collected by VAS scale to further understand the effect of wearing conventional complete dentures on eating and enjoyment of food, and help explain any differences in responses to the VAS scale. The authors tested face validity, content validity and reliability tests. The responsiveness of an instrument developed primarily for measuring changes over time is important (Guyatt et al. 1987a; Locker et al. 2004). Responsiveness of any instrument or questionnaire refers to the ability of a measure to determine or reflect change (e.g., improvements or deteriorations), which could happen within the selected sample (Guyatt et al. 1987a). Therefore, the objective of this study was to apply the ESIRE questionnaire to a cohort study on patients requiring replacement dentures to determine any change in ERQoL among edentulous patients, before and after complete denture replacement. The primary aim was to determine if replacing complete dentures impacted on ERQoL. The null hypothesis (H<sub>0</sub>) is there was no change in the average response of the ESIRE scores over the two time points. In other words, there would be no difference in the ERQoL, before and after treatment with new conventional complete dentures. The alternative hypothesis  $(H_1)$  was there is a change in the average response of the ESIRE scores over the two time points, in that, there would be a difference in the ERQoL, before and after treatment with new conventional complete dentures. The

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secondary aim was to measure responsiveness of the ESIRE questionnaire to measuring changes in ERQoL over time among this sample of complete denture wearers.

#### 5.2 Aims and objectives

### 5.2.1 Aim

To determine any magnitude of change in ERQoL among edentulous patients after conventional complete denture replacement, to gain in-depth information on social and emotional issues related to the eating with dentures, and to assess the responsiveness of the ESIRE questionnaire to change in ERQoL.

#### 5.2.2 Objective

To apply the ESIRE questionnaire in a cohort study on edentulous patients with existing dentures and who need new conventional complete dentures, to collect data on ERQoL.

## 5.3 Methods

#### 5.3.1 Study design

A prospective cohort study was conducted on patients (complete denture wearers) from Newcastle Dental Hospital, Newcastle upon Tyne, UK from September 2015 to June 2016.

## 5.3.2 Ethical considerations

A positive ethical opinion was previously sought (see chapter 4, section 4.3.2).

#### 5.3.3 Study participants

Patients meeting the inclusion criteria (see chapter 4, section 4.3.3), who were commencing treatment with conventional complete dentures, were approached at one of their treatment visits to the Prosthodontic clinic. Following a verbal explanation of the main aims of the study, potential participants were invited to take part in the study by giving them a participant information sheet (Appendix E), and were asked by the researcher to give verbal and written consent (Appendix F). All participants were assigned to undergraduate dental students under supervision for denture replacement, and according to the standard Newcastle Dental Hospital protocol (Figure 5.1).



Figure 5.1: Flow chart showing stages of provision of conventional complete dentures. Adapted from Newcastle Dental Hospital with permission from Department of Prosthodontics.

## 5.3.4 Sample size

The sample size was determined using data from previously published research (Ellis et al. 2007). Using paired *t*-test power calculation, it was estimated that 48 patients would provide 80% power to detect a significant difference between the mean values of total ESIRE scores before and after treatment, at a significance level of  $\alpha = 0.05$ . The aim was, therefore, to recruit approximately 80 patients with a target of 48 to complete the study, based on refusal to participate and attrition.

#### 5.3.5 Completion of the questionnaires

Participants were asked to complete the ESIRE questionnaire (Appendix B) on two occasions in their home, in their own time. The first questionnaire was provided to the patients during one of their scheduled visits to the clinic prior to insertion of the new dentures. Instruction on how to complete and return the questionnaires during their subsequent visits or provided with a sealable, stamped, addressed envelope to send the questionnaires by post. After that, the research team recorded the date of insertion of replacement dentures, and gave a second identical follow up ESIRE questionnaire to all participants for completion, one month after the insert date. The second questionnaire was specifically related to the new conventional complete dentures, and the participants were unable to refer the responses they had originally made in the first questionnaire about their original or existing dentures. Instructions on how to complete the questionnaire were repeated, and sealable, stamped, addressed envelopes were given to all participants to send the questionnaire back to the research team by post. To avoid bias, administration of the questionnaires was undertaken by the researcher (HA), who was not involved with treatment. A unique identification code allocated for each participant was used to link the two questionnaires.

#### 5.3.6 Data analysis

As the ESIRE questionnaire has two parts, quantitative and qualitative, analysis of each part was done separately. For the quantitative data, an Excel database (Microsoft Office Professional Plus, 2013) was used to enter the raw data (scores) for the purpose of subsequent analysis using IBM SPSS Statistics 23.0 software (SPSS Inc., Chicago, IL, USA). Descriptive analysis was performed using frequency measures for categorical variables (e.g., gender, age group, way of referral, regular dental visit, number of dentures used before and period of wearing dentures), and mean, median, standard deviation, standard error, percentiles, and confidence intervals for continuous variables (i.e., ESIRE score). Normality test (Shapiro-Wilk test), skewness, and kurtosis were used to test the normality of distribution of the data. In order to test the difference between the pre and post-treatment ESIRE scores, the assumption of normality was tested using the difference between paired scores, rather than the raw scores themselves based on the 'Central Limit Theorem (CLT)' (Field 2013), which argues that this assumption is often satisfied for large data sets (n > 30). Paired t-test was used to determine the mean difference of total ESIRE score, before and after provision of new conventional complete dentures. Paired t-test was, also, used to assess the mean differences of the scores for each domain of the ESIRE questionnaire. Independent sample t-test was used to determine gender differences in the ESIRE scores after the treatment. Sequential Bonferroni correction procedure (Holm 1979) was used to minimize the probability of 'Type 1' error (rejecting the null hypothesis when it is true). Cohen's standardized effect size (Cohen's d) was used to measure the Effect Size (ES) (the difference between two means expressed in standard deviation units). It was calculated by measuring the difference between the means of the two groups (pre-and post-treatment) divided by a standard deviation of group one (using pre-treatment ESIRE variance). Cohen's benchmarks (small: ES= 0.2, moderate: ES= 0.5, and large: ES  $\geq 0.8$ ) for interpreting the effect size were used to indicate the magnitude of change observed (Cohen 1988). Responsiveness to change (Deyo et al. 1991) was measured by comparing the pre and post-treatment ESIRE scores. A decrease in the effect of social and emotional issues around eating with dentures should generate an increase in the ESIRE scores, reflecting an improvement in ERQoL. Responsiveness was initially investigated using Paired t-test to determine any difference in the mean of total scores, before and after provision of new conventional complete dentures (Deyo et al. 1991). Effect size was also used to evaluate the responsiveness of the ESIRE questionnaire (Cohen 1988). Responsiveness of the ESIRE questionnaire to changes in ERQoL was also quantified using a Standardised Response Mean (SRM) in which the mean difference in scores for an instrument, divided by the standard deviation of the change in these scores (Husted et al. 2000). Significance level was set at p < 0.05.

For the qualitative data, a Microsoft Word document was used to enter and analyse the free text collected from the pre and post-treatment ESIRE questionnaires. Qualitative data were categorised into six main themes based on the six domains of the ESIRE questionnaire. Indicative quotations from all interviewees were coded according to study number; for example, (P01, P02...), gender; Male/Female (M/F) and age of participants during their

recruitment to the study. All identifying data including patients' names, initials, or hospital numbers were kept strictly confidential.

## 5.4 Results

# 5.4.1 Patients recruitment

Figure 5.2 shows participant's journey during the cohort study. The total number of patients that have been invited to participate in the study was 117 patients. From those potential participants, 40 (34.19%) patients declined to participate in the study for different reasons mainly time or some patients found the topic is not interesting. The number of participants, who agreed to participate, and signed the consent form of the study with the researcher was 77 (65.81%). Once consented, the researcher provided the participant with the first copy of the ESIRE questionnaire. Ten (13%) participants withdrew before completion of the first ESIRE questionnaire for various reasons mainly time. Sixty-seven (87%) participants returned the first ESIRE questionnaire. The number of participants, who had their new dentures fitted in their mouth, was 60 (100%). From those participants, seven (11.67%) dropped out from the study due to many reasons mainly time, being not interested to continue in the study, and failure of their new dentures, and 53 (88.33%) participants received a second (follow up) ESIRE questionnaire. From those participants, who received the second ESIRE questionnaire, 50 (94.34%) participants returned the second ESIRE questionnaire to the researcher, and three (5.66%) participants dropped out before completion of the second ESIRE questionnaire. The reason behind this drop out was unclear for two participants and due to failure of the new dentures for one participant.





# 5.4.2 Quantitative data (VAS scores)

Table 5.1 illustrates characteristic of participants according to different variables. Seventyseven participants were recruited to participate in the study. Fifty participants aged 52-85 years (mean age, 72 years, with 46% >75 years), 21 males (42%), and 29 females (58%) were completed both questionnaires. Participants were either referred by their General Dental Practitioners (GDPs) from primary health care (n=38 (76%)) or were self-referred (n=12 (24%)). At the time of recruitment, a large percentage of participants (84%), had worn two or more set of dentures for three years or more.

Variables	Number	Frequency (%)
Gender		
Male	21	42%
Female	29	58%
Age group (Years)		
< 65	8	16%
≥ 65-74	19	38%
≥75	23	46%
Way of referral		
Referred by GDPs	38	76%
Self-referral	12	24%
Regular dental visit		
Yes	37	74%
No	13	26%
Number of dentures used before		
< 2 dentures	8	16%
$\geq$ 2 dentures	42	84%
Period of wearing dentures		
< 3 years	8	16%
$\geq$ 3 years	42	84%

Table 5.1: Distribution of participants by age, gender, way of referral, regular dental visit, number of dentures used before, and period of wearing dentures.

Figure 5.3 and Figure 5.4 display descriptive statistics and distribution of pre and posttreatment ESIRE scores. The results shows that the data of this study were normally distributed in which Shapiro-Wilk test values were 0.97, (p>0.05) for pre-treatment ESIRE scores, and 0.96, (p>0.05) for post-treatment ESIRE scores. Data were also not skewed in which z value was 1.26 for the pre-treatment ESIRE questionnaire, and 1.21 for the posttreatment ESIRE questionnaire. Over all, the post-treatment ESIRE scores were higher than the pre-treatment ESIRE scores. This difference between total scores of pre-treatment and post-treatment was reflected by their values of mean 39.91 for the pre-treatment ESIRE questionnaire and 60.24 for the post-treatment ESIRE questionnaire, median, 38.79 for the pre-treatment ESIRE questionnaire and 57.76 for the post-treatment ESIRE questionnaire.



Figure 5.3: Distribution of the pre-treatment ESIRE scores.



Figure 5.4: distribution of the post-treatment ESIRE scores.

Figure 5.5 shows box plots of the distribution of the pre- and post-treatment ESIRE scores. Visual inspections of these pox plots showed that the pre-treatment and post-treatment scores were approximately symmetrical with no obvious outliers. The higher post-treatment treatment ESIRE scores than pre-treatment ESIRE scores were reflected by their percentile values in which both; upper 82.76 and lower 45.43 quartiles of post-treatment ESIRE questionnaire were greater than upper 50.95, and lower 24.45 quartiles of the pre-treatment ESIRE questionnaire. Similarly, this difference was reflected by their mean, median and percentile values of each domain.



Figure 5.5: Box plots illustrating descriptive statistics of total pre- and post-treatment ESIRE scores<sup>1</sup>.

<sup>&</sup>lt;sup>1</sup> X-axis represents the ESIRE score; y-axis represents the pre-treatment and post-treatment Boxplots. Pretreatment: Mean=39.91, median=38.79, upper quartile=50.95, and lower quartile=24.45. Post-treatment: Mean=60.24, median=57.76, upper quartile=82.76 and lower quartile=45.43.

Table 5.2 shows paired sample statistics and effect size of the total ESIRE scores, in addition to the score all domains. Descriptive statistics of the difference between paired scores showed that the data were approximately normally distributed (Shapiro-Wilk test statistic 0.96, p>0.05, and not skewed, z-value 1.83). The sampling distribution was approximately normally distributed for all domains. The result showed a statistically significant difference (mean difference=20.33, p < 0.001) between the mean of the total ESIRE score, before and after treatment. In addition, there were improvements in the ESIRE scores before and after the treatment for all domains. Using a sequential Bonferroni correction test, all P-values were significant at a table wise 0.05 level. The effect size was calculated by measuring Cohen's d. It was large (0.95) for the total score, and ranged from medium (0.59) for the domain relating to 'time for eating or preparation of meals' to large (1.30) for the domain relating to 'enjoyment of food/ eating' with the exception of the domain relating to 'interruption to meals', which was small (0.37). Values of SRM were also large (0.87) for the total score, and ranged from medium (0.54) for the domain relating to 'time for eating or preparation of meals' to large (1.06) for the domain relating to 'enjoyment of food/ eating' with the exception of the domain relating to 'interruption to meals', which was small (0.36).

Domain	ESIRE scor	es-Mean (SD)	Mean difference	95%	• CI+	Paired-t test	Effect size
	Pre-treatment	Post-treatment	(SE)	Lower	Upper		
Enjoyment of food/ eating	33.87 (21.02)	61.15 (24.89)	27.28 (3.63)	19.99	34.56	P<0.001*	1.30 <sup>a</sup> 1.1 <sup>b</sup>
Self-consciousness/ embarrassment	45.04 (24.52)	63.18 (28.95)	18.13 (3.88)	10.35	25.92	P<0.001*	0.74 <sup>a</sup> 0.66 <sup>b</sup>
Interruption to meals	45.80 (33.69)	59.08 (34.29)	13.29 (5.27)	2.69	23.88	P<0.05*	0.37 <sup>a</sup> 0.36 <sup>b</sup>
Confidence when eating	52.66 (28.93)	71.39 (25.67)	18.73 (4.84)	9.01	28.45	P<0.001*	0.65 <sup>a</sup> 0.55 <sup>b</sup>
Time for eating or preparation of meals	46.47 (31.18)	64.94 (30.08)	18.47 (4.85)	8.73	28.22	P<0.001*	0.59 <sup>a</sup> 0.54 <sup>b</sup>
Functional ability to eat	25.71 (20.42)	43.87 (28.59)	18.16 (3.67)	10.78	25.54	P<0.001*	0.89 <sup>a</sup> 0.70 <sup>b</sup>
Total score	39.91 (21.36)	60.24 (24.22)	20.32 (3.30)	13.69	26.95	P<0.001*	0.95 <sup>a</sup> 0.87 <sup>b</sup>

+95% Confidence Interval of the Difference. P< 0.05 denotes significance. P<0.001 denotes highly significance. \* P value is significant at table wide 0.05 level using a sequential Bonferroni correction procedure. Measures of responsiveness, (small=0.2), (moderate=0.5), (large  $\geq$ 0.8): Cohen's d using pre-treatment ESIRE variance <sup>a</sup>, and SRM <sup>b</sup>.

Table 5.2: ESIRE scores before and following complete replacement dentures. Descriptive statistics for total score and scores for each domain.

Table 5.3 presents the change in ESIRE scores for male compared with female participants. There was a non-significant trend (P=0.07) towards a greater increase in score in males compared with females. No statistically, significant difference in between men and women was observed for change in the following domains: Enjoyment of food/eating, interruption to meals, confidence when eating and time for eating or preparation of meals. However, a statistically significant greater change in score was obtained for men compared with women for the domains of self-consciousness/ embarrassment and functional ability to eat.

	Change in the ESIRE score between pre- and post- treatment								
Domain	Male (n=21) Mean (SE)	Female (n=29) Mean (SE)	<sup>a</sup> <i>P</i> -value						
Enjoyment of food/ eating	32.76 (6.00)	23.31 (4.43)	0.20						
Self-consciousness/ embarrassment	27.71 (6.13)	11.28 (4.67)	0.04						
Interruption to meals	23.10 (7.43)	6.34 (6.91)	0.11						
Confidence when eating	23.67 (8.48)	15.31 (5.70)	0.40						
Time for eating or preparation of meals	19.95 (8.16)	17.48 (6.05)	0.81						
Functional ability to eat	27.38 (6.39)	11.45 (3.97)	0.03						
Total score	27.29 (5.76)	15.31 (3.65)	0.07						

<sup>a</sup> *P*-value determined using Independent sample t-test.

 Table 5.3: Gender comparison of change in the ESIRE score one month following treatment.
Figure 5.6 shows the percentage of pre-and post-treatment ESIRE scores after transforming them into three levels (low, medium, and high). Most pre-treatment ESIRE scores were medium, 44% with 42% being low, and 14% high; while, for the post-treatment ESIRE scores, the percentages of a medium and a high score was 44%, and 12% had a low score.



Figure 5.6: Percentage of pre- and post-treatment ESIRE scores classified as low, medium, and high, before and following complete denture replacement (n=50).

# 5.4.3 Qualitative findings

# **Enjoyment of food/ eating**

Before treatment, the majority of participants commented that existing dentures negatively influenced enjoyment of eating and to a lesser extent drinking, particularly outside the home in public places or with relatives or friends. As one participant reported:

"Really badly, don't go for meals with my partner anymore. On holiday cannot eat what I want. Makes me depressed as I eat junk food and put weight on. I am constantly being told to lose weight by my consultant as it affects my condition." (P42, M63)

Other participants were embarrassed, felt a discomfort, and attributed this to poorly fitting dentures and chewing difficulty:

*'I find eating in public embarrassing as the dentures tend to move about and I find biting into food impossible. Sometime food gets under the bottom dentures.'* (P11, F69)

These sentiments are reflected by the low pre-treatment ESIRE score (Table 5.2).

When the patients were asked about their satisfaction with their ability to chew foods, some were dissatisfied mainly due to poor fit and instability of the dentures, particularly lower dentures. This affected their ability to chew hard or tough foods:

"Unable to chew an apple unless it is sliced or stewed. Top set is fine but bottom set keep rising when I chew and the food gets under the palate, so I have to remove the bottom set to enable me to eat my meal." (P35, F74)

However, chewing difficulty was less of an issue for other participants; one participant mentioned:

"I manage to chew pretty well with most foods." (P11, F69)

The ability to taste foods seemed to be not affected by wearing dentures for most participants, who were satisfied with their taste ability, as one participant reported:

'I am quite pleased with the taste of food, I am not sure whether false teeth make any difference with the taste of food.'' (P44, M69)

However, for some, taste was affected by inability to chew foods:

*'Because I am not chewing my food properly, I swallow bigger amounts, so therefore I can't really taste my food the way I should.''* (P23, F75)

After treatment, the most common response of most participants was achieving a degree of enjoyment of food or eating with their new dentures and this was reflected by the higher scores for this ESIRE domain that were achieved post rehabilitation (Table 5.2).

"Very good fit and comfortable. Able to taste food properly. Dentures fit well and don't move about when eating. Make it enjoyable when go out with friends and family." (P04, M65)

Despite the improvement of scores following treatment, and the positive comments of many patients regarding enjoyment of eating and drinking, some participants still had eating problems with their new dentures. For example, one participant mentioned a serious impact of new dentures on eating:

"Can only 'suck' my food then swallow if soft/ small enough. New dentures are only ok for cosmetic use. No eating, drinking sometimes ok. No real food eaten for 20 months. Very boring [for eating], some foods all the time dentures [are] out in a napkin. Some food gets stuck in my throat. So avoid lots of food on menu. Meat, vegetables, apples etc. any hard foods that you have to bite into. Unwell, not a balanced diet for ages. No pleasure to eat out or have a wide range of food." (P45, F67). It seems that despite improvement in the overall score of this domain, there is still a loss of enjoyment of foods during eating, possibly due to chewing difficulties.

#### Self-consciousness/ embarrassment

Before denture replacement, there were several examples where participants were extremely self-conscious or embarrassed because of their existing dentures during eating, and to a lesser extent, during drinking. One participant reported a typical story of the impact of complete dentures on social and emotional issues around eating with dentures:

"Because teeth drop and I start whistling, generally feel uncomfortable and embarrassed. Don't go out and eat in public at all. On holiday, take teeth out before eating carry them around, and moan to partner, everyone knows I have problems with teeth and people give advice, try to make jokes and live with it but I get depressed and frustrated." (P42, M63)

After denture replacement, many participants described feelings of not being as self-conscious or as embarrassed as they had been before. A number of statements from the patients supported the improvement in the mean score of this domain (Table 5.2), for example:

"Not a lot with my new dentures." (P32, M70)

"..... I have had no embarrassing moments really." (P12, F79)

Nonetheless, for some participants the experience of self-consciousness or embarrassment continued after treatment. One participant, who mentioned a similar story before and after denture replacement, pointed out a typical example of this:

"I look very old, ugly without the dentures in my mouth, but have to remove them if I want to eat in a cafe. Make me depressed, not wanting to go out for social events etc. Feel sick, older due to types of foods I eat/ swallow. Dentures only stay in if I do not move mouth muscles in any way, so only talk when denture in mouth not eat. Cannot eat anything, while denture in mouth.... Hide behind a napkin, as mouth is horrible, when trying to keep food inside, before able to swallow food can drop back into palate. Make me withdraw from many events in normal life, don't enjoy any food now, as bored having same food week after week for 20 months. Don't eat with dentures, I can't." (P45, F67)

It appears that denture replacement can decrease the feelings of self-consciousness or embarrassment among some denture wearers. Nonetheless, for some, such feelings continue after denture replacement despite the significant overall improvement of the ESIRE score of this domain among the study population. Movement and falling out of the dentures during eating, and associated interruptions to meals could be reasons for this embarrassment.

#### **Interruption to meals**

Prior to the treatment, many respondents interrupted their meals to clean foods from their existing dentures. Several participants considered doing such process as annoying and embarrassing, particularly outside the home:

*"The embarrassment of having to be excused when I leave the table to go to bathroom to clean the dentures."* (P35, F74)

"It is very annoying as you would have to make an excuse to leave the table way through a meal. If I try to manage until the meal is finished, I would often end up with an ulcer where food had irritated." (P24, F65)

*'It's fine when I am at home, but very awkward if I am out.''* (P29, F62)

After treatment with new dentures, there was indication that for some, interruption to meals was less of an issue that before, for example:

"This has not occurred with my new dentures." (P09, F75)

*"This rarely happens and has really no effect on me. It just needs to be done."* (P18, M82)

However, the smaller improvement in the score for this domain (Table 5.2) is reflected in the finding that some participants continued to experience interruption to meals to clean their new dentures from some foods (e.g., seeds and nuts). They described the process as annoying or upsetting especially if dentures have been fixed with fixative and food got underneath them:

*'It is only rarely when I eat tomatoes nuts and seeded bread. But I continue to try stick to my normal diet.''* (P12, F79)

*'It is very upsetting as you need to excuse yourself and it is obvious something is wrong.''* (P24, F65)

*"This is very uncomfortable and inconvenient especially with using a fixative."* (P19, F77)

Although, for some patients, interruption to meals continued, adversely affecting confidence to eat in public places and in front friends and relatives, denture replacement reduced the interruption to meals for some, and overall, the score for this domain increased.

# **Confidence** when eating

Several participants had experienced a lack of confidence during eating and drinking with their existing dentures before treatment because they had concerns that their dentures may fall down during eating or drinking. When participants were asked about their level of confidence when eating and drinking and what affected this, one participant replied:

"The fact that the denture will move and I will be unable to finish a meal. I do feel less confident when eating out and am often relieved when the meal is finished and I have manged." (P24, F65)

A lack of confidence during eating and drinking adversely affected food choice and social interaction with others:

'It limits my choice of foods, apples for example can only be eaten by cutting into small pieces with a knife.'' (P46, M75)

*"It makes me not want to go out for meals as I am always uneasy. In case anything gets stick or the denture drops."* (P11, F69)

Despite the overall improvement of the score of this domain (Table 5.2), many participants did not provide free text answers to explain their VAS scores. The level of confidence increased after dentures replacement for some participants, who became more confident with their new dentures; for example, one participant explained:

"Lot more confident, now I have new dentures." (P32, M70)

Other participants did not lack confidence, particularly at home, but many had concerns when eating outside their homes, suggesting that eating out remains a problem for them:

"Doesn't affect as much now [compared with when participant was 16 years of age]." (P15, M52)

"Doesn't affect me at home. Only when eating out as there might be a food on my teeth." (P50, F68)

The loss of confidence during eating with dentures can in part be attributed to movement and falling down of the dentures, which was regarded as an embarrassing issues. Likewise, the increase of confidence during eating may be attributed to the increase of fit and stability of the new dentures.

#### Time for eating or preparation of meals

Before treatment, participants described taking a long time to finish meals, meaning food became cold, and that they were the last person to finish a meal, which caused them embarrassment. These issues were regarded as a major concern by denture wearers. Many patients used denture fixatives or pastes to fix their dentures during eating to alleviate this. One participant reported:

"If I am still eating when others have finished they tend to watch me eating. I don't like to be the only one eating when others have finished I may be holding them back from the next course. I always ensure that my dentures are held in place as good as possible by applying a fixative, usually Poligrip ultra." (P46, M75)

After denture replacement, there was an improvement in the overall score of this domain (Table 5.2), and many patients seemed unconcerned about the time it took them to eat a meal:

*``I am not concerned at all. Sometimes with my old set, I might put some Poligrip on them. If it was an important do [special occasion].''* (P44, M69)

However, some patients still had concerns about the time it took to eat a meal, and used fixatives or pastes to fix their new dentures during eating, particularly when eating out with company:

'In company, I sometimes leave my meal unfinished if I am slow. Sometimes it's cold before I am finished not a happy chappy. I always use a fixative when I eat in company, I couldn't eat without it.'' (P19, F77)

Using denture fixatives to fix new dentures during eating may be a means to increase confidence when eating but could also be an indicator of poor retention and fit of the dentures.

# Functional ability to eat

Before treatment, there were many examples of patients, who were struggling to eat hard or tough foods (e.g., apples, steaks, seeds and nuts, sticky or chewy foods, and lettuce). One participant described almost all functional difficulties associated complete dentures:

"I could never bite into an apple, my teeth do not meet so I could not bite into anything. I would be scared I would snap a tooth this happened a couple of years ago. Pips and seeds get trapped under my denture and if I do not get them out immediately, I get ulcer. I can manage steak if it is extremely tender. I love nuts but like seeds they get caught under denture and ulcer are the result. Sticky or chewy foods would stick to denture and pull off fixative, so very uncomfortable. If I try to eat lettuce on its own, the teeth obviously do not meet properly at the back so it would be too thin to be eat." (P24, F65)

Despite the significant improvement in overall score with regard to functional ability to eat (Table 5.2), several participants reported the same difficulties in eating hard foods after denture replacement. For example, one participant was experiencing continued eating difficulties with her new dentures, and mentioned a similar story to his experience with old dentures concerning the ability to eat hard or tough foods:

"I would never try to bite an apple as I know I would not be able to. Seeds get caught under denture. Steak would have to be very tender. Nuts gets caught and this hurts often causing ulcer. Sticky or chewy foods would stick to dentures and pull them apart. Lettuce is so thin and very hard to eat. I know that my new dentures is better than my old one. I still need paste and they are nothing like having your own teeth but they are better and once they have been altered they are catching I am sure I will be quite satisfied." (P24, F65)

However, another participant commented that she could manage to eat some hard foods with their new dentures better than the old ones:

'I can chew steak better on one side. It does not take me as long as it used to. Find it easier to eat lettuce than before.'' (P29, F62)

Despite the significant improvement in score for this domain, the functional ability to eat hard or tough foods is one of the main eating-related problems that was described by some denture wearers after provision of the new dentures.

In general, there were examples of a good cooperation and communication between the patients and the dental team responsible for their treatments highlighting the importance of establishing a good relationship between them that helps preparing the patient psychologically to successfully receiving the treatment. This could be one of the reasons for improvement of the post-treatment ESIRE scores. For example, several participants had described their feelings and impressions regarding the successfulness of their treatment with new dentures in different ways. They were satisfied and thankful to the students and the dental staff, who did the treatment:

"Full mark for operator... she has done a great job on my dentures. And thank the rest of the staff for their smiles of welcome when you walk into the department. My dentures no longer move when speaking or eating. I can now enjoy eating again." (P37, F78)

"My new dentures make meal times a much nice experience, thanks to X sorting the problem with the lower dentures." (P09, F75)

"With my new dentures, the student I was under who took her time to make sure they fitted perfectly, I am now very pleased with them." (P10, F80)

"My dentures have made a huge improvement of my life. I am very happy with the dentures that I have been given." (P47, M82)

'I have been without a good set of teeth, as I paid  $\pounds 220$  were so useless. Since I got my new teeth from the dental hospital, I am over the moon as I cannot fault them as I can eat anything'' (P43, M67)

On the other hand, most eating related difficulties that had been highlighted by the qualitative data were functional and related to eating (e.g., difficult to chew or bite hard foods, pips and

seeds get underneath dentures, bites get stuck in teeth, sticky or chewy foods tend to pull dentures out and pain and discomfort during eating with dentures). This could indicate that it is importance to address such problems in any future dietary advice or intervention for denture wearers.

'I am not able to chew apples or steak but overall I am very happy with the dentures I have. ''(P38, M70).

"only eating soft food same every day, no proper meals/meat etc." (P45, F67).

"Current set of teeth do not fit; it's like wearing a pair of size 12 shoes when you only take a nine. I paid 500.00 pounds (2 sets) and neither pair fit." (P42, M63).

"Because my dentures are so loose that I am not able to chew." (P13, F81).

"Dentures move and get stuck in food then have to remove all from my mouth and separate/ clean dentures." (P45, F67).

*"Both top and button teeth not fitting correctly. Food getting under the dentures."* (P05, F84).

I try not to eat any type of food with pips or seeds as they always get under my bottom denture and this causes ulcer. Because I have to cut the steak into small pieces to try and chew it more satisfactory this hurts my gums. I very rarely eat nuts as they are very hard to eat and they also get under my dentures. Sticky foods stick to my dentures and my bottom denture tends to move about, also cheesy food aches my jaws also my bottom denture moves about. (P08, F74).

In conclusion, the qualitative findings revealed that denture replacement can positively improve the enjoyment of food/eating, socialising, self-consciousness, interruption to meals, comfort and function. Such findings support the results of the quantitative data in which there were improvements in the total ESIRE score in addition to the score of all domains. However, for some denture wearers, wearing complete dentures still has a negative effect on social and emotional issues around eating even after denture replacement indicating that providing eating advice for denture wearers is warranted. This implies that those patients might benefit most from some eating advice, although all patients may benefit to some extent.

# 5.5 Discussion

So far, this is the first study that has longitudinally followed the effect of denture replacement on ERQoL. In this study, the percentage, 58% of edentulous women was higher than that of men, 42%. This result in agreement with the finding of Viola et al. (2013) in which the percentage of edentulous women, 74.3% was higher than that of men, 25.7%. Such findings could be explained by the fact that women are more susceptible to the tooth loss than men (Wennström et al. 2013). The percentage of edentulous patients aged 65 years and less was 16%. The prevalence raised to 38% for those between 65 to 74 years old and 46% for patients aged 75 years and over. 76% of the patients were referred by their GDPs to the Dental Hospital indicating that most cases were supposed to be complicated or difficult. This assumption is supported by an argument stated that most patients being treated with in the Dental school are more likely to have certain problems in wearing complete dentures before their attendance (Davis et al. 2000; Forgie et al. 2005). High percentage, 84% of patients had been worn two or more dentures for period of three years and more indicating that those patients possibly have the ability to quickly adapt to the new dentures, and easily overcome potential eating problems possibly, due to cumulative experience of wearing complete dentures. Findings of this study reported relatively low pre-treatment ESIRE scores (more negative eating outcome), and high post-treatment ESIRE scores (more positive eating outcome) in terms of ERQoL. This difference in the scores has been reflected by values of mean, 39.91, median, 57.76, and percentiles (lower: 45.43, and upper: 82.76) of the total pretreatment scores in comparison with the corresponding values of mean, 60.24, median, 38.79, and percentiles (lower: 24.45, and upper: 50.95) of the total post-treatment scores. It was also reflected by the percentages pre-treatment scores in comparison to the percentages of posttreatment scores (Figure 5.6) in which the percentage of high scores increased dramatically from 14% at pre-treatment period to 44% at post-treatment, and the percentage of low scores decreased considerably from 42% in pre-treatment period to 12% in post-treatment period though. It could be argued that most complications associated with old dentures such as over extension of the flanges of the dentures due to continual residual ridge resorption, poor retention and stability, attrition of teeth, chewing difficulties, compromising speech and appearance were possibly resolved by provision of new dentures. In addition, social and emotional instability of patients were probably resolved by replacement dentures with good fit and retention, consequently increased satisfaction might be responsible for such difference in the scores (Demers et al. 1986; Sheiham et al. 2001b).

A highly statistically significant improvement between pre and post-treatment ESIRE scores has been found in the present study. Equally, there were significant differences in mean of pre-and post-treatment ESIRE scores for each domain (Table 5.2). Based on the assumption that using multiple t-tests on small sample could lead to loss of a statistical power each time the test repeated (Holm 1979), the sequential Bonferroni correction procedure was applied to

minimize the probably of getting a significant result purely by chance. By using this formula in the current study, all p-value were significant at a table wise 0.05. These findings reject the null hypothesis (H<sub>0</sub>) (there would be no change in ERQoL, from before to after denture replacement), and support the alternative hypothesis (H<sub>1</sub>) (there would be a change in ERQoL, after treatment with new conventional complete dentures). The significant improvement of the post-treatment of the ESIRE scores could be attributed to different factors: first, the presumption that denture replacement can enhance retention, stability, and occlusion; hence, improve chewing, and subsequently patient's satisfaction. Newly fitted dentures could have optimal retention and stability (Bartlett et al. 2013), which could have a positive influence on using dentures for eating (Fenlon and Sherriff 2008). In addition, social and emotional instability of patients were probably resolved by replacement dentures with good fit and retention, consequently increased satisfaction might be responsible for such difference in the scores (Demers et al. 1986; Sheiham et al. 2001b). Second, most participants were referred to the dental hospital by their GDPs from dental practices, and were therefore more likely to be experiencing particular difficulty with their dentures; hence, such patients could feel a more positive impact after denture replacement due to significant improvements from enhanced retention, stability, and carefully prescribed occlusion schemes. Studies reported that patients' satisfaction after a dental treatment is likely depend on their expectations before the treatment (Smith and McCord 2004); hence, it could be argued that participants in the present study had low expectations because most of them had been referred by their GDPs due to previous denture relating problems. Moreover, older people wearing dentures for long time are more likely to accept the fact of being edentulous as a part of their ageing process, cope with limitations of dentures, and adjust their expectations of oral function accordingly than their younger counterparts (Locker 1992; Allen and McMillan 2003a). Since the majority, 84% of participants in the present study were aged 65 years and above, it could be argued that those participants had a low level of expectation (in terms of impacts of the new dentures) in comparison with younger patients, and they were less demanding and accepted the limitations of the complete dentures. Therefore, these reasons could influence their responses to the follow up ESIRE questionnaire. However, it is not uncommon to have a response bias in studies involving completion of self-administration questionnaires. Response bias is a generic terms used when participants do not give an accurate or honest response during completion of self-administrated questionnaire (Furnham 1986). Respondents in studies, which involve selfadministration questionnaires, may only select the most extreme choices or answers offered (Meisenberg and Williams 2008) or they could think that they should answer the questions

according the researcher's inclination (Davis et al. 2000). There is always a risk that people, who come to a clinic and get their treatment (e.g., complete dentures) free will, feel grateful and then want to give a positive scenario or feedback about their treatment experience. To minimise the effect of response bias, the research student asked and encouraged all participants to answer the questions honestly in their home in their own free time to maintain independency in expressing their own opinions. Moreover, sealable envelopes were provided to all participants for completed questionnaires to ensure that the dental team, who were responsible for the treatment had no access to the participant' responses. Denture satisfaction is likely to be influenced by the prosthodontic experience of clinicians (Kimoto et al. 2013). Such influences cannot be ruled out as a factor contributing towards increased patient satisfaction with the treatment. Researchers concluded that new complete dentures finished by undergraduate dental students are technically, satisfactory in terms of fit and occlusion (Davis et al. 1986; Peltola et al. 1997). Literature's findings could be reflected in the present study in which undergraduate students, who were supervised by clinicians with good clinical experience, did all treatments. In addition, some participants had some post-insertion complications related to some technical issues during construction of the dentures; consequently, they indirectly excluded from the study because they either repeated the treatment or had been referred to the consultants to start a new treatment plan. Those patients refused to complete the second ESIRE questionnaire because they did not use their new dentures for eating. This is possibly affected the results of the present study.

Measuring the size of change in ERQoL is essential in order to get some practical idea about the clinical significance of the results. Cohen's standardized effect size (Cohen's *d*) is widely used as a mean to detect 'the clinical meaningfulness' (Allen and McMillan 2003b; Kuo et al. 2013), and was used in the current study. The effect size was either medium or large for all domains of the ESIRE questionnaire; thus, the improvements were clinically significant. Due to the difference in study design, aims, objectives, age and sample size, it was difficult to compare the effect size of the present study with other studies. However, the effect size was similar to the findings of (Allen and McMillan 2003b), who demonstrated a moderate to large ES for change in OHIP score for patients treated with conventional complete dentures at Newcastle Dental Hospital. The effect size of the current study was greater than that of other studies that used OHIP-EDENT (Heydecke et al. 2003b; Kuo et al. 2013). Figures of ES obtained in the present study show a large effect size after treatment with new conventional complete dentures, give us information about the magnitude or strength of this clinical

outcome (the positive clinical effect of denture replacement on ERQoL). They indicate that treatment with new conventional complete denture can improve functional ability to eat among denture wearers, their enjoyment of food and eating, and their social interaction with others.

For the majority of domains, there were no gender differences in magnitude of change in ESIRE scores suggesting that prosthetic rehabilitation improves ERQoL to a similar extent regardless of gender (Table 5.3). However, the statistically significant between gender difference in the improvement of scores for self-consciousness/ embarrassment and functional ability to eat shows that improvements were lesser for women. These differences resulted in a non-significant trend towards a greater increase in total ESIRE score for men overall. Such findings differ with previous research concluding that gender difference has no impact on patient satisfaction and quality of life of complete denture wearers (Geckili et al. 2012). The findings suggest that prosthetic rehabilitation is less able to reduce self-consciousness or embarrassment and to overcome functional difficulties for women compared with men. Women being more self-conscious when eating with dentures resulting in greater embarrassment in social life than male patients may explain this (Hurd 2000; Trulsson et al. 2002). Moreover, women may wish to eat foods that are more functionally difficult to eat compared with the foods that men wish to eat, although this theory warrants further investigation. The findings of the gender differences are in agreement with results of Pan et al. (2008), who reported that older men were more satisfied with conventional dentures than older women in terms of aesthetics and ability to chew. Although it has been reported that women show more improvement in overall OHRQoL after complete denture therapy (Sivakumar et al. 2015), the current findings suggest that might be due to impacts on quality of life factors other than functional ability to eat foods and self-consciousness on eating.

A secondary aim of this research was to measure the responsiveness of the ESIRE questionnaire. Responsiveness to change of oral health instruments is often assessed by using different measures such as effect sizes for the change scores, the minimal importance difference (MID), the standardised response mean and Guyatt's responsiveness index (Locker et al. 2004). In this study, effect size and SRM were used to provide a first evidence about the responsiveness of the ESIRE questionnaire to change in ERQoL. If the ESIRE questionnaire is to function as an outcome measure for use in evaluating changes in ERQoL and monitoring patients it should also be responsive to changes in health status over time. Results of this study showed that the ESIRE questionnaire was responsive to change in ERQoL among the

sample of denture wearers. However, the main aim of the present study was to evaluate the effectiveness of treatments (new conventional complete dentures) not the responsiveness of the ESIRE questionnaire.

No previous studies have prospectively investigated the impact of denture replacement on ERQoL. However, the quantitative data from the present study concur with data from other studies, which used OHIP-EDENT to measure changes in OHRQoL, including issues around eating after denture replacement. For example, several studies reported a significant improvement in patient's satisfaction and OHRQoL among patients treated with new conventional complete dentures (Adam 2006; Viola et al. 2013; Nuñez et al. 2015; Sivakumar et al. 2015). However, the findings are in contrast to other studies (Allen 2005; AlBaker 2013) reporting no improvement in patient's satisfaction and OHRQoL after denture replacement. The current data are comparable to that from a retrospective qualitative assessment of the impact of tooth loss and dental prostheses on ERQoL (Hyland et al. 2009), which also highlighted lack of enjoyment of food, self-consciousness or embarrassment, interruption to meals, lack of confidence when eating, restriction of social interaction with others, and limitation of food choice as the main effects of edentulism on ERQoL. However, a positive effect of denture replacement upon social and emotional issues around eating with dentures, despite the persistence of some eating-related problems was also noted in this study. Findings of qualitative data of this study concurred with the findings of other studies (Davis et al. 2000; Trulsson et al. 2002), which concluded that edentulousness and subsequent rehabilitation with complete dentures can negatively affect the confidence, self-consciousness, and social interaction with others, particularly during eating. The authors presumed that most problems, which associated with wearing dentures are, arise from edentulism rather than from the dentures per se.

# 5.6 Strengths and limitations

To the researchers' knowledge, this is the first prospective cohort study exploring the effect of denture replacement on ERQoL using a mixed-methods approach. However, the study had some methodological limitations; first, there were concerns about whether dental hospital patients are typically of the edentulous population receiving replacement dentures. Moreover, all patients were from the Northeast of England, which could mean that the data are not

widely generalizable. Nonetheless, it could be argued that the results are applicable to groups of people, who have comparable sociodemographic features and clinical profiles globally

In the present study, participants completed the follow up ESIRE questionnaire approximately one month after provision of new dentures. One month after treatment with new dentures has been used as a follow up period in previous studies evaluating elements of OHRQoL, and patient's satisfaction (Ellis et al. 2007; Kimoto et al. 2013; Sivakumar et al. 2015). However, the effect of denture replacement on the quality of life and patient's satisfaction could change over a longer period of time (Bergman and Carlsson 1985; Fenlon and Sherriff 2004). Thus, it might have been desirable to follow up the same participants for longer (i.e., three months, six months, and after one year); nevertheless, limited resources and time scale of this study did not enable this. Literature suggests that changes in OHRQoL after treatment are subjected to 'response shift effects', and this is attributed to the fact that the perceived meanings of OHRQoL test items could be reconceptualised, reprioritised, or recalibrated by patients (Hamidou et al. 2011; Reissmann et al. 2016). The present study did not evaluate the 'response shift effects' in conceptualization, internal standards and values of main ERQoL domains due to limited time and sample size. Therefore, it could be argued that changes in the ESIRE mean scores after denture replacement need to be tested to ensure that post-treatment scores reflect a true change in patients' ERQoL. This can be done using structural equation models on large sample size. Nonetheless, implementing such analysis was not feasible due to limited resources and time scale of this project.

Paired-t test, effect size, and SRM are used in evaluating the responsiveness of subjective patient-reported outcome measures (Deyo et al. 1991). In the present study, findings of paired-t test and ES, in addition to SRM considered as an initial investigation of a responsiveness of the ESIRE questionnaire to change in ERQoL. However, it is worthy to mention that the present study focused on evaluating the effectiveness of the treatment (denture replacement) on ERQoL rather than the responsiveness of the ESIRE questionnaire since it was the primary aim of the study, which is a part of large PhD project exploring the impact of wearing conventional complete dentures on eating experience. Moreover, using other measures of responsiveness (e.g., minimal importance difference, Guyatt's responsiveness index and receiver operating characteristic curve) was impractical since conducting a responsiveness study might require a large sample size (Locker et al. 2004), which was infeasible with in the limitations of the study.

# 5.7 Clinical implications

The results of this study improve the understanding of the impact of denture replacement on ERQoL. Clinicians are encouraged to pay more attention to the impact of wearing conventional complete dentures on social and emotional issues around eating. The findings should motivate clinicians and inspire specialists in Prosthodontics and oral rehabilitation to continue providing conventional complete dentures as a suitable treatment option for edentulous patients.

#### 5.8 Conclusions

Denture replacement can directly improve ERQoL highlighting a benefit of using conventional compete denture as a treatment option for edentulous patients. The highly significant improvement in the ESIRE scores indicated 'clinical meaningfulness' of the effect of denture replacement on ERQoL. Moreover, the data provide the first evidence of the responsiveness of the ESIRE questionnaire to changes in ERQoL among a population of conventional denture wearers.

# Chapter 6. Opinions and Views about Advice on Eating with Complete Dentures: A qualitative Study

# 6.1 Chapter Overview

This chapter discusses the main scope, underlying philosophy and the methods of data collection and analysis used in exploring the opinions and views of denture wearers, dentists and DCPs on advice about eating with complete dentures. It, also, includes some strengths and limitations, and conclusions of the present study.

#### 6.2 Introduction

Recently, researchers have shown an increase interest in conducting qualitative research targeting health care systems to understand its complexity from patient and healthcare provider's perspective (Nicholls 2009b). Developing or evolving of concepts helping researchers to grasp social phenomenon in naturalistic but not experimental settings is the substantial goal of the qualitative studies (Pope and Mays 1995). Although it is difficult to define qualitative research clearly, Ormston et al. (2013) described it as 'naturalistic, interpretative approach concerned with exploring phenomena from the interior and taking the perspectives and accounts of research participants as a starting point'. Conducting such qualitative studies is useful in terms of expanding our thinking and practice, and understanding of the complexity of healthcare. In other words, qualitative studies help us to understand the meaning of certain phenomena in health care rather than the causal nature of it, which is often described by quantitative studies. In general, qualitative studies focus on individual experiences, values, attitudes, behaviours, and interactions and try to answer mysterious questions (Nicholls 2009b). More specifically, data that have been obtained by such studies are fundamental to explore and provide a detailed information about patient experiences and views during eating with dentures which could have a negative impact on patients' lives (Obrez and Grussing 1999a; Trulsson et al. 2002; Hyland et al. 2009). For example, Obrez and Grussing (1999a) conducted focus group interviews with complete denture wearers (mean age 64 years) to explore their perception and views on different aspects of chewing foods with complete dentures. The authors concluded that the texture of food is one of the main factors, which determine the choice of a successful coping strategy by denture wearers to chew food. Previous research shows that rehabilitation of edentulous

people with complete dentures may not be enough to achieve adequate nutritional intakes or positive dietary changes (Sandström and Lindquist 1987; Sebring et al. 1995; Bradbury et al. 2008; Wöstmann et al. 2008). Similarly, the fact that edentulous patients need to wear complete dentures has an important negative impact on social and emotional issues around eating with dentures or ERQoL (Hyland et al. 2009). Edentulousness and even after rehabilitation with complete dentures can negatively affect enjoyment of food, social interaction with others and confidence when eating. Therefore, providing eating advice for denture wearers is beneficial (Moynihan et al. 2012), and evidence suggests implementing dietary behaviour change intervention may be linked to both dietary and health benefits (Makwana et al. 2014). There have been few studies investigating the effect of delivering dietary interventions or advice to edentulous individuals wearing complete dentures (Ellis et al. 2010; Moynihan et al. 2012; Prakash et al. 2012; Bartlett et al. 2013). For example, Bradbury et al. (2006b) reported that provision of new complete dentures alongside dietary counselling was associated with improved food intake (e.g., vegetables and fruits). However, the content of most of these dietary advice/interventions were based on information from the intervention's designer perspectives. There has been little research about device on eating with complete dentures from patient's point of view. Moreover, there is a need to explore views and opinions of dental health providers about eating advice given to denture wearers. This eating advice or information could help the denture wearers to overcome eating-related problems. Such a gap in the literature is unlikely to be answered using a quantitative study design; therefore, a qualitative study was conducted with participants in North East England to understand their experiences and perceptions about advice on eating with complete dentures.

# 6.3 Aims and Objectives

# 6.3.1 Aim

To explore and analyse views of denture wearers, dentists and DCPs about advice received and given on eating with complete dentures.

# 6.3.2 Objective

To conduct a qualitative study (i.e., focus groups) with service users (i.e., denture wearers, dentists and DCPs) from Newcastle Dental Hospital to obtain qualitative data that inform appropriate eating advice and intervention for denture wearers.

# 6.4 Methodology used

# 6.4.1 Study design

Qualitative study using focus groups as a method of data collection.

# 6.4.2 Ethical considerations

A positive ethical opinion was previously sought (see chapter 4, section 4.3.2).

# 6.4.3 Qualitative sampling

A purposive non-probabilistic sampling aimed to reflect opinions or views of a diversity of participants from Newcastle Dental Hospital, Newcastle upon Tyne, UK. Table 2.1 shows inclusion and exclusion criteria of the study.

Sampling inclusion criteria			
Denture wearers	• Edentulous patients wearing conventional complete dentures.		
	• Participants able to give verbal and written consent, and are		
	fluent in the English language.		
	• Age $\geq$ 18 years.		
	• Being able to sign the consent form of the study.		
Dentists and	ntists andThe range of selected dentists and DCPs should to be:		
DCPs	• Familiar with the topic under study.		
	• Known for their ability to respectfully share their opinions.		
	• Willing to volunteer about one hour of their time.		
	• Being able to sign the consent form of the study.		
Sampling exclusion criteria			
Participants unable to	o give informed consent to participate in the study.		

# Table 6.1: Study sample inclusion and exclusion criteria.

# 6.4.4 Study sample (Participants)

#### **Denture wearers**

A purposive sample of denture wearers (both genders) were invited to participate in series of focus groups. Each group aimed to have 5-8 participants. Denture wearers were a sub-sample of a large cohort study in which all participants were recruited from the Newcastle Dental Hospital, Newcastle upon Tyne, UK. All participants had already read the participants information sheet (Appendix E) and signed the study consent form (Appendix F) during their participation in the cohort study. Important background information about those participants being studied had been obtained through preliminary fieldwork during patient recruitment and completion of the questionnaires during conduction of the cohort study. This informed our decision during their treatment visit to the dental hospital. The researcher contacted the potential participants via phone or email 7-10 days prior to the session. Finally, all participants were telephoned the day before the focus group to remind them and confirm that they were still willing to attend the session.

#### **Dentists and DCPs**

A purposive sample of selected range of health providers (i.e., dentists and DCPs) were invited to participate in series of focus groups. Each group aimed to have 5-8 participants. Groups were stratified by gender and occupation to obtain participants with different backgrounds in the field of dentistry. Participants, who were identified by the clinical lead of the Prosthodontic clinic in Newcastle Dental Hospital, were contacted, either directly or via email, informed about the purpose of the study, and invited to take part in the study verbally and by giving them participant information sheet of the study (Appendix G). Participants interested in taking part in the study were contacted by the researcher to arrange an appointment for a meeting and a verbal and written informed consent obtained from them (Appendix H). They were also informed about the time and location of the session.

# 6.4.5 Topic guide of the focus groups

Participant' views and opinions on advice on eating with complete dentures were explored using a topic guide. The topic guide was not given to any participant prior to the discussion. The topic guides were developed by the researcher (HA) and independently reviewed by two supervisors (PM and JF) and two experienced qualitative researchers (MB and RH) to assess the content validity of them. They ensured that the questions accurately represented the topic under study (advice on eating with denture). An inductive and iterative approach was used in which as discussions progressed, the topic guide was evolving according to data collected and analysed. Prompts were used for transition between themes and, when necessary, probes were used for exploring in-depth information on each theme. The final version of the interview topic guides with denture wearers and dentists and DCPs are available in (Appendix I) and (Appendix J) respectively.

#### 6.4.6 Conduct of the focus groups

The focus group study involved three steps: a) conceptualization (determining the purpose of the focus groups, determining the target group, and developing a plan to estimate the time and resources needed to conduct of the focus groups); b) interview, and c) analysis and reporting (Marczak and Sewell 1991; Krueger and Casey 2002a). In the focus groups, a facilitator or moderator and assistant moderator were used. In this study, focus groups were facilitated by a team consisting of a moderator (the researcher: HA), and assistant moderator (MB, an experienced qualitative researcher) between February 2016 and June 2016. While the

moderator facilitated the discussion; the assistant moderator took notes and operated the digital recorder. Both the moderator and assistant moderator kept a reflective dairy in which observational notes (e.g., body language) had been written during the discussion, and summary notes written immediately after the interview. The moderator and assistant moderator sat together after each session, discussed the outcome of each discussion, and wrote the summary notes using a university computer.

A standard protocol for the conduct of the discussions was followed to ensure consistency. Focus group discussions started with a general introduction, which included: welcome; introducing the moderator and the assistant moderator to the participants; introducing the participants to each other; explaining the purpose of the discussion, and going through ground rules before starting the recording and the discussion. Dentists and DCPs participants were informed that the aim of their focus groups was not to criticize their practice or examine their knowledge, but to obtain information about advice on eating with complete dentures to help denture wearers enjoy eating with dentures and indirectly improve healthier eating. After getting permission from all participants, all group discussions were audio recorded using a digital voice recorder (Olympus WS-832). The audio recordings were anonymously stored on a university computer using numbers and letters linked to the study, and professionally transcribed verbatim by a professional company after seeking a confidentiality agreement. The professional company had no links with the participants involved in the study. All transcripts were imported into Word documents for subsequent qualitative analysis. Anonymised transcripts were cross-checked with original recordings by the moderator to ensure accuracy. Following this process, the audio recordings were deleted. The discussions were conducted in the seminar rooms at the School of Dental Sciences, Newcastle University. These rooms have a comfortable and convenient location, since they have a door for privacy, table, and chairs to seat a circle of up to 10 people. A beverage (e.g. Tea, coffee, water) and light snack (e.g. Sandwiches, fruit platter) were offered to all participants.

#### 6.4.7 Analysis of data

In this study, conduction of the focus groups continued until data saturation was reached (when no new ideas or themes identified from the data collected). Inductive and iterative approaches were used for data analysis by that the topic guides of these focus groups were flexibly used, modified and evolved from one discussion to another in highlight of new unanticipated emerged themes. Principles of constant comparative techniques or analysis

(based on collecting and analysing the data in the same time) (Glaser 1965) were broadly used during data collection until data saturation was reached. Framework analysis (Ritchie and Spencer 1994), which has been modified by Ritchie et al. (2013) was used to analyse the data generated from these focus groups. It involves six key stages: (i) familiarization; (ii) construction of initial thematic framework; (iii) indexing and sorting; (iv) reviewing data extracts, (v) data summary and display using framework, and (vi) abstracting and interpretation of the analysed data. The research team, following certain criteria, sought rigour in the analysis of the data. They ensured transparency of the analysis process by providing an honest and clear counting of the actual methods used to analyse the data and maximised the validity by providing evidence or quotation from the data for each interpretation they made. Moreover, they maximised reliability in which the triangulation approach was used to assess the process of analysis, in other words, data were initially analysed by the researcher, evaluated by two academic supervisors, and finally, reviewed by an independent author. Furthermore, they compared data within and between cases using framework matrices of the data set (Green and Thorogood 2009). The analysis was systematic, sequential, verifiable, and continuous. The researcher worked systematically through each transcript (transcripts by transcripts) to identify themes and sub-themes among the participants' responses. Data were independently reviewed by two members of the research team (the supervisors: PM and JF). At each stage, the data were sent to a third independent reviewer (RH: an experienced qualitative researcher) to assess and triangulate the emergent themes. Indicative quotations from four focus groups were coded according to study number (P01 to P12), male/female (m/f) and age of subjects during their recruitment to the study.

The next sections contain further details about stages involved in the data analysis process.

#### **Familiarisation:**

In this stage, the researcher read and reviewed the transcripts multiple time for the purpose of familiarisation with the raw data set. During familiarisation with raw data, the researcher used sheets of paper and listed interesting topics under a preliminary 'coding list', logging them as they emerged. Irrelevant information against our topic guide and the objective of the study had been checked to ensure the comprehensiveness of this list. The list informed our decision to construct an initial thematic framework.

#### **Constructing an initial thematic framework:**

In this stage, the researcher used a Microsoft Word document to construct an initial thematic framework, and arrange themes and subthemes hierarchically. Each theme and subtheme was given a name and number for the purpose of differentiating them from each other. Moreover, themes and subtheme were briefly described for the purpose of clarifying its meaning. They were descriptive rather than abstract. The framework was designed based on a combination of themes derived from the research questions or aims, emergent themes, and those derived from the topic guide for exploration in the focus groups. During this period, the researcher reviewed the initial themes, identified the interconnections, and ensured that no relevant data had been overlooked. The initial thematic framework was then reviewed by three independent reviewers.

#### **Indexing and sorting:**

Indexing or coding refers to the method of labelling the data according to thematic framework (Ritchie et al. 2013). In this stage, the researcher wrote or noted the thematic references in the margin on a hard copy of the transcripts for the purpose of labelling the data. This technique was very important for the researcher in understanding the meaning of the data. A line-by-line coding of the transcripts (Strauss and Corbin 1990) was used by the researcher to generate different themes and sub-themes. Inductive coding was used in which examining and coding data were done concurrently. When the indexing step completed, the researcher started the process of sorting the material with similar content or properties. In other words, sorting the similar subthemes into major themes. This process was achieved by cutting and pasting the highlighted raw data in a computer word document, and placing them in a new thematic document.

#### **Reviewing data extracts:**

In essence, the researcher re-examined and refined the indexed or coded data in terms of dividing one theme or merging subthemes to improve coherence in the data. Non-indexed data were examined to know if important themes were missing from the framework. The initial thematic framework was refined at this stage, thus the main themes and sub-themes were finalised.

#### Data summary and display using matrices:

In this stage of data management, the researcher inspected the indexed and sorted material, assessed its meaning and relevance to the subject under study, and displayed the data via construction of framework matrices on a Microsoft Word document. Each matrix included two columns; one for the cases (e.g., participants ID or other demographic characteristics) and the second for themes and subthemes (e.g., a data summary of each subtheme was written for participant in the study). Summaries were written in a way, which retained the 'context' and 'essence' of the meaning and language of the participants (Ritchie et al. 2013). In other words, key terms, phrases, and expressions of the summaries represented the language of the participants. Moreover, the researcher's analytical comments were written and entered to the framework matrices to implicitly and explicitly highlight the relationships between different themes for each participant (Figure 6.1). Based on this matrix-based format (Ritchie et al. 2013), comparisons were made in both directions; horizontally (between separate parts of the thematic framework for each participant), and vertically (across participants within a single thematic matrix). The researcher summarised all the data related to each theme across all transcripts. In other words, the researcher completed one thematic matrix and then moved to the next one. At this stage, the researcher reviewed the themes, examined the interconnections between them, and ensured that no relevant data have been overlooked. Framework matrices were constructed by the researcher, assessed by the supervisors, and then reviewed and discussed with the third independent reviewer.

Theme 2: Advice recommended by denture wearers				
Participants	2.1: eating food differently	2.2: trial and error	2.3 Using denture fixative	
P01 F, 74 y Participant ID	CUT OR SLICE YOUR FOODS She recommends cutting food a lot more up rather than biting it.	PATIENCE AND PERSEVERANCE Keeps having a retry and do not give the dentures up completely. Thinks that it is a matter of trial and error.	USING DENTURE FIXATIVE IS A CONTROVERSIAL ISSUE She stopped using denture fixatives because of their side effects mainly a bad taste. They did not help her enjoy what she eats. Q. 196-200 TYPES OF DENTURE FIXATIVES USED Fixodent.	
Р02 М, 65 у	START WITH CHEWABLE ODS, THEN GRADUALLY BUILD YO KSELF UP He emphasised on giving the gums a couple of weeks to settle down and harden up, so initially it is not recommended to eat hard foods such as steaks and apples, so when you eat such foods, Instead of big bites you just try take nibbles off	PATIENCE AND PERSEVERANCE Patience and persevering are important to adapt to your new dentures, especially in the first two weeks. Thinks that it is not something that cannot be resolved, it is something that denture wearers themselves can get resolved.	He did not use any type of denture fixatives since he has got good gums and well-fitted dentures. See 1.2 and 4.1 Researcher comment	
P03 F, 65 y	CHOOSE FOODS, WHICH IS SUITABLE FOR YOU She tried certain type of food and it was a nightmare, so she just tried other alternatives.	She believes that there is nothing that is banned; it is the food that you have banned yourself because it is not suitable for you.	USING DENTURE FIXATIVE IS A CONTROVERSIAL ISSUE If she does not use denture fixative, she probably cannot chew anything. However, in many occasions, halfway through an orange, dentures start moving all over the place again. Q.126-133.	

# Figure 6.1: Extracted example of a framework matrix for the theme: Advice recommended by denture wearers.

#### Abstracting and interpretation:

After completion of all stages of data management, the researcher reviewed the framework matrices, including data summaries, against the transcripts and the indexed data to see if any further changes or merging of the themes and subthemes is required, and to read the managed data, reassemble them, and determine if they met the research objectives. No changes were made to the themes or subthemes at this stage and the final framework matrices were finalized. Then, the researcher moved to the next stage of the analysis process, which is the 'abstracting and interpretation', this stage involves more analytical than descriptive properties. This stage is the main goal of qualitative research, in which the researcher tries to explore and conceptualize the main ideas or concepts from the data (Richards and Morse 2012). In this stage, the researcher used headings or criteria suggested by Krueger (1994) for interpreting coded data. These criteria include: words (consider the actual words used and their meaning); context (how the wording of the facilitator's questions and participants' comments affect the context within which the comments of participants are made); internal consistency (taking in consideration any changes in view or attitude by the participants); frequency and extensiveness of comments (considering how often a comment or opinion is repeated and how many participants repeated it); specificity of comments (considering comments of personal experience); intensity of comments (considering to the expression of the depth of feeling in comments of participants); big ideas (determining major concepts or

ideas, which emerged during the discussions) (Krueger and Casey 2002a). The transparency of framework analysis has been demonstrated at each stage of data analysis in which the analysed data were compared back to original data to ensure quality and rigour of the research method (Douglas 2002).

# 6.5 Results and discussion

Based on the practical principle of simultaneous presenting and discussing the data of the qualitative studies (Pope and Mays 1995), the analysed data are discussed and presented together. The presenting quotations have been used throughout the discussion to support the discussed data and provide evidence about the representativeness of the qualitative data obtained. The data and discussion section will firstly look at themes that emerged across patients (denture wearers) group. It will then go on to the themes that emerged from the dentists and DCPs group.

#### 6.5.1 Patients (denture wearers) data

The response rate of denture wearers to participate in the focus groups was low. 77 patients were invited to take part in this study, but only 21 (27.27%) agreed to participate and signed the consent form of the study. From those, who signed the consent form, only 10 (46.62%) actually participated in these focus groups whereas 11 (53.38%) withdrew from the study. A purposive sample of ten denture wearers (four females and six males, mean age 69.4 year) participated in the focus groups. Fortunately, data saturation was reached after holding two focus groups. The number of participants was five participants per group. Four themes emerged from the analysed data with numbers of subthemes (Table 6.2). Each theme was considered and discussed as follow:

Key themes	Subthemes	
Theme 1: Advice received about eating with	1.1. Simplicity of the advice.	
dentures.	1.2. Reasons for not receiving eating advice.	
Theme 2: Advice recommended by denture	2.1. Eating food differently.	
wearers	2.2. Trial and error.	
	2.3. Using denture fixative.	
Theme 3: The concept of denture fit and	3.1: Denture fit and stability.	
stability.	3.2: Importance of denture adjustment.	
Theme 4: Preferred format of eating advice.	4.1 Patient leaflet and web-based	
	information.	
	4.2. Holding support groups.	

# Table 6.2: Final key themes and subthemes of patients (denture wearers) data.

#### Theme 1: Advice received about eating with dentures.

The majority of participants in these focus groups had received no advice about eating with dentures despite of wearing dentures for long period.

"My dentist, I mean could be four years ago I got my other dentures, and I got no, nothing from him, any advice about how to eat. I got, this set I've got now, erm, they weren't really that good, you know. And I went to the dentist, I went back, I mean I paid for them and I went back. The third time he said, "If you come back..." They were still hurting you know for eating. And he said, "If you come back again, you'll have to have a new set made" (P01, F74).

"No, I've never been given advice from any dentist, not that I've been for a long time." (P02, M65).

"The only advice I've ever been given is, "Just use paste." that's the only advice I was ever given, "Just use paste to keep them in place" (P03, F65).

"Nobody told me what you had to do, how you had to eat. We didn't get anything like that, none whatsoever." (P08, M75).

Such findings do not concur with the guideline of National Institute for Health and Care Excellence (NICE 2016a), which mentioned that advice on diet should be given for all patients by dental staff, and this advice should be tailored to meet individual needs and based on the "evidence-based toolkit of delivering better oral health" by Public Health England (PHE 2016). However, this evidence-based toolkit did not mention any specific eating advice for denture wearers suggesting adding such advice to the toolkit in the future. Participants mentioned different reasons for not receiving eating advice from the dental team. Some participants were not keen to receive eating advice (that help them eat well and enjoy eating) from dentists because of a perceived difficulty for the dentist to provide the patient advice about eating habits. In addition, patients could respond variably to such eating advice. Such response possibly depends on their age, gender, food preference, systemic condition, and psychological situation. This seems to be in agreement with what the literature reported in which patients' adaptation on eating with complete dentures vary according to different individuals (Obrez and Grussing 1999b). Others believed that denture wearers are better placed than dentists in terms of what, how, when and where they could eat with their dentures. Such findings indicate that advice on eating with dentures could be better to come from the patients themselves rather than from the dentists or DCPs.

"But, as regards the dentist, I cannot see how a dentist can give you advice on your eating habits, when they're not on this side of your teeth, you know what I mean? I don't think they really could give you a lot. You know. You could tell you what, as I said before, tell you what foods to eat or enjoy, which is good for ya, but whether you could cope with that, whether your denture stays, is another matter." (P04, M69).

"But as X said before, the dentist doesn't know what's going on behind here, only you can say, "Not having that." It's yourself that knows what you can do and what you can't do at the end of the day. Really you can't, can't really, have the full experience of it, you need the experience to be able to sort it out." (P06, M70).

A lack of dental knowledge among some participants was another reason for not receiving eating advice in which several patients did not know that dentist could give them advice on eating with dentures. Simply, they did not think about that, so they did not ask the dentists about giving eating advice. Others believed that three or four decades ago, dentists never thought about giving eating advice to their patients suggesting that dental practice differed historically.

"Never even thought about it. It's, to be quite honest it's not something I've ever considered. Never really considered, never looked at that aspect of it. You know." (P05, M69).

"I didn't know you could. Never thought about it." (P03, F65).

'I think may be 30, 40 year ago they never thought about that. You know. It wasn't, wasn't in the, you know, the, the criteria.'' (P06, M70).

One participant talked about guilt and not feeling that they were deserving of advice. She described thinking that giving advice about eating with dentures was not the responsibility of

the dentists because their job was to make the dentures and ensure that they are as best fit as possible, but providing eating advice to the patients was outside their professional remit. It could be argued that the dentists or the dental team are the persons, who are responsible for providing and adjusting dentures rather than giving advice on how to function with these dentures was seemingly a common belief among many participants in this study.

"I really didn't expect any. I thought, "Well, you've lost your teeth, it's up to you," you know, to get on with it. But I really didn't expect anyone to help me with advice or- Not something I expected. I thought I was asking too much, it was my problem. You make my dentures, you make sure they fit, right, and I, I Erm, he's a busy man, he's an expert, it's what he's doing. Erm, I didn't think that was open so I couldn't ask because I would think I was asking too much." (P10, F82).

It could be concluded that an overwhelming majority of patients reported that they did not receive advice about eating with dentures from the dentists or the dental team. If received, the advice was very simple or general and not necessarily related to enjoyable or healthier eating. Several denture wearers in the current study were not keen to receive advice on eating with dentures because they thought that they were more experienced than the dentists or other dental staff. Denture wearers described the knowledge they had gained through experience and how the dentists were not best placed to advise them, as they were not denture wearers themselves. They described feelings that they might had a good experience to know what kind of foods they can eat and enjoy with the dentures over the time regardless if these foods are healthy or not.

#### Theme 2: Advice recommended by denture wearers

Participants described different ways through which they can enjoy foods or eating. Several participants introduced the concept of 'trial and error' in which adapting to the new dentures occurred through the experience of trying and failing. Participants emphasized the importance of patience and perseverance in adapting to the new dentures in terms of eating, especially in the first two weeks.

"I think it's just been, it's been a matter of trial and error to find out yourself what actually affects your eating habits. I think you need a lot of patience. But over a period of time, as your dentures, as X says, once they settle in, and they start to bed in and get better and better and better, you find you can go back to them foods that you used to like, you can eat them, but, it's a, it's a matter of time." (P04, M69).

Don't give up on it, you've got to persevere that little bit. I think it's more a case of don't give up on the first, the first time when you get them, [being able to eat] the food that you like, try to keep trying, you know. Yes, because everybody here, they'll eat

something that somebody else can't. You know what I mean? So it's a case of, when you first get dentures, erm, don't think that what you're like in the first week or two is going to affect you long term. (P02, M65).

The findings appear to be in agreement with other studies (Trulsson et al. 2002; Awad et al. 2003), which argued that despite of several denture wearers experienced eating problems; they persevered, particularly if there is no pain associated with eating with dentures. The author also concluded that feeling helpless and accepting denture difficulties as a part of their daily life were main feelings described by most denture wearers. This could highlight a lack of information about eating with complete dentures given by the dentists to their patients.

Eating and preparing food 'differently' were the other advice suggested by several participants to resolve the problems of eating with dentures and enjoy what they eat with them. Many strategies, which were consistent with recommendation of NHS Choices (2017) had been suggested by different participants in these focus groups:

- Eating food in different way.
- Cutting and slicing hard fruits such as apples.
- Cutting tough foods like brown bread into small figure-like portions.
- Chopping meat or steak.
- Overcooking and using the slow cooker to prepare some foods such meat.

"I mean I used to love an apple. Chomp into an apple no bother, my own teeth, but now you have to cut them into slices. You know? That's one of the basic things. You choose... You see, you can still eat the same foods but you tend to eat them differently whereas I would pick up a Golden Delicious apple and I Now I peel it and I slice it and I still eat it, still enjoy a Golden Delicious apple, but you eat it in different ways, in smaller pieces and... You know. You can still have a banana. I still have a banana on me. I eat Fruit and Fibre in the mornings, it's like cardboard, but I have a banana sliced up on it, on the top on it, and I will just let it soak a little that little bit longer. I haven't' really changed what I eat because I've got dentures. I've just changed the way that I eat them.'' (P07, M59).

"But what I found, I can't eat- Well, I don't eat steak now, I don't think I could. So I've got about three slow cookers and I get good quality beef and just put it in there with the seasoning and I enjoy that as much. Slow cook and I have no problems with my meals because my vegetables are cooked and gravy or the sauce to go with it. Erm, and anything I put in it, any kind of beef or pork or chicken comes out." (P10, F82)

One participant illustrated a typical story about how the denture wearers could eat or prepare the food 'differently' and enjoy what they eat: "Now I've got to chop an apple up, slice it up into pieces and the same. Well, I eat-I like fish mainly, I do eat meat occasionally and chicken, but I have to cut my food up a lot smaller now. And I obviously take a lot longer time to eat my food. If I make toast, sometimes I have toast, erm, there, and certainly the brown bread which is quite nice, but if it's a bit crusty, as you say, I've obviously got to have my teeth in. But I've then got to-I do cut down, I think you said, like, in finger sort of size, cut, cut it up in smaller portions so I can, erm, and it's easier, I find it easier to eat. And on any food, I like fish more than any, mostly. But again, if I cut the pieces up small, it takes lot longer to eat but I do enjoy my food. Meats more tender I, I would suggest that the elderly who are getting the dentures would recognise that and, and do it. And they would learn very quickly that, "Okay, I can't eat a bacon butty but," like the other guy, they could cut it up, "I could up though and cut it in to pieces and eat it." So I think people adapt, adapt to that situation. People of, well I would say, of my age." (P08, M85).

Another piece of advice suggested by participants was starting with chewable foods, then changing to harder or tougher foods and gradually building up and enjoy eating. This could help giving the gums a period to adapt to the new dentures. Again, such advice is in line with recommendation of the NHS Choices (2017) pertaining to eating with dentures.

"Well it will be initially, first couple of weeks is where you'll be eating but you'll not (be) eating what you, what you'll be able to eating in a few weeks' time, that's what I find, you know, you, you've got to, a couple of weeks period where your food isn't going to be the same as in a few weeks' time, you know. You can't go straight down and get your steaks and your apples, you know. You know, you, you've got to let your gums settle down and harden up for a couple of weeks." (P02, M65).

Despite the difficulty to eat healthy foods such as fruits and vegetables, participants emphasised the importance of overcoming functional difficulties (i.e., chewing and biting difficulties) at the beginning of wearing dentures then, gradually adopting a healthier eating style when eating with dentures:

"I think, if you're [open] to what you really should be eating, I think you should be eating stuff that's nutritional, good for ya. But, erm, I find with dentures, when, when you're eating, if it's particular food what you like and you cannot eat, you cannot digest it properly because you can't chew it properly and that affects your system. Erm, on the long term I should imagine, and the short term, erm. So to me you've got to go for foods initially that you can, er, put up with, put it that way, erm, and digest, and chew properly, erm, as X said as time goes on, you, your gums settle etc. and your teeth settle, you move onto other foods which is probably more nutritional." (P04, M69).

Similarly, several participants discussed the possibility of choosing appropriate or suitable foods in terms of eating with dentures. For example, if the denture wearers find that certain type of food is difficult to chew, they can select alternative foods, which are easier to eat or chew.

"And when I'm not in work I have ham and eggs, scrambled eggs on your toast makes-You still get the texture of the toast but the scrambled eggs make the toast softer. I, I mean on holiday I've done, I stayed away from the bread because, obviously, the bread on holiday is the crusty rolls and you can't- I mean, my lass can eat then because she's had her dentures for years, but I couldn't manage a crusty roll so I'm... No bread. Yeah, no bread, but I've had rice instead. So instead of having chips and stuff like that, I mean, jacket potato, jacket potato and rice." (P07, M59).

Another participant suggested some tips during eating in public; for example, choosing foods, which are easy to eat and chew with the dentures, avoiding hard foods, and eating slowly.

"....but, as regards eating, when I do go out, out with my friends, for coffee and a sandwich or what, a snack, they're all into buns, erm... You know, the modern thing now, you go out and you get chunky buns. Erm, so I've got to eat slow, my teeth, try to clear my mouth, try to clear my mouth a bit, you know. And, erm, I avoid sausages with the skin on. You know, because I eat cheese, you know, I have [milky], I have yoghurt, erm, and all the things I like so perhaps I haven't, erm, come up against that real problem." (P10, F82).

Many participants highlighted the use of denture fixatives during eating and this issue was a matter of controversy between the participants. As movement of dentures during eating is common among several denture wearers, some patients believed that using denture fixatives was useful in making the dentures stable, and consequently, facilitating eating with them, others did not use or stopped using denture fixatives because of their side effects mainly bad taste, which adversely influenced enjoyment of eating:

"Certainly on the top ones. To me, it's very helpful on the, on the top one." (P08, M82).

"Can't eat without it." (P07, M59).

*'I've never used any artificial means of me teeth, I don't believe in it, because as you see it tastes awful.''* (P04, M69).

"I would say, mines was moving. I tried myself to use Fixodent they call it, and it was awful. Er, back, it wasn't good for my stomach really, I think I was putting too much on, and it was just terrible, and I wasn't enjoying my food at all. So I just stopped using." (P01, F74).

Interestingly, one participant spoke about the short lasting effect of denture fixative, which could mean it failed during a meal possibly due to dissolving of the denture fixative.

*'I certainly can't eat, I've got to wear the paste still. If I don't, I cannot chew anything. I've had every one of those different tubes trying to find the one that doesn't taste, I don't* 

like it if it's got the zinc in, cause that's a metallic taste in your mouth. Erm, I eat a lot of fruit, and I find when I put the paste on, I can manage to eat some foods but you know the one's that acidic because it just takes the paste straight off. So halfway through an orange the teeth are moving all over the place again. You know, so it depends on, I still haven't found a paste that's really good.'' (P03, F65).

Not dissimilar to application procedures of denture adhesives described by Duqum et al. (2011), one participant suggested some practical tips, which they found useful in applying denture fixatives and improving eating with dentures:

- Before putting fixative, ensuring that the mouth is dry by using a clean towel. So it is completely dry or as dry as possible.
- Putting small amount of fixative on dentures.
- Taking the towel out and straight away wearing dentures.
- Waiting for 5 to 10 minutes for them to settle down, then brushing teeth to remove excess materials.
- Feel confident during eating.

"Yeah. Well a little tip, cause obviously I'm still getting used to my bottom ones, when you put them in, give them five minutes to set and then brush your teeth. With my dentures, see, I, I'm, and been using, I've just been away on holiday, obviously, and you're eating most times and drink through the day. So you fix it with Polygrip, you get up in the morning, you fix your dentures in. You wait 10 minutes for them to settle down, get all, like you say, get all the other crap out of your mouth like the overspill, and then go for breakfast, 8 o'clock, 10 o'clock whatever. And that denture will stay in place reasonably well 'til dinner time. So you put a towel- What I do is I put a towel in my mouth and I bight on it. So it's completely dry or as dry as possible and then, obviously, I've got my dentures sitting waiting with the Fixodent on and then the towel comes out and it goes straight in. I find that that is much, much better. And it gets a better fix. But, like you say, the bottom ones is always- My tope ones, for all they're a little bit slack, once they're fixed, they're fixed all day, most of the days. The bottom ones, you're having- I'm having to fix them preferably just before I go for a meal, cause then I'm confident that they're going to be okay for the meal. (P07, M59).

Literature has shown that denture fixatives can improve retention of complete dentures (Neill and Roberts 1973; Munoz et al. 2012; Yegin et al. 2017), masticatory efficacy (Cheng and Zhao 2010), patient satisfaction (Gendreau et al. 2009), and OHRQoL (Nicolas et al. 2010) among denture wearers. Similarly, Bartlett et al. (2013) suggested improvements of food intake (i.e., vegetables and fruits) and nutritional intake (i.e., Vitamin C, saturated fat and protein) within a month of the delivery of simple dietary advice and denture adhesives among complete denture wearers. However, authors of this study were not sure if the improvement of

diet was due to the use of adhesive or attributed to the delivering of the dietary advice. Some of these findings were reflected by the data from the current study in which some participants found that the use of denture fixatives useful in stabilising the denture in the mouth during eating; however, others complained of the bad taste associated with their uses. To sum up, the majority of participants reported that eating with dentures is not a straightforward process. Participants emphasised that patience, perseverance and time are required for adapting to new dentures. In the first few weeks, for most denture wearers, it is preferable to start with chewable foods and avoid hard or tough foods, then gradually change to other foods or choose alternatives. Eating or preparing such foods in different ways, in addition to use some denture fixatives were helpful in stabilising dentures during eating for several participants.

#### Theme 3: The concept of denture fit and stability

Several participants discussed the concept of denture fit and stability in terms of eating. They described thinking that getting properly fitting dentures can improve eating, help the denture wearers overcoming functional or eating-related problems, and eat what they choose.

"Everybody can eat the same thing here, but they'd have a different effect, effect on, depending how your teeth fit. I must admit since I've had the new ones here they're an excellent fit on the bottom and the top. Erm, I, I don't have a problem with anything, I've one more adjustment to do at the top for the front teeth, apart from that I can eat anything again. Apart from harder stuff, I've got to get that sorted but, the teeth themselves stopping, and stopping them from moving, it makes it easier for me to eat anything more or less that I choose without any functional difficulty". (P02, M65).

One participant described the feeling when foods get trapped underneath the dentures if they are not fit properly:

"The problems I have are denture moves and sticks to foods and stuff gets underneath the, the palate and- When, when I get erm, jam or, you know, if you got a little seed underneath, oh, the agony. It feels as though you've got a boulder underneath." (P08, M75).

Therefore, participants thought that the key factor of eating with the dentures is the proper fit and stability.

"...., and I felt, I've just been listening, and the secret of it is getting them to fit properly, if you've got good fitting dentures that's the secret of it..." (P01, F74).

These findings are in agreement with the literature, which suggests that the stability and retention of complete dentures are necessary to function with them (Scott and Hunter 2008;

Rehmann et al. 2016). These could be the reasons why high retention and stability of ISOD over conventional complete dentures are possibly lead to the improvements of the oral function (Prithviraj et al. 2014), and OHRQoL (Sun et al. 2014), and patients satisfaction (Boven et al. 2015). Trulsson et al. (2002) reported that edentulous people treated with ISOD perceived it as an integral part of the body mainly due to its functional advantages highlighting the importance of denture fit and stability in overcoming functional difficulties during eating with dentures.

Several participants reported that fitting of the dentures could take couples of weeks depending on the sore or 'pressure points', which ae mostly associated with pain during eating. Therefore, sometimes, the patient needs to take the dentures out during eating to allow for the healing of the gum, then he or she can wear them again until the gums adapt to them. Therefore, perseverance may be important in order to adapt to new dentures, particularly for the first few weeks of denture provision.

"When I got my dentures, erm, I haven't got them in, as I say the new ones, in, I brought some bread with me and I ate it and it felt not too bad, you know. Now when I got home I think, erm, it just started again. I had, like I say, a pressure point, and something was, and it was really sore and painful and I must say, he said, "Take them out if they hurt." And I tried to persevere for about another half hour and I tried something else to eat and it was still sore so I did, I took them out. 'cause he says, "You'll only get an ulcer." Things like that, and you don't want that in your mouth, if it's really hurting, and it did. '' (P01, F74).

This finding is reflected in the findings of other studies (Takamiya et al. 2012), which concluded that mucosal trauma was the main reason behind not eating with complete dentures among approximately 26% of edentulous people, and (Heydecke et al. 2004), which found that approximately 50% of denture wearers reporting pain one month after denture replacement.

Several participants emphasised the importance of visiting the dentist more than once in order to adjust the new dentures. They described a belief that visiting the dentists periodically to adjust the dentures is important to get the rid of sores and pain associated with properly fitting dentures. This could determine the type of food the denture wearers can chew and eat in the future.

"But it was just a little sore, maybe these were, they're champion now, they, they, at first it was a little bit sore, put them out, try them again the next day, give the sore a

chance to clear, when you're [open] through the night, and then if it's not too, as long as you can bear it, stick with it and your gum will get better into it. But, but, if it's too severe, no you don't wear them big. I mean, I get these done twice, but they're champion now. The last time I got them done, when I first got them done again, adjusted, the first day they were still a little bit sore, sometimes the soreness is from the time before, and your gum hasn't had time to get over it. '' (P06, M70).

"I've done it about five times, I've got one, one more but I think it's about six or seven times now. So that makes it easier from the eating side. The last time I come, I found, I couldn't chew on that side, was a problem there. Since they've done that little adjustment, I can eat anywhere in the mouth now so, that determines the type of food I can eat now, I'm back to, eating anything that I want. Just keep trying them but do get them adjusted if they're not fitting properly. But things will get better but they'll not be an instant fix." (P02, M65).

These findings are in agreement with the literature, which points out the importance of patient follow-up visits for the adaptation of the new conventional complete dentures in terms of psychological and functional perspective (Veyrune et al. 2005; Takamiya et al. 2012; Komagamine et al. 2016b). The numbers of review visits of adjusting the new dentures depend mainly on the adaptability of each individual to new dentures (Panek et al. 2006), and the adaptability is varied from one person to another (Carlsson and Omar 2010).

The findings revealed that many participants thought that getting dentures with good fit and stability is a key factor in relieving pain and discomfort associated with eating with dentures and determining type of foods denture wearers can eat, particular hard or tough foods. This could be achieved through continuous perseverance and visits to the dentist to adjust the dentures; however, literature has shown that the number of post-delivery adjustments is largely influenced by the amount of residual ridge remain (Komagamine et al. 2016b), which directly linked to the denture fit and stability (Huumonen et al. 2012). Therefore, for those patients having eating problems related to poor denture fit and stability due to not enough residual ridge to support the dentures, it might be better for them to get ISOD. Such type of treatment could be suggested by the dentists after identifying patients with eating related problems as suggested by a study on experience of edentulous patients about prosthetic rehabilitation (Trulsson et al. 2002). Alternative to providing ISODs, which are often difficult in terms of practical and economic perspectives, denture wearers could try new strategies or techniques for eating and cooking for better enjoyment of food, rather than seeking fixed prosthesis or repeatedly, adjusting their current dentures.
# Theme 4: Preferred format of eating advice

It was apparent that one of the most important ideas emerged from the group discussions was a patient leaflet, which could be used as a tool to provide advice on eating with dentures for the denture wearers. Some participants suggested providing a leaflet including general information on eating with dentures. Dentists could give general information about the potential eating problems with dentures and general advice about how the denture wearers can overcome these eating problems.

"You might, you might sit if you pull advice down. Where before you used to eat an apple biting it, you might not be able to bite it now with your new dentures but you can still eat it if you just slice it up. You know, things like that. I just- General, erm, a general thing.....and therefore, for a dentist, just if they're in coming here, the dentist here, instead of having a lot of paraphernalia sent out, just a little leaflet, as X said, 'You might have problems eating this but this, we suggest, is how you could cope with it.'' (P08, M75).

Moreover, one participant suggested that the leaflet could include general information about eating with dentures because the dentists cannot provide personal or specific information for each individual.

"So it's a list of, "This is what you eat now, when you get dentures you will find that you struggle with this." "And eat the same foods but, instead of doing that, do this," you know? And it gives you that, sort of, advice, and you're prepared for it then. You don't just suddenly say, "Oh, I'm going to try that, I'm not going to eat that and I'm not going to do that." Because it gives you the suggestion, or at least the confidence to, well, they say I [can't], so I'll try. ..... I would have thought that, obviously, you can't do personal plans for everybody, the dentist. But it would be- Just general advice about how to function with dentures. People who used to wear dentures- Didn't have dentures here and now they have dentures they, they now tend to eat more of this." (P07, M59).

These findings are reflected in the literature, which shows that patient leaflets are widely used as a form of patient health information materials used in different health care systems to educate the patients and promote the general health (Moerenhout et al. 2013). Research has shown that providing pamphlets (e.g., 'eat well' and 'good life') as tools of dietary advice for complete denture wearers can improve diet (e.g., vegetables and fruits) (Bartlett et al. 2013). Nevertheless, delivering a healthy dietary advice in form of pamphlets alongside the use of denture fixative improved quality of diet among complete demure wearers (Bartlett et al. 2013). The researchers predicted that the influence of such intervention will last longer based on the fact that once healthier behaviour established, it is likely to continue. It could be argued that providing a leaflet that considers functional problems with eating could encourage a discussion between denture wearers and dental professionals about the content of the leaflet at

review visits. Such leaflet could help people to eat well and enjoy what they eat with dentures if it incorporates healthier eating message.

Other participants thought that a general information or tips on eating with dentures might be useful in leaflet format with a link to a website or app for further information about eating with dentures, particularly for younger people, who are likely to have an internet access. This approach (a combination of a leaflet and website) had the potential to delivering information about eating to a large number of people according to their preferences.

"Well, for the younger ones and that, like, as I say I was 18 when I first got mine, I've had mine 48 year. Erm, but the way things are going now, the apps, for the younger ones that's all they know, "Paper, no." You know, "Just look it up on my phone." You know. If they've got the information of, what app to download but it's still a bit of paper, you'd have that on the bottom of the paperwork, you know, "For further advice, go on this app." Or whatever. So, you've got the option of being able to read the paper, but [it's another one] to get the app, it's only one line with an address on it, isn't it, you know. '' (P01, F74).

*'I would say a leaflet and have something on the internet, because most people are on the internet nowadays.''* (P09, F66).

"I think a leaflet, you get a leaflet on how to clean your dentures and that when you're finished and what to do. Maybe a leaflet going along with that, at the same time, would be, I don't know how, I do have the odd app, but I'm not really that way inclined, I wouldn't so apps wouldn't be much good to me, personally. Erm, I think a leaflet with the information about the, the denture, at the same time, might be the best way. Erm." (P03, F65).

The reason behind the suggestion of integrating a leaflet linked to a website is that some participants thought that, nowadays, the internet is available for many older people, therefore for those people, who are 'tech savvy', they can go online and get more detailed information on eating with dentures.

"Yes, but people who tend to get dentures are later on in your- I mean, people in the future will have grown up with the internet. But in my [life], like with my wife, and she struggles to turn her phone on. Yeah, don't get me wrong, yeah, my wife as well. She's got a tablet now and she sits and plays games. But five years ago, you know, it would have been better in a leaflet form. Now, as the future's going, it would be, like, go to that webpage, all the information's on there. You just need a webpage or an advice page or whatever, you know, and you could look it up yourself." (P07, M59).

These findings are in agreement with previous research, which concluded that implementation of internet health interventions (e.g., using mobile) have expanded rapidly because of the

growing connectivity and increasing global ownership of devices by large proportion of population (Kay et al. 2011). However, the idea of the website was not shared by other participants, who suggested that for older people or those, who have no access to the internet or are not 'tech savvy', the preferable format was the patient leaflet.

"And, erm, as I say you talk about handing leaflets out, most oldish people are not computer literate, so they couldn't get advice in that respect, and it's, it's short term, because these things change, all the time, it's change." (P04, M69).

"Yeah, but you would also, you would also need a leaflet form for people who don't use the internet. That's what I'm saying, not everybody uses the internet, they're not all computer-savvy. I've got mates that are in their 60s that don't even have mobile phones. They don't want anything to do with modern technology." (P07, M59).

However, according to findings of Office for National Statistics (2016), there are increasing figures of access to the internet among people age 75 years and over in the UK in which the percentage of internet users among this age increased dramatically from 19.9% in 2011 to 38.7% in 2016. The percentage of internet users among this age group increased to 41% in 2017 (Office for National Statistics 2017a) and 44% in 2018 in which men (51%) are more likely to use internet than women (38%) (Office for National Statistics 2018). Therefore, it might be feasible in the near future to deliver a web-based dietary intervention for the denture wearers taking in account the tangible increase in internet use among older people.

Participants did not like the idea of a support group, which has been suggested within the focus groups with dentists and DCPs. Reasons stated for not being in favour of a support group were sharing personal details about how dentures have affected life (particularly outside of eating). This is demonstrated in the below quote:

"To be honest, I wouldn't, I wouldn't be coming back again in as much as, like you say, for- There's lots of things I would like to discuss but I wouldn't do it in front of the ladies. You know what I mean? There are other sides to eating that your dentures affect. You wouldn't discuss that in a group discussion. Not with women present, you know? It doesn't just affect your eating, it affects your sex life and everything. But you wouldn't do that in an open discussion. Because it's, it's not just eating, you don't just use your mouth to eat. I mean, believe it or not, I love karaoke. Right? And I was frightened to get up in case my dentures came out. Half way through the song, you know what I mean? Cause you can, "Right, 'ah-ha-cha-ha'," and I'm singing along, and "Oh, I'll manage this," and I got up and you're thinking, "I think you're half way through, yes, but my dentures could just suddenly jump out. '' (P07, M59). Others discussed the difficulty of gathering people together to hold such support groups exemplifying the low response rate of the patients in completion of the questionnaires and attending the focus groups of the current project.

'I don't think a group discussion really would work. I mean, how many people have filled those forms in and how many people's arrived for this discussion?'' (P09, F69).

# Summary of findings of focus groups with patients

Although many participants mentioned that they did not receive eating advice from the dental team, they valued the importance of getting general information or advice on eating with dentures from the dental team in form of a leaflet linked to a website that patients can find or perhaps, share information on eating with dentures. However, some participants had concern that not all denture wearers have an access to the internet or being 'tech savvy', so the idea of integrating them together seems to be much more practical and useful for most edentulous people. In other words, people could receive a leaflet, which includes general information or eating tips followed by a verbal explanation by one of the dental staff, probably the dental nurse to give the patients a general idea about the content of the leaflet. The leaflet could include a link of a website or app for further information, so the patient can search the website and get detailed information about eating with dentures, perhaps from other denture wearers.

#### 6.5.2 Dentists and DCPs data

Eight dentists (one female and seven males) and four females DCPs (two dental hygienists and two dental nurses) participated in the focus groups. Data saturation was reached after holding two focus groups. The mean duration of the focus groups was  $45.22 (\pm SD \ 14.86)$  minutes. The sample size was purposively selected and each mixed group was made up of six participants. Most dentists were consultants and therefore, directly involved in the management of the denture wearers. In this section of the data, the emergent and recurrent themes focused upon advice given about eating with dentures, barriers against giving eating advice, and strategies suggested by participants (Table 6.3). These themes were presented and discussed simultaneously.

Key themes	Sub-themes
Theme 1: Advice given about eating with	1.1. General eating advice.
dentures.	1.2. Specific eating advice
	1.3 Adjusting dentures rather than adjusting
	eating
Theme 2: Barriers to giving eating advice:	2.1. Perceived value of the advice.
	2.2. Behavioural, life style, and socioeconomic
	barriers.
	2.3. A lack of knowledge and training.
	2.4. Giving eating advice is the responsibility of
	other persons
	2.5. Time and financial barriers
Theme 3: Strategies suggested by	3.1: Web-based information.
participants.	3.2. A patient leaflet with verbal explanation
	3.3: Holding support groups.

# Table 6.3: Final key themes and subthemes of the dentists and DCPs data.

# Theme 1: Advice given about eating with dentures.

The majority of participants, particularly dentists and dental nurses were involved in giving general eating information or general advice on eating with dentures. Examples of advice given by them were:

- Informing denture wearers about the eating difficulties associated with wearing complete dentures.
- Encouraging the denture wearers to eat foods, which are easy to chew initially, and gradually building up themselves until they get used to the dentures.
- Advising denture wearers to start with soft foods, then advance to more hard or tough foods.

"My advice was usually to try and get people to understand that they could not eat the same foods, probably, that they could when they had their own teeth. So I think that a lot of patients thought that when they got their complete dentures they could carry on as before but, er, in my experience that does introduce limitations. So that was probably an acknowledgement of the problem almost wasn't it?" (P01, M, dentist).

*''I think we, I mean I think we do give fairly general advice, whenever you replace any kind of restoration to the mouth you give some advice, whether it's a small intra-*

coronal restoration or whether it's a denture, but to a very limited degree. You know, and I think it is about you giving advice about managing things are easy to chew initially, things that are easy to swallow and gradually building up and, and, kind of, reweaning yourself. 'Cause I think the, the process that the, the analogy that I often draw with these patients is it is like learning to eat all over again, it's like trying to imagine that you've never had solid food before and starting from scratch and building up and gaining the confidence and the capacity to cope with increasingly complex, er, food textures.'' (P03, M, dentist).

"I usually just say, you know, to start, I think like everyone set when you have a new pair of dentures is a bit like a new pair of shoes, to wear them in slowly and start with softer foods and sort of work into more difficult things really. But it's just very general advice and not a lot." (P05, M, dentist).

It appears that dentists and DCPs were used to provide general eating advice (which could help denture wearers enjoy eating) rather than providing a more formal induction into how denture wearers might function with a set of dentures. Such advice given by the dental staff are in line with recommendations by NHS Choices (2017) in which the denture wearers have to start with soft foods, cut them into small pieces, eat them on both side of the mouth, and avoid sticky foods, then gradually eat other types of foods. However, it could be suggested that this simple advice recommended by the NHS choices needs to be expanded to include further detailed information, new meal ideas, and recipes on eating with dentures based on patients' experience. Such advice could be obtained from the denture wearers themselves.

Interestingly, the leaflet or the advice sheet used in the dental hospital included very simple and limited information about eating with dentures, and it does not include advice about what and how to overcome functional difficulties related to eating with dentures as reported by one participant. Such simple information on the advice sheet could reflect a shortage in educational and motivational programmes about how to cope with the new dentures with regard to eating.

"I got the advice sheets when I knew I was coming here to see what we actually have written down, and for partial dentures, complete dentures and immediate it all says the same. And it says that the patient should cut their food up small and eat, eat on both sides and there will be some dietary adjustments. That's what's written down, you know, that we give out to the patients. There were two lines that just says, again, "Try and chew on both sides, cut your food up small and expect adjustments." (P02, F, dental nurse).

This finding is supported by a quotation of another participant, who mentioned that advertising leaflets of certain denture fixative companies are available in the dental clinic.

"The leaflets (that we have) are for care and cleaning. The only leaflets with regards to food, I would suspect, are from the manufacturers of Polygrip and the information that's given to us by the companies." (P10, F, dental nurse).

When the participants have been asked first about giving healthier eating advice to the edentulous patients, most dentists, if not all mentioned that they did not provide a healthier eating advice for the denture wearers. However, some dental nurses reported that were involved in giving 'informal' general or healthier eating advice if requested.

"My only real, erm, contact with nutrition and dentures were when people, maybe in old people's homes, nursing homes, have lost their dentures, lost a lot of weight, then I'm sometimes called in to make a quick set of dentures. But there was no real nutritional advice." (P04, M, dentist).

"I would provide very simple advice, as X says, about having a soft diet and the slowly building it up as they get used to the prostheses. But I wouldn't particularly go into healthy eating." (P09, M, dentist).

"I think in my years working in practice, and even in here but more so in practice, any advice given to the patients was very informal and we would come out of surgery and they say, "These are great but..." The patient would be approaching the dental nurse or anybody other than asking the dentist the question, "He's done his job but now what do I do?" I was employed as a dental health educator in practice, plenty of children and plenty of diet advice there, and even adults, but never for denture wearers. It was something that was never addressed unless the patient directly approached a member of the team." (P10, F, dental nurse).

The dental hygienists described being involved in giving dietary advice, offering cleaning advice, and taking diet histories from dentate people, but reported rarely being involved in giving healthier eating advice for denture wearers. This is demonstrated in the below quote:

"And as a dental hygienist it was definitely part of my role throughout my career to offer dietary advice, and sometimes take diet histories from people. But rarely, in the case of people with dentures, and surrounding issues like this, it was more seen to be something if somebody had a high decay rate they're the patients who you'd do that kind of tailored advice to, not somebody with dentures. Although I would offer a lot of cleaning advice... I never offered anybody any nutritional advice." (P06, F, dental hygienist).

Providing specific eating advice for specific group of patients was discussed by several participants. Participants reported that they rarely provided specific eating advice or healthier eating advice for specific patients listed below:

- Patients with maxillofacial defects and wearing dentures in oncology department.
- Patients referred from other hospitals and suffered from weigh loss due to ill-fitted or lost dentures.

• Patients returned back with eating problems or if advice requested (e.g., for specific people who ring up the dental hospital and ask for help).

Again, most of the advice was probably general and functional rather than healthier eating advice.

"Erm, with my background in, erm, oncology, erm, sometimes we have to give much more specific advice to recognise the anatomical changes that those patients have, have experienced. And, and even greater limitations sometimes when wearing complete dentures. And also some of those patients will've been tube fed for a while, so it's actually reintroducing an oral intake that is of prime importance in those patients. So we give quite specific advice in terms of managing things that are soft, er, relatively easy to swallow, erm, and using increased, er, amounts of, erm, water to, to aid in, in swallowing. So that's really specific to that, that, that type of patient. My experience with, with more conventional complete denture wearers is, is not dissimilar in that, erm, you will get some patients who will come back and report that they have difficulty eating. And then you can sort of focus on, "What is it you're having difficulty eating?" and try to, to give them some advice on how they may either manage those foods or find alternatives. So it, it's, it's very variable. And I wouldn't say that I had a particularly general approach, it was very much bespoke to each individual patient. '' (P03, M, dentist).

"Perhaps it's only when patients come back with problems that we then might try and identify what those are. It may be problems with eating, it may be problems with fit or stability." (P07, M, dentist).

"But going back to what X said about patients who've lost their dentures, we get the general hospital, the RVI/Freeman, ringing us where patients have lost dentures wanting urgently to have new dentures made. And I work with X and the advice she gives them is that they, you know, they can get the nutrients from the various, er, the substances, the, the meal replacements. Yeah, we do. On our department we do really, if a patient rings up and they're having problems we'll give advice, we wouldn't ask, go away and ask the clinician, we'd, you know, have enough experience to be able to, to help and, and advise as best we can. And there are certain people with expectations again who want to be able to eat an apple or a steak, and unfortunately we say to them, "Well chop your apple up" and that's not what they want to hear, they want to be able to wear a denture and be able to eat into an apple." (P02, F, dental nurse).

"I think the only time I've ever come across any dietary advice given is with the osteopathy patients in max-fac. They're given a sheet with some recipes on and some suggestions of what to eat, but that's it. They're given the sheet, "There you go", amongst everything else that they're given and they are monitored for losing weight and things after. But they are just handed a sheet with very little discussion, there are a few suggestions. At least it's something but really these patients, primarily the ones I've seen, are in their 20s and all they want to know is when they can get back to eating McDonalds, that sort of thing of, "When can I eat my normal diet?" But they have got a sheet." (P10, F, dental nurse).

However, one participant described some healthier eating advice the she gave for some patients such head and neck cancer patients or referred patients, who have difficulty functioning with their complete dentures. Eating tips provided were:

- Try to add vegetables and meat to the homemade soup.
- Try eating eggs and fish which are soft and protein rich.

"I think that sometimes if the patient raises it initially when they first come in... Many of the times we've seen patients who have been referred in because they're having difficulty functioning with their complete dentures, and if the patient volunteers the information at the beginning you'd probably go into more of a history about it. Some of the patients say that they have difficulty eating salad, tomatoes and tomato skins. So some of the patients attend feeling that they can't have a healthy diet because they have difficulty actually incising some of the, what we would regard as, healthy foods and so as a result feel that they have to have a softer diet as a result of that. Some patients do have concerns that it affects their diet and nutrition as a result of the fact that they don't feel that they can actually function as well with the dentures. I guess that's one of the things that we try to focus on but I'm not sure that we really reflect on it at the end of the process. Certainly if patients are having difficulties with their dentures and they feel that that's affecting their nutrition, and when they discuss that in consultation, sometimes I would often give them suggestions of things that they could have which would potentially help in the process whilst we're waiting to make new dentures for them. Sometimes I would suggest things like, "If you make some homemade soup then that should have all the nutritional benefits, the vitamin C and all the benefits of the vegetables", and if they're using meat in their soup as well. I might suggest things like soft eggs, which are a good source of protein, or fish, which again is a good source of protein. It's often the protein that they feel they're not able to manage. I suppose sometimes I would give them ideas. Certainly in relation to the head and neck cancer patients, where it's really important to maintain their protein so that they heal and recover, I guess I try to encourage them in relation to that. But it's not necessarily having a healthy diet, it's really so that they can recover from their radiotherapy or whatever they're undergoing. '' (P11, F, dentist).

Most participants and the dentists in particular described focusing on the technical issues of denture construction and adjusting dentures rather than adjusting eating, in that they think that their duties are to make good set of dentures, provide them to the patients, and adjust them rather than giving eating advice, which helps people enjoy what they eat and indirectly improve healthier eating.

"I think the best thing we can do is do our best to make the best set of dentures possible for that individual. Yeah, look how many times we've had somebody come in here with what we think is a very poor set of dentures and we've managed to make a really good set." (P04, M, dentist).

"I think, from a personal point of view, we're quite bad at doing this (eating advice) because the focus tends to be on comfort and fit, and by default we assume then that if they're comfortable with it, for example the prosthesis is not rubbing, then we might assume that they're then able to function with them. Yes, it wouldn't be part of your standard review process. If you did make a review for a patient, and that's a big if, if you did make a review for a patient stort you would be making adjustments to try and improve comfort rather than to try and enhance the

*social aspects of denture wearing and interaction with other people.* '' (P07, M, dentist).

"You know, we try to design dentures in such a way that they will be able to function well with them and then obviously we deliver them and review them, check that they're comfortable and they're able to eat, but it's rare that we actually review people frequently enough to ensure that they're completely able to manage the full range of foods that they might choose to eat. Probably yes, because if the patients attend complaining that they have difficulty eating certain foods then we're looking technically at the dentures to see what we could do to improve upon them to make them function better, or what we believe will function better with the dentures. But we probably don't actually assess the outcome of that formally at the end of the process." (P11, F, dentist).

One participant was wondering about the fact that adjustment of dentures could make the people eat different food items and enjoy what they eat, but could not improve healthier eating highlighting the importance of implementing of other approaches (e.g., dietary advice or intervention) to improve healthier eating among denture wearers.

"I'm not sure, although I haven't researched it, that there's a huge amount of evidence to say that if you have well-fitting dentures you eat a healthier diet than somebody who doesn't have any dentures. I think there was a study done here comparing implant over dentures with regular dentures with your nutrition and as far as I remember there was no difference between the two groups but maybe there was something about the study which wasn't sensitive enough." (P08, M, dentist).

It has been found that the quality (e.g., stability and retention) of complete dentures are not necessarily important to improve healthy eating (Allen and McMillan 2002; Shinkai et al. 2002a; Moynihan et al. 2009). For example, Sebring et al. (1995) concluded that provision of new well fitted conventional complete dentures or ISODs could improve masticatory efficiency, but not necessarily increase dietary intakes. Moreover, although vegetable and fruit intakes improved among patients treated with complete dentures, particularly those with ISODs, the intake of theses food items did not reach the minimum level (400 g of fruit and vegetables per day) recommended by WHO (2003). Similarly, there was no advantage of being treated with ISODs, which probably have more retention and stability than treated with conventional complete dentures in terms of dietary intake in the absence of specific dietary counselling (Hamdan et al. 2013; Boven et al. 2015) indicating that adjustments of the dentures for better good and stability could improve eating, but not healthier eating. Prosthetic rehabilitation of edentulous patients with complete dentures (e.g., conventional or ISODs) in conjunction with the dietary advice or counselling can improve healthier eating among denture wearers indicating the importance of delivering dietary advice or intervention on eating with complete dentures to help denture wearers eat well with dentures (Moynihan et al.

2012; Prakash et al. 2012; Komagamine et al. 2016a). Data of the present study reflected what was mentioned in the literature regarding to the importance of denture fit and stability in improving eating with dentures, but not necessarily eating healthier food.

In conclusion, most dentists and DCPs used to give general eating advice about eating with dentures to edentulous people. Such advice could help patients overcoming some eating problems and enjoyment of foods. In specific situations, dentists and DCPs gave specific advice to specific patients. Nonetheless, dentists were focusing on adjusting dentures to improve function and indirectly enjoyment of foods not to improve healthier eating. However, it could be argued that although providing denture with good fit and stability is necessary for eating, fitness of the denture could improve enjoyment of foods, but it does not mean that denture wearers can eat healthier foods.

#### Theme two: Barriers to giving eating advice:

Different barriers to providing advice on eating with dentures emerged from the focus groups with dentists and DCPs, and these are: Perceived value of the advice; behavioural, life style, and socioeconomic barriers; lack of knowledge and training; feeling that giving eating advice is the responsibility of other persons; and finally, time and financial barriers.

# Perceived value of the advice

Several participants had a concern about the perceived value of the advice (particularly healthier eating advice) possibly due to lack of knowledge and motivation to change among the target people.

"I mean there, there is another public health adage that any public health measure that requires the cooperation of the public will not work. (Laughter). Which is why we wanted fluoridation, which is why we put vitamin D in margarine, or whatever they do, it, it's very difficult to get people on board. That, that's one of the classic public health dilemmas. The people that listen to you are the people who don't need to listen to you. The people that need help are the ones that have, perhaps, not got the educational background and the motivation to do so." (P01, M, dentist).

Some participants did not like the idea of being 'a third person' to give advice about eating with dentures to people, who have other medical conditions such diabetes and get dietary advice from other doctors or dieticians. The reason behind that was people could not have the enthusiasm to listen to them.

"But going back to my mum, she wore dentures, she had her teeth removed when she had her fourth child. And, erm, but I think when they get to a certain age when they've been wearing dentures for a long time they've got other medical conditions and they go to hospital and they get a lot of general dietary advice from the other medical conditions. They do see dieticians elsewhere about blood pressure, diabetes, things like that. So, I think, if we're coming along as a third person keep going on about eating healthily then they're not going to want to listen really." (P02, F, dental nurse).

Such a finding could reflect the fact that oral health is perceived to be a low priority in comparison with general health, and this is in agreement with the result of Frenkel (1999), who concluded that the prioritization of oral health by nursing management is low.

Other participants talked about importance of the experience that the denture wearers had to adapt to the new dentures during the year of wearing them. They exemplified that wearing complete dentures is like receiving a prosthetic limb; both of them need time and experience rather than giving a list of information, and the denture wearers are, sometimes more experienced than dentists who are providing the dentures for them.

"I think there's a, there's an assumption that, you know, you give somebody a set of, er, dentures and they immediately know how to eat with them. And, er, it, it's kind of ironic because if you were making a prosthetic limb you wouldn't expect them to be able to get up and go away and run with it straight away and you'd probably want to give them some, you know, degree of physiotherapy and biomechanical advice. And we don't do that with denture. Erm, and, and I think, you know, the, talking about the limitations of dentures and eating is something which we try to deliver on the undergraduate course. We recognise that to replace 32 or even 28 highly specialised organs with two pieces of plastic is ridiculous in the extreme. And, and I think, you know, we perhaps do need to be more mindful of the fact that we need to give our patients advice. But it, it's, on the other side of that we often have very experienced denture wearers, sometimes who are more experienced than the clinicians who are providing the dentures for them. (P03, M, dentist).

Some participants reported that providing the patients with a new set of dentures, and asking them to eat healthier foods simultaneously was difficult and impractical. In addition, there are many available nutritional advices for those people, who have the willing to change their eating habits instead of relying on information from the dentists.

"Yes, I, I would say that there's a lot of nutritional advice out there and, erm, I think denture wearers, if they're keen and they want to eat healthily, erm, they will do as far as they can. And then the dentists have a limiting factor. I think, I think I would find it difficult. I think most dentists would agree me that I find it hard to give somebody a new set of dentures they then go and say, "Go and buy some raw carrot." (P04, M, dentist).

Several participants mentioned that giving advice on eating with dentures is probably patronizing for the patients and problematic for them. In the data, an example was given that

if the dentists set a gold standard eating advice to the patients and they are not satisfied with the dentures, they may come back again because they did not achieve these criteria, subsequently, the dentists are ending up with retreating these patients again and this is what most clinicians do not like to happen.

"And it, it, and X again. If, if you, one of the things that, which is horrible but which we do with denture patients, that is lowering their expectations and, and trying to explain that, "You won't be able to do this, you won't be able to do this" because there's such an expectation that they are like your teeth back and every dentist will tell you they're a, they're a replacement for no teeth, they're not a replacement for teeth. And by giving them this, "You can eat these, these recipes will work" and they get the recipe, they go, "I can't eat it" then suddenly we're remaking the denture and, and actually you think, "For you we're going to struggle to make this much better unfortunately." (P05, M, dentist).

Many participants described thinking that giving eating advice could constitute a supplementary element of patient care and management, and, as such, seemed to focus on giving eating advice (e.g., sugar intake) to dentate people rather than edentulous people because they think that those people were already lost their teeth.

"There are so many other pressures on healthcare professionals working in primary care that these bits of additional advice are the, sort of, the embellishments and the aspirational elements of patient care and management, or how I would see it anyway, for denture wearers rather than the essential aspects of care which go back to the points which X made about functionality and comfort. As a result of that the focus is on dentate patients to keep and not edentate patients because they've already lost them (teeth)." (P07, M, dentist).

With regard to behaviour change advice (e.g., dietary behaviour change), several participants emphasised on the importance of frequent monitoring and reviewing target people to ensure adherence to the advice, and, subsequently, effectiveness of the advice. They also mentioned that advice should target population rather than individual because the effect of one to one advice is potentially very limited. Hence, the perceived value of such eating advice is going to be limited as well.

"when you're giving lifestyle and behaviour change advice- You can't give it once and expect that to work, so you sort of coaching style of health coaching and seeing them frequently and reviewing them and giving them tips, more tips along the way, is really a, a kind of thing that you're looking at that would have more success." (P06, F, dental hygienist).

"I think sometimes when it comes from us you're only affecting the person in front of you whereas really you need a bit of a movement, in a way, which will help these people." (P12, F, dental hygienist).

It seems that several participants in the study were not sure about the perceived value of the advice given by the dental team to the denture wearers, especially if they were not keen to receive such eating advice, particularly healthier one because such advice need periodic evaluation and regular check-up to work. Moreover, it is surprising that denture patients are not seen by some participants as important for dietary help. It could be argued that, the dental team could provide support to the denture wearers in terms of enjoyment what they eat with their dentures in form of simple advice or information to help them improve eating with dentures.

# Behavioural, life style, and socioeconomic barriers

Several participants highlighted that most people, who tend to lose their teeth earlier came from low socio-economic background, and they already had poor diet before provision of complete dentures. So it seems difficult to change their dietary behaviour or life style habits because most of those edentulous people have limited budgets and they might not being able to buy healthier foods such fresh fruits and vegetables, instead of that, they can buy processed foods which are cheaper, softer and easier to eat.

"I was saying that there is those sort of socio-economic skew into this in that a lot of the people who tend to lose their teeth earlier came from disadvantaged background who already had questionable diet before they ever were introduced to complete dentures. So, erm, yeah, I think it's interesting, it'll be, the parameters on what's considered to be healthy probably goes a lot wider than just people just wearing dentures. I still think that for a lot of the patients who've lost teeth early their diet before they lost their teeth probably didn't fall into the category of the recommendations anyway. Erm, so I think the transition to dentures for some of them is probably, while a bit of a shock in one way they probably weren't eating their lightly cooked broccoli and stuff beforehand. Again, it's a socioeconomic skew on it, the, the people from poorer backgrounds were already eating, as X says, lots of processed food, things that they just found easy, convenient, and which is easier to market to a certain section of the population. (P01, M, dentist).

"I think you go back to the economics as well, er, you know, how well off your patients are. Erm, can they afford to buy all this fresh fruit, nuts and, you know, erm, foods or is it easier to buy the more processed things, erm, which maybe are softer and they can eat with dentures, so therefore they've never had the problem, never seen having dentures as a problem. But I think it goes back to the economic and the social backgrounds of the people as well as, you know, again, erm, they're maybe not used to eating a lot of these foods. I mean, is there a scope for where you could say, you know, "If you're on a limited budget" you know, "The- this is what you could do, these are replacements." Erm, and people are older and what they like to eat changes, their taste. Or maybe it's quality of life as well for some people. It, it's nice to sit and eat a cream cake because they can't eat a carrot with their dentures but it makes them feel good and it makes them happy.'' (P02, F, dental nurse).

Literature suggests that the economic, social, and behavioural factors (Sheiham et al. 1999; Marshall et al. 2002), in addition to the price of meals are important determinants of food choice (Kamphuis et al. 2015). Similarly, understanding of these determinants is fundamental for developing health (i.e., dietary) behaviour change interventions for older people (Lau 2008). These seem to be reflected in the study data when several participants highlighted the importance of behavioural and socioeconomic as barriers against changing their dietary behaviour. Participants described thinking that most denture wearers from low socioeconomic level used to eat processed food, which is probably unhealthy. The processed foods are mostly rich in fat and cholesterol, and have low fibre, minerals and vitamins (Moynihan et al. 1994) could lead to loss of pleasure during eating (Lamy et al. 1999), and overweight (Lee et al. 2004; Makwana et al. 2014). Therefore, providing information or advice about eating with denture could help increase their knowledge and change their behaviour towards healthier eating style.

In addition to the economic factors, behavioural factors were also highlighted by some participants, who mentioned that changing the dietary behaviour of an individual is very difficult process. Changing health behaviours of those people might need the collaboration of the whole society, and behaviour interventions should target the community rather than individuals.

"I certainly think so. I think it's economic as well because your diet is based on your economics. If you turn round and say, "Actually, you haven't got a very healthy diet", like you say, if they didn't have a very healthy diet before then that's the problem. It's like teaching someone how to brush their teeth correctly isn't it? You hit barriers all the time because they don't want to be told these things. I do think there are two issues as well. I think the healthy side of something is, like you said, the World Health Organisation push that and that's great, but, like we've said a few times, if they didn't eat that before what do you in trying to re-educate on that level as well as about what they can eat? Or should you be focusing on, "We'll try and keep you to the diet you already had" which is not, from a healthcare perspective, not right because you should be encouraging them to have a healthy diet. It's very complex as to where you start with it." (P10, F, dental nurse).

"I think it's really difficult to give somebody health, healthy eating advice when they leave the hospital and they're walking back home and they're passing a McDonalds and they're hungry, you know. When they go in the supermarket and there's, you know, they're bombarded by advertising of great sugary products and stuff. It's so difficult. It, society needs to take issue with this as well really, I think." (P06, F, dental hygienist). "It wouldn't be unusual to find that I would be speaking to someone about their dietary intake without really, I'm realising as I'm sitting here, asking what they'd ever eaten before. I'm talking about people who've maybe had a lot of surgery and then have difficulties with eating diet. But then you discover that they always had very disordered eating prior to this so it's then even more difficult to get a healthy diet because the diet was very disordered before any changes. So that is a barrier. I think I'll touch on something that X mentioned, it's all about behaviour change. As I know, and as he knows, through doing a lot of work with smoking and trying to get people to change their oral hygiene habits, behaviour change is very, very difficult, very difficult indeed. It almost has to be national pressure, in a way, rather than a one to one intervention. It has to be more of a general health approach towards healthy eating and focusing in on what our niche group, of complete denture wearers, and how they can be helped. I think sometimes when it comes from us you're only affecting the person in front of you whereas really you need a bit of a movement, in a way, which will help these people.'' (P12, F, dental hygienist).

Some dentists reported that there is a difference between how the denture wearers use their dentures and how they feel they should use them depending on the social circumstances (whether they are at homes or in other public places) highlighting the importance of patient's experience and acquired skills in dealing with such situations (e.g., eating with dentures at different public places).

"I think there is very much a social aspect to denture wearing. In a public place people may do different things to what they do in their own home. They feel much more comfortable wearing one of the two sets, if we're talking about complete dentures, around the house to eat, talk and function but they might do something very different outside of the house where they feel there's a different social norm perhaps. So if they're eating in a restaurant they might feel obliged to try and eat with both sets of teeth whereas at home they might use one use them and how they feel they should use them depending on the social circumstance." (P07, M, dentist).

This finding is concordant with previous research, which is shown that eating with complete dentures varied according to the social circumstances, in that many denture wearers felt embarrassed, less confident, and not enjoying what they eat in public places or with friends than at home or with other family members (Trulsson et al. 2002; Hyland et al. 2009; Kelly et al. 2012).

Some participants found that the concept healthier eating is a 'new trend' and considered that many older people do not care about it and giving them healthier eating advice is likely 'patronising'; therefore, it is sometimes difficult to convince people, particularly older people about the changeable fashion or concept of healthy eating.

"I think an age thing, they don't know the trans-fats, the good fats, the bad fats. I think it's, it, healthy eating's become a new, a new thing for us to do. When I was a child we, my mam didn't say, "Have you had five bits of fruit to eat?" I think it's become a new thing that we, we're all [Crosstalk]......You see a lot of these people are of a certain age and they've been, they've brought families up, they've cooked and took care of children, grandchildren, you know, and to be telling them what is healthy- Really it is, it's very patronising. I know- We can change some things, yeah, we can do it, yeah, positive. (P02, F, dental nurse).

"I, I think that element of it is difficult enough for somebody who's educated. Because there's such a lot of conflicting and confusing information and the fa- the fashion seems to change from almost one decade to the next. I mean, you know, 10 years ago we were talking about the, the risk of saturated fats and here we are now starting to embrace dairy products all over again. So I think it is very difficult to give a, a, you know, a consistent understandable message to, to patients, and particularly those whose cognitive capacity might also be impaired." (P03, M, dentist).

Others mentioned that most denture wearers have a real impairment with their capacity to eat healthier food, so changing dietary behaviour among such people might be difficult because food selection is likely influenced or determined by the patients' perceptions, which is totally subjective.

"And, I mean, you know, you can extrapolate that to the general population, erm, you've only got to look at how many people don't necessarily eat a healthy balanced diet who are not a denture less to see that you've got an even bigger problem when you're dealing with someone who's, who's got a severe, erm, impairment in terms of their capacity to eat and, and is wearing complete dentures." (P03, M, dentist).

"I think also sometimes it's the patient's perception of what they're able to manage as well isn't it? So I don't know whether they would feel, "I can't manage to eat those things. I can't eat those things. I don't like to eat those things." It's quite a personal thing isn't it, someone's diet and what they choose to eat." (P11, F, dentist).

It could be argued that social, economic and behaviour factors have been highlighted by the participants in this study as important barriers factors, which could influence any eating advice given to the denture wearers by the dental team.

#### A lack of knowledge and training

Public Health England (PHE 2016), and the National Institute for Health and Care Excellence (NICE 2016a) reported that dentists and DCPs should support patients to change dietary behaviour. Surprisingly, most participants in these focus groups, particularly dentists felt unprepared and lacking in knowledge to teach the denture wearers how to eat a healthier diet with their dentures or to give healthier eating advice to the denture wearers. This could reflect the low level of knowledge about the gold standard of eating advice.

*"The more I think about it the more I think I feel untrained and that I would not have the skills to answer the questions you might quickly face about vegetarianism, certain* 

religious based diets which you might unwittingly stray into without wanting to offend a patient. I think there would be quite a bit of training required actually. It is bizarre actually that we spend our whole life dealing with the mouth but I can't think of a single lecture, certainly as an undergraduate, from a dietetics person. It's actually a bit humbling to realise that we don't actually have much to do with this and we probably should.'' (P08, M, dentist).

"I would say that I don't feel comfortable or knowledgeable enough about that subject to provide that advice so I would steer away from it." (P09, M, dentist).

These findings are in agreement with the results of other studies in the UK, which found deficiencies in the knowledge of healthcare professionals in relation to the oral care of the elderly people in different oral health care places (Preston et al. 2006; Young et al. 2008) indicating the need of the healthcare professionals for training courses.

These views differ from that of one participant, who seemed to feel that most dental nurses have enough experience to give eating device to the denture wearers.

"Yeah, we do. On our department we do really, if a patient rings up and they're having problems we'll give advice, we wouldn't ask, go away and ask the clinician, we'd, you know, have enough experience to be able to, to help and, and advise as best we can. And there are certain people with expectations again who want to be able to eat an apple or a steak, and unfortunately we say to them, "Well chop your apple up" and that's not what they want to hear, they want to be able to wear a denture and be able to eat into an apple." (P02, F, dental nurse).

Most participants reported that the dental team used to give eating advice regarding sugar intake and its effect on teeth because they probably have adequate training to give advice on sugar content of the diet, and this subject was adequately taught at the undergraduate level. In contrast, they rarely used to give advice on eating with dentures and most of them feel unconfident to give healthier eating advice to the denture wearers.

"We, we do, that's what we teach and we do, and when we teach diet history it is pretty general, it's not, we do focus a little bit on the number of, erm, non-sugar intakes but it's, it, you know, there's no point going into it just like that, we would look generally on, on everything. Erm, but pretty, we just don't do it a lot with denture wearers. And I suppose from what you were saying there... When I think about denture wearing, because we don't, we aren't denture wearers it's very hard to, to, to get yourself in that place where you could give them good advice." (P05, M, dentist).

"Going back to what you were talking about if we felt we were adequately trained. I think the only thing that I feel moderately adequately trained to give advice on is the sugar content of the diet because that's something that we were taught in dental school and it's something that we look at carefully and keep up to date. So certainly in relation to the prevention of tooth decay that's something that we feel relatively comfortable giving advice about, but not always in relation to a general healthy diet. (P11, F, dentist).

In order to overcome the problem of lack of information relating to advice on eating with dentures among the dental staff, particularly the dentists, some participants suggested giving more training about eating with dentures at the undergraduate level.

"I think that, as X said, it really stems from education. I think at an undergraduate level we're quite poor at communicating that to our students. The importance of that is that maybe we ourselves don't know the impacts that poor diet will have in the longer term for denture wearers. Again, there is the assumption that if they're not coming back they're okay but perhaps they're not. How you would change that and how you would modify that would mean started very much from the beginning again, looking at the undergraduate curriculum and trying to deliver an intervention there. Which means that for every single denture that that student, and then healthcare professional from the point of graduation onwards, every bit of information they deliver to a denture wearer includes some sort of additional advice." (P07, M, dentist).

In general, literature stresses the importance of oral health education or training for the health care professionals, who responsible for delivering oral care for older people (Preston et al. 2006; Young et al. 2008). This seems to be supported by the findings of the current study in which several participates highlighted the great need for training courses about giving advice on eating with dentures to the denture wearers.

# "I think there would be quite a bit of training required actually." (P08, M, dentist), "I think we could possibly do with more knowledge." (P12, F, dental hygienist).

It could be argued that PHE should consider providing eating advice for denture wearers in delivering of better oral health toolkit or conducting training courses or modules to improve experience of the dental team with regard to providing eating advice for the denture wearers.

In summary, the participants' knowledge and experiences seemed to vary according to their work context or disciplines, majority of the participants in this study, however, seemed to have limited knowledge about giving eating advice, particularly healthier eating advice to the denture wearers, and feel they have not had adequate training with respect to this. The inability to give healthier eating advice to the denture wearers is mostly attributed to their limited knowledge about the gold standard of healthier eating advice.

#### Giving eating advice is the responsibility of other persons

Several dentists preferred to take them out of the equation of giving advice, particularly healthier eating advice to the denture wearers because they believed that denture wearers

could find a difficulty in digesting the advice, particularly healthier eating advice from a dentist rather than from dietician or nutritionist, who are likely the best persons to do that.

"I think, I think, and I think patients might find it a little bit difficult to stomach that (eating advice) coming from a, a dentist rather than, you know, perhaps from a dietician or someone with a nutritional background." (P03, M, dentist).

"I certainly don't, no. Perhaps there may be other avenues available if you feel that somebody's really struggling with managing any diet at all, then it may be a referral through a general medical practitioner to a dietician." (P08, M, dentist).

Some participants had concerns about the situation in which if the advice comes from the dental team or staff, it might contradict that given by dieticians, who are experts and adequately qualified to give eating advice.

"Of course, just from what you're saying X, when we work with the dietetic team in relation to the oncology patients often the advice that we're trying to give them is conflicting. The dieticians are trying to maintain their nutritional status and trying to ensure enough calories so that they don't lose weight. We're trying to tailor their advice so that they don't have too much sugar in their diet, particularly between meals whereas dietetics are really about adding sugar to drinks, lots of puddings...It's very difficult because in the reality of the situation it's more important that the patient lives through the patient than-Yes, the priority is that they'll do better through treatment if they maintain their nutritional status. So we have to take the advice of the dietician because, of course, they are the ones that are qualified to do it.'' (P11, F, dentist).

Literature reports that one to one counselling sessions provided by a nutritionist resulted in improving food and dietary intakes among denture wearers (Bradbury et al. 2006b). However, recent research has shown that simple dietary advice provided by dentists in dental clinics is also effective in increasing the intake of nutrients and foods among complete denture wearers (Komagamine et al. 2016a) indicating that providing eating advice by the dentist in the dental clinic is more practical than tailored dietary counselling provided by nutritionist or dietician. Such findings contradicted to the results of this study in which most participants felt unprepared to give eating advice, particularly healthier eating advice indicating the importance of training courses for them.

One participant suggested that trained dental nurses could be the best individuals to give eating advice to the patients.

"Yeah. If you're going to go it you'd have to, you, you, really who's going to be doing it? Wouldn't, wouldn't, in reality it wouldn't be the dentist, it'd have to be trained dental nurses who are trained in dietary giving." (P05, M, dentist). Interestingly, most dental nurses and dental hygienists agreed and suggested they would be happy to help denture wearers by giving them eating advice, especially if there are appropriate infrastructures and enough time.

"I am sure there are plenty of nurses out there who would be happy to go through a short course, or something like that, for extended duties on anything, as long as you know you've got the correct information and direction at the time." (P10, F, dental nurse).

"We can change some things, yeah, we can do it, yeah, positive." (P02, F, dental nurse).

"Erm, I think that, I think it would be a great thing for dental nurses and dental hygienists, I think they'd love to be involved in stuff like this. I don't know how realistic it is that practices would have, as X has said, the space and the time to allow people to. But I think they'd love to expand their role and take on something like that." (P06, F, dental hygienist).

One participant thought that combined efforts from various disciplines might be useful to put solutions for the situation, in that many people such as healthcare professionals, GPs, dieticians, medical nurses and district nurses could be involved in giving eating advice to the denture wearers.

"So there would need to be a number of other possibilities of capturing or delivering the same information, whether it be in leaflet form, video, audio, whatever it might be, or even, as X said, through the other healthcare professionals that that person has in their life, GPs, perhaps dieticians, medical nurses and district nurses. There could be a lot of people involved." (P07, M, dentist).

In the current study, although many participants suggested that giving advice on eating with dentures is the responsibility of other people (i.e., dieticians or nutritionists), some of them nominated trained dental nurses to do that taking into consideration the availability of adequate time and infrastructures. Others, however, recommended the collaboration of different people from different disciplines of health care to support the denture wearers, help them enjoy what they eat with their dentures, and indirectly promote healthier eating.

# Time and financial barriers

In general, the literature highlights time and lack of adequate reimbursement as influential factors in provision of dental care for older patients (Stevens et al. 2008; Carson and Edwards 2014; Bots-VantSpijker et al. 2016). This seems to be reflected in the data of the current study in which most participants, particularly dentists attributed their inability to provide advice,

particularly healthier eating advice on eating with dentures to inadequacy of time and financial supports within the constraints of the 'NHS framework'.

"I worked out what my timescale was to be able to complete dentures within the restrictions of the NHS framework, and I had to do it, from start to finish, all stages, 20 minutes. So I have not got time to talk to people about how to cook their broccoli and stuff, it was this enormous time, as X says." (P01, M, dentist).

Given their experience in general practice, some dentists pointed out in addition to the impracticality of spending the dentist's time for providing eating advice, infrastructure (e.g., spare room), and 'salaried people' are also required.

'If I could just, the, the problem always with dentistry is, is the time to do these kind of things. You know, erm, worked in general practice for many years before I took on this role and, you know, it's not uncommon for people to do a denture fit in five minutes or, you know, ten or fifteen minutes. You know, we, we barely have time to be polite and do the work to add a 15/20 minute, 30 minute chat is, it's not feasible. You'd need to delegate that work and you'd have to have an infrastructure within the practice to get, you know, other salaried people doing it 'cause it's just so expensive if it's the dentist's time. To have a, sort of, 20 minute chat with someone about their diet it, you know, incredibly expensive in, in practice for that.'' (P05, M, dentist).

Similarly, another participant highlighted that giving eating advice to the denture wearers needs a 'dedicated person' to sit with patients and give them advice on eating with dentures.

"But again it's not having that specific member of staff who has the time to do that. And I think that's, that's just in, there's so many good initiatives in health but they need the, a dedicated person who has the time to spend with the person." (P06, F, dental hygienist).

The data suggested that dental nurses could be eligible to provide advice on eating with dentures if there are financial compensation, training, and enough time. One participant reported that the financial cost of providing eating advice to the denture wearers by the dental nurses or dental health educators might be less in comparison with that doing by the dentists.

"But, X again, we did in our practice, we did have a dental health education centre and all the dental nurses were trained, so we used to do that, which is a lot less expensive than the dentist's time. (P02, F, dental nurse).

Moreover, many of participants in the study sample thought that their contract does not reward them, and in the absence of health measures, which evaluate the outcomes of these extra duties, there will be no necessary 'driver' to deliver such eating advice for the target people. "I agree with what X said, at the moment the contract doesn't reward that. Certainly from the point of view of primary dental care there would need to be a driver, either a patient benefit so, "If you give this particular set of advice this patients going to live longer, have less cancer and less chance of diabetes", whatever it might be. There needs to be a tangible health benefit or a measurable health benefit otherwise they will continue doing what they're doing because they're not getting paid any more for it." (P07, M, dentist).

Some participants were uncertain about the value of spending the time of the health care system on improving nutrition as indirect way for improving overall quality of life, and whether that could ever be reflected in fee payments for making dentures, and whether you would have to focus it on certain types of patients.

"What it touches on, I suppose, is whether in the bigger picture there is value to the healthcare system investing time to improve the overall wellbeing via nutrition and whether that could ever be reflected in fee payments for making dentures, and whether you'd have to focus it on certain types of patients?" (P08, M, dentist).

It could be concluded that most participants, particularly the dentists, pointed out inadequacy of time for providing eating advice to the denture wearers. Some wondered about the value of spending such time and its outcomes from healthcare system perspective.

# Theme three: Strategies suggested by participants

Three strategies have been discussed by the participants in these focus groups to help people overcome the eating problems with dentures, enjoy what they eat, and indirectly improve healthier eating with dentures. These are:

# A patient leaflet with verbal explanation

Several participants in the current study reported that the leaflet is in expensive tool and an easiest way to give information on eating with dentures. Moreover, sitting with the patients, explaining the content of the leaflet, and showing them example of appropriate foods could increase the effectiveness of the leaflet.

"I think- X. If, if, if the patients have said that they would like a leaflet that seems like a really good indication that they would like a leaflet, and do a leaflet, you know what I mean? That sounds brilliant. I think it's, it's, economically it's, by a million ways, the, the easiest for us. And I imagine that would be very powerful because that's how I get the best results when I'm teaching people to clean, you know? But, you know, as I think about it that probably would be a good thing to have a, a, a selection of foods and go, and this, and show people, and, and how to with a, with a nurse there, you know, it would be, it would be good. 'Cause a leaflet, all of those things it's not the same as, quite, sitting and doing it with people.'' (P05, M, dentist).

"I think, I think the thing with a leaflet is it's good if somebody sits with you and goes through the leaflet. I think it'd mean more to people. Erm, I think that taking a nutritional leaflet to a patient user group of people who wear dentures and seeing them pick it apart and put things in there that are really relevant and make a really nice leaflet would be an amazing thing to do." (P06, F, dental hygienist).

Previous research has shown that giving coordinated dietary advice in form of pamphlets with verbal explanation for about 20 minutes with reference to other resources (e.g., food guide) for further information were effective in improving dietary intakes (e.g., fruit, vegetable, and protein) in edentulous individuals requiring new conventional complete dentures (Komagamine et al. 2016a). Data of the present study supported the existing literature and highlighted the importance of using a leaflet as a method of giving advice about eating with complete dentures.

Sitting with the patients, showing them examples of food items, explaining the content of the leaflet could be done by well trained and salaried dental nurses or dental hygienists. This was discussed by some participants in which there are many dental nurses and dental hygienists are happy to give eating advice and explain the leaflet content to the patients if they get training courses and enough time. In addition, some dentists seemed ready to do that as well if there is enough time.

"Erm, I think that, I think it would be a great thing for dental nurses and dental hygienists, I think they'd love to be involved in stuff like this. I don't know how realistic it is that practices would have, as X has said, the space and the time to allow people to. But I think they'd love to expand their role and take on something like that. (P06, F, dental hygienist).

"Just going my mind there was utilising it in practice and certainly utilising your dental nurse with things like that. I don't know because it's been a long time since I worked in general practice but there was certainly a growing trend for dental health educators working alongside the hygienist to take away the advice sort of things, and the show and tell sometimes. So that would be utilising the dental nurse in practice. I am sure there are plenty of nurses out there who would be happy to go through a short course, or something like that, for extended duties on anything, as long as you know you've got the correct information and direction at the time. (P10, F, dental nurse).

*"If there was some really nice information, a nice website or a nice leaflet, I would definitely utilise it."* (P09, M, dentist).

In contrast, other participants thought that there is no unique or specific leaflet, which can be applied to all denture wearers due to the tremendous effects of edentulism and prosthetic rehabilitation on the patient's life, particularly if the fact that some people do not like to get information in a leaflet format is taken in consideration. "I think it also, you're getting into learning styles. There are some people who love lists of instructions. I love reading, if I get a new bit of hifi or something I just love to read the instructions from cover to cover, my wife puts them straight in the bin and learns a different way. So I would respond to be given a leaflet on advice, my wife it would go in the bin. It's just so difficult though because there's such a huge spectrum of success with complete denture wearers that you could have a leaflet that standardised that rice, and we all know some patients can go out and eat anything others can eat nothing but they're prefect dentures, as X said. Most people are somewhere within the middle of that spectrum. But one of the problems you, we continually get is people coming and saying, "But I don't understand this, my sister can eat anything she wants." Enormous impact denture wearing can have. And that is the problem, there isn't a simple leaflet that will apply to everybody. (P01, M, dentist).

It could be argued that the leaflet was the format of the eating advice which was recommended by many participants in this study. Sitting with patients and explaining the content of the leaflet could support them and improve eating with dentures, particularly if the leaflet leads the patients into a link of a website, whereby they can get further information about eating with dentures, and do more interactive activities.

#### Web-based information

As internet nowadays is widely used for delivering health behaviour change interventions for older people (O'Brien et al. 2016), several participants discussed the possibility of having an internet forum where the denture wearers can post and get advice from their colleagues highlighting that this approach could be better than giving information by the dentists or the dental staff. Another suggestion was a website with a noticeboard, which might be useful way to put recipes and exchange information between the denture wearers; therefore, in addition to the leaflet, a website with more interactive features could be a good way to providing such eating advice. Such suggested solutions are in the line of many other studies (Cook et al. 2007; Revenäs et al. 2015), which reported the utilisation of the internet and web-based information as a tool in delivering health promotion interventions.

"I imagine the best place to get advice would be off others with that condition. And I don't know, I mean the, I think now the best would be something quite anonymous like an internet forum. Clearly not appropriate for the group, well not clearly, but possibly not appropriate for the group that we're looking at. But that kind of thing, reasonably anonymous where you can post and get advice from your colleagues would be much better than us giving them the advice. The only ideas I have that maybe haven't been said as, a website with a noticeboard which I think, I, the noticeboard might be the most useful way to put recipes and things like that, from denture wearers to denture wearers. (P05, M, dentist). "But as far as educational sort of styles or, or methods are concerned leaflets are one but there could be a website which might be another, just referring to a website. 'Cause some people like more interactive, erm, things, you know." (P06, F, dental hygienist).

The views above mentioned participants differ from the opinions of others, who seemed to have concerns or worries about the fact that most older people (e.g. 75 plus) are not 'tech savvy', particularly those, who are not worked in an 'office type environment'. This could make their involvement in such website is difficult.

"I think that as patients are getting older and older before they get to the point of being a denture wearer we still have a cohort of people that are not that tech savvy and they're not that tuned into using internet technologies. I'm talking probably of the 75 plus age group. The people in their 60s have probably had to had some sort of IT in their workplace, perhaps, or at least are aware of it. Whereas the people that we are looking at are 70 plus and are more likely to have medical problems, more likely to suffer from dementia, and all of these other issues, may not have access to or be very comfortable in using those sorts of forums." (P07, M, dentist).

"I agree with X. I think the technology is fantastic but I'm in my 50s and I will come across of my age group who are not tech savvy at all, depending on what sort of job they've had. They may not have worked in an office type environment or an environment where there was a lot of technology used, and that's a huge barrier. So I think it might be a while before those types of technology can be used. I think definitely in the future but not at the moment." (P10, F, dental nurse).

These findings seems to be incongruent with figures of Office for National Statistics (2016) in which there is an increasing in the level of internet use among British people, particularly those 75 years old and over.

Finally, although concerns about how a DCPs would get involved and would this leave them open to criticism because they will be so visible online were highlighted by some participants, it could be suggested that designers of such web-based information could use website's features in which all the information related to users identities be kept strictly confidential.

"It would also take a dental care professional who's very involved, willing to put their views on the internet and these sorts of things. I think there would be quite a few people who would be a little apprehensive about that, and opening yourself up to attack. It's a bit of a daunting thing to do." (P09, M, dentist).

It could be argued that using website is a good idea to provide advice on eating with dentures in this digital age, where everyone turns to the web for information and keep up to date. Such concept could be effective in improving eating with dentures, and utilised by the denture wearers, if we take in consideration the growing trend of using internet among people aged 75 and over in the UK. This website could incorporate a web-based dietary behaviour change intervention.

# **Holding support groups**

The idea of holding support groups in which denture wearing champions might be able to give advice to the other denture wearers with eating difficulties, was suggested by one participant and supported by some participants in these focus groups.

"And the other, the other idea I have is maybe, erm, like denture wearing champions who wear dentures, they've lived through it and they might be able to have an advice you could call, have an advice line or could give advice. Some- someone who wears them and, and is supportive of other people. 'Cause I know that works incredibly well with other, erm, disabilities if you have, it's usually a really good support to people who, say, have lost a limb is other people who've lost a limb who, you know, who, who give them support in the early days. And we, that just as an idea could be something we could do with denture wearers, you know. (P05, M, dentist).

Similarly, given their experience in oncology, some participants exemplified the relationship between survivability rate and social supports.

"But X idea of getting them into support groups, I mean that's worked really well in oncology. They- They've found that survivability in oncology's big factor of patients feeling good support." (P01, M, dentist).

In contrast, several participants, however, indicated that people might not be comfortable to take part in the support groups or embarrassed to speak about the impact of dentures in front of strangers due to the fact that they have dentures, have to take dentures out, talk about dentures and be seen without their teeth.

"I think that would have to be a very particular kind of patient, first of all, to volunteer the fact that they're a denture wearer. There are quite a few patients who are very embarrassed about the fact that they have dentures, have to take dentures out, talk about dentures and be seen without their teeth. I think that would reach quite a small group of patients. I don't know how many patients would be willing to come onto a focus group. Admitting that they were denture wearers, with the risk of having to show themselves without teeth, there would be one or two patients but I think that would be difficult." (P08, M, dentist).

"I agree. Even in one to one consultations with denture wearers they will be covering their mouth if their dentures are not in place and they wouldn't be willing to smile, they wouldn't be willing to talk. That's just on a one to one basis let alone talk about how that impacts on their lives with a group of strangers." (P07, M, dentist).

*'I agree. So many patients would just not be seen without their dentures.''* (P10, F, dental nurse).

Some mentioned that the number of participants in these support groups might be limited in comparison with behaviour health interventions, which could reach a large number of people. This is illustrated in the below quotes:

'I think you're also talking about really small numbers here. So it's not an intervention that's going to affect a lot of people. It's going to be a very small group. '' (P09, M, dentist).

"I think it would be a very self-selective group." (P07, M, dentist).

Literature suggests that health behaviour intervention should be scalable in which to increase the effectiveness of the intervention, it has to reach large proportion in the population (O'Brien et al. 2016). Participants in the present study discussed this issue and concluded that the number of people, who might participate in these support groups, could be small; consequently, this could reduce the effectiveness of these sessions or forums. It could be concluded that despite of its potential role in enhancing social support and feeling of confidence among people, using face-to-face support groups are unlikely to be appropriate approaches for particular people, who do not like to speak in front of other foreign people about sensitive issues around eating with dentures. Therefore, designing a website that incorporates online forums could be beneficial for denture wearers.

# 6.6 Summary of the main findings

# 6.6.1 Patient's data

The main findings of these focus groups can be summarised into several key points:

- Patients described an experience of no eating advice, particularly healthier advice received from dentists or dental staff.
- Although some patients believed that they are more experienced than the dentists in terms of how they can cope or with the denture, others liked the idea of receiving information pertaining eating with complete dentures.
- Most patients thought that information might be useful in a leaflet format (with a link to website for further information) and could prompt a discussion between themselves and dentists or DCPs.
- Most patients believed that having a denture with good fit and stability is a key factor in overcoming functional difficulties and improving eating particular tough or sticky foods. Therefore, they were often using denture fixatives before eating a meal.

# 6.6.2 Dentists and DCPs data

The main findings of these focus groups can be summarised into several key points:

- Dentists and DCPs reported that advice given was mainly general and functional indicating that they were adjusting the dentures rather than adjusting the diet of the denture wearers.
- Specific eating and in some instances, healthier eating advice were given by the dental staff to specific groups of patients (e.g., patients with oral defects in maxillofacial and Oncology departments).
- A similar eating advice was given (if requested) to some denture wearers, who suffered from eating-related problems.
- Most dentists and DCPs felt that they were not prepared or trained enough to give advice, particularly healthier eating advice. They felt that the most useful advice would probably come from the denture wearers themselves.
- Lack of time and incentives were other reasons for not giving advice on eating with dentures indicating that the current NHS contract for relevant dental health providers needs to be modified.
- Not dissimilar from the patient's findings, the dentists and DCPs reported that a patient leaflet and a website are the most appropriate methods of providing advice on eating with dentures.
- Dentists and DCPs highlighted the importance of denture fit and stability for proper eating with dentures.

# 6.7 Strengths and limitations of the qualitative study

This study had some strengths and weaknesses in terms of the study design, methodology adopted, and sampling technique. It is the first qualitative study conducted in the UK with regard to advice on eating with complete dentures. In this study, the researcher's epistemological stance is interpretivism in which the researcher belief in multiple realities (each individual has own 'unique experience'), and he has to explore the social world through the participants' perspective. His ontological position is subtle realism in which he accepts the existence or truth of outside reality (e.g., patient's reality) independent to his perception, but since he is a clinician and researcher (has a considerable knowledge about the topic under study), he realises that he cannot completely isolate himself from the social world studying it during interpretation of the data.

Despite the existence of different methods of data collection in qualitative healthcare research, in this study, focus groups method was chosen because we were looking for accessing the interpretations and arguments of the participants in group situations. The aim was to obtain in-depth information from participants about the kinds of eating advice likely to be useful to the denture wearers. The intention was to gather a wide range of views of those who are involved in the provision of dentures, aftercare for dentures and from users of dentures to inform proposed health promotion materials (eating advice and intervention) for the intended audiences or users (denture wearers). In other words, focus groups were conducted as a complementary method alongside the co-design or development method (see chapter seven) to inform developing more structured patient-centric eating advice and intervention. Focus groups were adopted as a method to collect the data. This type of data collection method allowed the researcher to gain a breadth of information from the participants about the studied subject. Interaction between participants is the unique feature of this method of qualitative data collection (Kitzinger 1994). Such interaction between participants informed the selection of the most potential strategies, which could help people overcome the eating problems with dentures, enjoy what they eat, and indirectly improve healthier eating with dentures. Using focus groups allowed the participants to generate ideas and solutions about eating with complete dentures. These can be useful in designing and developing intervention. Other data collection methods seemed inappropriate for the purposes of data collection. However, by using focus groups approach, it was difficult for the moderator and assistant moderator to obtain in-depth information as in one-to-one interview, which is often used for the purpose of obtaining in-depth details about the studied subject (Fitzpatrick and Boulton 1994). Sometimes, the group discussion seemed to get side-tracked producing irrelevant data, and this was not avoidable. Moreover, it was noticed that one predominant participant dominated one of the group discussion. This was not the case with other focus groups. Low response rate of denture wearers to participate in these focus groups was another limitation of this study. The majority of denture wearers, who agreed to take part in the cohort study and completed the questionnaires did not like the idea of participating in the group discussions for different reasons, mainly time and they did not like to speak in front of other people. This made the process of allocating participants difficult due to limited resources and time scale of this project.

This study used combination of techniques to analyse the data. For example, certain criteria by (Green and Thorogood 2009) were implemented during data analysis to increase rigour in the analysis of the data. Moreover, based on principles of constant comparative analysis used collect and analysis of the data was done at the same time until data saturation reached. Furthermore, Framework analysis by Ritchie and Spencer (1994) adopted to analyse the data of this study. This approach was chosen because it includes a number of distinct and highly interconnected key stages, which makes the analysis process simple, systematic and rigorous (Ward et al. 2013). It also makes the process of comparison of both within-case and between-cases much easier (Ritchie et al. 2003). One of the most distinctive aspect of this framework analysis is that it allows themes to emerge from the research questions; as well as, from the participants' comments (Rabiee 2004; Ritchie et al. 2013). This framework has been successfully used to analyse data generated by both; one to one interviews (Al-Baghdadi 2015), and focus groups (Holmes et al. 2008). However, utilising combination of analysis methods was not stress-free process, particularly for analysing data from focus groups.

In this study, a purposive non-probabilistic sampling was used in order to gain a depth and breadth of perspectives from denture wearers, dentists and DCPs, who might be expected to have differing experiences and opinions to understand the studied phenomenon (advice on eating with complete dentures). Dentists and DCPs were known for their ability to respectfully share their opinions. This was recognised through preliminary fieldwork with them in the Dental Hospital during patient's recruitment for the cohort study. Although homogeneity of participants in focus groups is important and more likely to help open discussion (Sim 1998), mixed groups were conducted to ensure a breadth of data collection. Nevertheless, as this is a qualitative study, the analysed findings might represented only the participants' perceptions and views about advice on eating with complete dentures, and not necessarily be generalizable for the whole community of complete denture wearers.

#### 6.8 Conclusions

These four focus groups have provided a view of how dentists and DCPs in addition to the denture wearers conceptualise advice on eating with dentures, and the debate surrounding this advice. They have also provided an insight about healthy eating advice, the barriers or reasons for not providing such eating advice, and some potential methods or strategies for providing advice on eating with dentures, which could improve ERQoL and indirectly promote healthier

eating. Peer delivered advice might be useful especially in a leaflet format with a link to website, where people can share information. The detailed information derived from these qualitative interviews might be useful in the future to inform an appropriate eating advice or dietary intervention for the denture wearers. Holding these focus groups was a part of ongoing project to inform development of eating advice and intervention to support the dental health providers and help denture wearers eating well with dentures. The next chapter discusses how the co-design team worked together to produce a person-based or patient-based eating advice and inform intervention development for the denture wearers.

# Chapter 7. Co-development of A prototype for Patient-Centred Dietary Advice

# 7.1 Introduction

Edentulism and subsequent rehabilitation with complete dentures is a major issue in the life of people, and associated with eating problems or difficulties (Bradbury et al. 2008; Furuta et al. 2013). Several studies have shown that eating with dentures has a negative impact on the life of denture wearers from an emotional and social perspectives (Hyland et al. 2009; Moynihan et al. 2009). Loss of enjoyment during eating with dentures, self-consciousness or embarrassment, and loss of social interaction with others are common eating related problems recognised among denture wearers. Such eating difficulties could put those people in a real predicament, which could indirectly result in adopting less healthy eating style. For example, wearing complete dentures could lead to a difficulty in eating some hard or tough fruits and vegetables (e.g., apples, carrots ... etc.), which comprise part of a healthy Mediterranean diet. Adopting a Mediterranean dietary pattern is beneficial, particularly for older people (Sofi et al. 2010b; Lee et al. 2012); however, achieving and maintaining a healthy eating style is not easy, and could require implementing dietary behaviour change intervention. Few tailored dietary behaviour change intervention studies have been delivered to edentulous patients (Bradbury 2002; Bradbury et al. 2006b; El-Feky 2007; Moynihan et al. 2012). However, most of them were designed with minimal input from target end users (patient-centred dietary behaviour change intervention). Robert et al. (2015) argued that "Patients provide insight, wisdom, and ideas, and we urgently need to include them more creatively as partners in change." Likewise, applying contemporary approaches for designing products or services is now an emerging and rapidly growing field in most developed countries (Bate and Robert 2006; Donetto et al. 2015). Similarly, involving users (e.g., patients and their families) in improving health care services has evolved from what so called passive role or involvement towards a partnership approach in which user's experiences are considered as an integral part of services improvement (Bate and Robert 2006). This could be done through using various methods such qualitative studies, surveys and other co-design techniques (e.g., modelling and prototyping, storytelling, group discussions, workshop, and online feedback). The literature shows many studies through which patient-centred services have been improved based on codesign methods in which patients and staff were working together (Rozenblum et al. 2012;

Lord and Gale 2014). Recently, Yardley et al. (2015) emphasised the importance of digital person-based approach in designing eHealth interventions and increasing their effectiveness. They argued that using the term person-based is more generic than patient-based because it involves exploring the opinions of both users and non-users. Such change in the methods of conducting research is probably influenced and enhanced by various factors such as the willingness of health organisations to improve health services in the line of patient experience and the rapidly growing service design, in addition to the feasibility of getting immediate feedback from patients by means of the internet and other social networking technologies (Bate and Robert 2007). Therefore, it is likely that involving patients as co-designers of patient-centred materials (e.g., eating advice or intervention) could help define the studied phenomenon (the impact of wearing complete dentures on ERQoL), highlight problems associated with it (e.g., eating related difficulties), and identify preferred solutions (e.g., eating advice or intervention). Despite many methods or approaches, which have been used to design health interventions, the current study used a systematic and sequential approach based on techniques of co-design to develop a prototype of patient-centred eating advice or intervention for denture wearers. This approach or co-development was based on the codesign technique used by O'Brien et al. (2016), which is specifically designed to boost a healthier lifestyle among people at retirement stage. No such co-design or development has been applied to design eating advice or intervention for complete denture wearers, and no previous studies involving denture wearers in the development of web-based intervention to help them enjoy eating and eating well with dentures were identified. This chapter discusses how the researcher and the research team worked with patients (i.e., denture wearers), and dental professionals (i.e., some dental students, dentists and DCPs) to produce a patientcentred eating advice on eating for denture wearers, that aimed to help edentulous people enhancing social and emotional perspectives of denture wearing and eat well with dentures.

# 7.2 Aims and objectives:

#### 7.2.1 Aim

To produce a prototype of patient-centred eating advice (i.e., patient leaflet) and inform intervention development for complete denture wearers.

# 7.2.2 Objective

To use an iterative co-design or co-development process to integrate scientific evidence from the literature, focus groups with service users (i.e., denture wearers, dentists and DCP) and a cohort study, in addition to working together with stakeholders to develop eating advice and intervention for denture wearers.

# 7.3 Methods and results

#### 7.3.1 Overview of methods employed and outcomes derived

In the current study, the method previously described by O'Brien et al. (2016) was employed (See chapter 2, section 2.4.14). This systematic, sequential and iterative co-design procedure entailed consecutive validation of evidence pertaining to eating with dentures, generation of new ideas on eating advice or intervention, visual displaying, analysing, reviewing and prioritising of core concepts of the intervention. The procedure was implemented by five consecutive stages or phases; each one had its own method and outcome (Figure 7.1). Outcomes from all stages of this process were used to inform the design of the eating advice or intervention. Results of each stage determined the methods for the next; therefore, this section is a combined methods and results. The following sections describe the five sequential stages of eating advice or intervention development.





Figure 7.1: Stages of co-design for producing of a patient leaflet on eating with complete dentures and developing a prototype of eating advice or intervention.
### **Stage 1 Procedure**

The aim of this phase was to collect evidence pertaining eating with complete dentures including the broader evidence base for effective BCTs applied in dietary advice or interventions. The researcher (HA) gathered the evidence from the literature review (including systematic reviews, meta-analysis and meta-regression, qualitative research (i.e., focus groups with denture wearers and DCPs), and a semi-quantitative and qualitative study (i.e., Cohort study on edentulous patients requiring denture replacement). Some electronic database such as Medline, Web of Science, Scopus and Google Scholar were searched to compile evidence pertaining to the impact of edentulism and subsequent rehabilitation with complete dentures on enjoyment of eating with dentures and eating-relating socialising (Hyland et al. 2009; Kelly et al. 2012). Moreover, information about the effective behaviour change techniques (which could be used in dietary behaviour change advice or interventions) were gathered from systematic reviews, meta-analysis and meta-regression (Michie et al. 2009; Michie et al. 2011c; Lara et al. 2014a). Furthermore, a series of focus groups with patients, dentists and DCPs were conducted to explore their experience and opinions about advice on eating with complete dentures. Finally, a cohort study on edentulous patients requiring denture replacement was conducted to measure the effect of optimizing dentures on ERQoL. The integrated evidence was based on dentists and DCPs' expertise, patient need and preference and scientific evidence illustrated in (Table 7.1).

# **Evidence base**

- Research found that edentulism and subsequent rehabilitation with complete dentures impacted negatively on enjoyment of eating with dentures and eating-relating socialising (Hyland et al. 2009; Kelly et al. 2012).
- Studies found that edentulism and subsequent rehabilitation with prosthodontic treatments (e.g., conventional complete dentures) have an a negative impact on functional aspect (e.g., chewing ability) of some foods (e.g., hard or tough foods such as apples, steak, nuts and seeds, chewy foods etc.), and this subsequently reduce food and nutrient intakes among denture wearers (Johansson et al. 1994; Joshipura et al. 1996; Sheiham et al. 1999; Lee et al. 2004; Bradbury et al. 2008).
- Research showed that implementation of dietary behaviour change interventions help in improving healthy diet among denture wearers (Bradbury et al. 2006b; Ellis et al. 2010; Moynihan et al. 2012).
- According to PHE guidance in 2014 (Delivering better oral health: an evidencebased toolkit for prevention), and NICE guideline in 2015 (Oral health promotion: general dental practice), the role of the dental team in supporting patients to change health behaviour is important. For example, the dentist may give very brief advice (and ensure this is written in the patient's notes). Dental therapists, health educators or dental nurses may undertake brief interventions and/or signposting to local services. Such guidance also advocate to ensure that training is available for the dental team to support patients to consider behaviour change and that dental team members access this training. However, no training courses about advice on eating with dentures are available on these guidance.
- Systematic reviews, meta-analysis and meta-regression (Michie et al. 2009; Michie et al. 2011c; Bhattarai et al. 2013; Lara et al. 2014a; Prestwich et al. 2014a) found that BCTs: 'follow-up prompts'; 'goal review'; 'self-monitoring'; 'goal setting behaviour and outcome'; 'action planning'; 'barrier identification/problem solving', and stress management/emotional control training') were possibly associated with increase effectiveness of dietary behaviour change intervention, possibly through enhancing self-efficacy.
- Qualitative research (focus groups) indicated that a patient leaflet linked to a website is the best way of delivering advice or intervention on eating with complete dentures.

• The cohort study (semi-quantitative and qualitative study) indicated the importance of delivering dietary advice or intervention to help denture wearers, particularly those with eating-related difficulties, eat well with dentures.

# Table 7.1: evidence base collected in Stage 1.

# Stage 1 analysis

After compiling data from the four core areas defined above, the evidence was summarized by the research student and reviewed by the research team (PM and JF). After discussions, the research team distilled the evidence into a list of "Evidence Statements" (NICE 2016b) to be used as an input of the next stage (Stage 2; a research team meeting).

# Stage 1 outcomes

The outcomes of this stage was a list of 'Evidence Statements' pertaining to eating with complete dentures (Table 7.2).

# **Evidence Statements**

- Wearing dentures leads to loss of enjoyment of eating. (Current cohort research, patient's focus groups, literature).
- Wearing dentures has a negative impact on eating-relating socialising. (Current cohort research, patient's focus groups, literature).
- Denture wearers consume a less healthy diet (with respect to fruits and vegetables, fibre, and macronutrients). (Current cohort research and literature).
- Optimising dentures/ replacing dentures improves Eating Related quality of Life (ERQoL). (Current cohort research).
- Dentists adjust the denture rather than adjusting the diet to overcome problems with eating. (Current cohort research, focus groups with patients, dentists and DCPs, literature).
- Patients received no advice on what they can realistically expect (with regard to ability to eat) following the provision of dentures. (Patient's focus groups).
- PHE and NICE stated that dentists and DCPs should support patients to change dietary behaviour; however, dentists and DCPs feel they have not had adequate training with respect to this. (Dentists and DCPs focus groups and literature).

- Lack of personal experience of wearing dentures underpins dentists and DCPs' reluctance to provide eating advice. (Dentists and DCPs focus groups, literature).
- Patients thought that dentists were not a credible source of information as they did not have first-hand experience of eating with dentures. (Patients' focus groups).
- Some evidence shows delivering advice in dental practice improves the diet of denture wearers. (Literature).
- Web-based eating advice or intervention is appropriate for use with older people (Dentists and DCPs focus groups, patient's focus groups, and literature).
- Promoting self-efficacy and using appropriate BCTs (e.g., goal setting behaviour and outcome, goal review, follow-up prompts, action planning, self-monitoring, barrier identification) increase the effectiveness of intervention for dentures wearers. (Literature).

# Table 7.2: Evidence Statements pertaining to eating with complete dentures.

# 7.3.3 Stage 2. A research team meeting

# **Stage 2. Procedure and analysis**

The aim of this stage was to develop ideas or concepts underpinning eating advice or intervention for complete denture wearers. Based on the previously described 'Evidence Statements', the research student drafted several ideas or concepts for developing eating advice or intervention. These ideas were critically discussed and redrafted by the research team (PM, JF and HA) in a team meeting, which last about 3 hours. During this meeting, the team devised a final version of eight concepts support eating advice or intervention.

# **Stage 2 Outcomes**

The research team called these concepts as 'Opportunities for Development' of eating advice or intervention for complete denture wearers (Table 7.3), which were the outcomes of this stage. These Opportunities for Development, in addition to the 'Evidence Statements' underpinned and provided formative principles and content of the next stage (Stage 3: Engagement through visual display with dental health professionals).

# **Opportunities for Development**

- Develop eating advice for denture wearers, that focuses on overcoming functional problems with eating (as indirect opportunity to provide healthier eating advice).
- PHE to include eating advice for denture wearers in delivering of better oral health toolkit.
- Include information on eating with dentures and providing dietary advice to patients in the dentists and DCPs undergraduate training curriculum.
- Develop an online support group/blog for denture wearers relating to eating better with dentures.
- Create videos on eating coping strategies to show in the Prosthodontics waiting room (capture those who are having most eating difficulty). This could be provided online as well.
- Produce a patient leaflet on eating with dentures.
- Develop a website or web-based information (to include a web-based intervention, online support group/blog, video, and the leaflet) in addition to recipes and healthier eating information.
- Develop Continuing Professional Development (CPD) courses on the subject for the dentists and DCPs.

# Table 7.3: Opportunities for Development of eating advice or intervention.

# 7.3.4 Stage 3: Engagement with dental health professionals through visual display

# **Stage 3 Participants**

The next phase was to elicit feedback and validate the Evidence Statements and Opportunities for Development with the dental health professionals. Participants in this stage were delegates at the Restorative Dentistry (RD-UK) and Specialty Registrar Restorative Dentistry Groups (SRRDG) annual conference 2016, which took place in a public place (Baltic building, Newcastle upon Tyne, UK). Dentists (either primary care dentists or specialists/consultants) and DCPs regularly attend this conference. Therefore, all conference participants were invited to engage in this stage by mentioning the main aims of this engagement phase during the welcome sessions of the conference and inviting delegates to visit a visual display of the work to provide their input. A flyer (including the chance to win a prize in a prize draw as an incentive) was included in the conference packs to encourage the delegates to visit the exhibition area (Figure 7.2). The aim was to engage a diversity of dental health professionals. Although it was not expected to find dental students in this conference, some under-graduate dental students (n=4) found this activity interesting, and participated in this engagement phase. The target number of participants for this engagement phase was 30 (primary care dentists or specialists/consultants, and DCPs, in addition to some under-graduate dental students).

# Do your patients eat well with dentures?

# Exhibition

We want your views. We are doing some research into eating with dentures as we want to help denture wearers to be able to enjoy what they eat and eat more healthily.

Come and visit our exhibition for the chance to win a £50 Amazon voucher.



On behalf of the research team: Hassan F. F. Al-Sultani PhD student Em ail: h.f.f.al-sultani@ncl.ac.uk Mobile: 07448134971



Figure 7.2: A flyer distributed to the delegates in the engagement phase.

# **Stage 3 Procedure**

In this engagement phase, the researcher (HA) interacted with dental professionals using verbal explanation and visual display as a mode of communication to communicate the defined Evidence Statements and Opportunities for Development, with the aim of validating them by eliciting feedback and exploring new (innovative) ideas that may have been missed (in Stages 1 and 2). The researcher displayed two posters during the two days of the conference. The first poster included the Evidence Statements (Figure 7.3), while the second poster involved the Opportunities for Development (Figure 7.4). Participants were provided with different coloured postcards, (Table 7.4) to comment on. These coloured postcards were designed to collect feedback related to the different displayed Opportunities for Development in addition to the Evidence Statements. An example post card is provided in (Figure 7.5), (see (Appendix K) about different types of postcards).



Figure 7.3: Visual displying of the Evidence Statements.



Figure 7.4: Visual displaying of the Opportunists for development.

•	Your thoughts and suggestions about eating advice that focuses on overcoming
	functional problems (pink colour).
•	Your thoughts and suggestions about the role of the PHE in providing guidance or
	toolkit on eating with dentures (light green colour).
•	Your thoughts and suggestions about integrating eating advice into the
	undergraduate curriculum (dark green colour).
•	Your thoughts and suggestions about the use of online support groups/blogs (red
	colour).
•	Your thoughts and suggestions about displaying a video on coping strategies in the
	waiting room and online (dark brown colour).
•	Your thoughts and suggestions about providing a patient leaflet on eating with
	dentures (blue colour).
•	Your thoughts and suggestions about a website or web-based intervention includin
	recipes and healthy eating information (light brown colour).
•	Your thoughts and suggestions about improving or enriching CPD for the dental
	team relating to eating with dentures (orange colour).
•	Your comments about the Evidence statements (grey colour).



Figure 7.5: An example of a post-card provided to the participants in the engagement phase.

# **Stage 3 Analysis**

Shortly after this phase, the researcher recorded all notes reported by participants during the verbal explanation and discussion, focusing on the main ideas discussed with them. Feedback or comments on the postcards from participants were summarised by the research student and critically analysed and discussed with the research team to explore new emergent ideas or themes. Analysing the results of this phase enabled fine-tuning of the Opportunities for Development and informed the forthcoming prioritisation stage (to determine which elements to develop further as part of this PhD).

# **Stage 3 Outcomes**

Feedback (in form of oral explanation and comments on postcards) about the Evidence Statements and Opportunities for Development from the participants were outcomes of this engagement phase or exhibition. Few comments were obtained concerning the evidence statements because most participants thought that this evidence was acceptable. Table 7.5 illustrates the feedback on Opportunities for Development from Engagement phase. This feedback provided the content of the next stage (stage 4: prioritisation exercise).

<b>Opportunities for</b>	Feedback or comment
Development	
Eating advice for denture	Tailoring of the dietary intervention: Whenever possible
wearers should focus on	advice should be tailored to specific issues rather than
overcoming functional	general information, so a range of information on specific
problems with eating (as	problems which clinicians and their patients can select on
indirect opportunity to	the basis of individual need could be provided.
provide healthier eating	Focusing on coping strategies: this is very important,
advice).	particularly for compromised patients; for example, using
	Cognitive Behavioural Therapy (CBT) as a talking therapy
	to change the behaviour.
	Focusing on the psychological component of advice: It is
	most important in denture wearers because if the patient
	has the willing to accept the advice, he can change his
	eating behaviour even with poorly fitting dentures.
	Changing the way of eating: Suggesting ideal foods that
	patients can eat adequately other than soft diet by applying
	'example of diet plans' to help the patients eat better.
PHE should consider	Delivering better oral health toolkit is used by so many
providing eating advice for	undergrads and recently grads, so it is potentially the best
denture wearers in delivering	method to make a change in the clinical practice.
of better oral health toolkit.	Expanding the expected toolkit to include information on
	eating with dentures; as well as, information on behaviour
	change because current guidelines such as these produced
	by PHE are largely an academic exercise that is far
	removed from behaviour change.
Dentists and DCPs	It is useful and essential for dental students to learn about
undergraduate training	giving diet advice (tailored to denture wearers), which
curriculum should provide	helps them improve the acceptance of complete dentures.
information on eating with	The dental undergraduate students described that "we have
dentures and providing	got advice on healthy eating and diet recommendation but
dietary advice to patients.	not specific to denture wearers, and as most undergrads
	will not wear dentures, we have little information or

	knowledge on what is difficult/easy to eat".
	It should be placed in the context of psychological models
	of communication and behaviour change.
	It should be integrated as a part of diet and nutrition
	module.
	Students can learn directly from the patients about their
	experiences in the dental clinic.
	Expert patients could be involved in talking to the students
	about their experience in support or focus groups.
	Holding seminars to practice giving advice and to learn
	how to tailor the advice to certain patients.
	Integrate it with denture delivering appointment.
	Managing patient expectations when giving denture as a
	treatment option.
Online support group/blog for	Some participants supported this idea because they believe
denture wearers relating to	that internet now is a good way to exchange the
eating better with dentures.	information and more access to the information (e.g.,
	information on eating with dentures) will eventually be
	beneficial. These support groups/blogs are also important
	for enhancing social support and feeling of confidence.
	However, one should pay carful note as they:
	• Are not suitable for everyone (e.g., those people
	who have no access to the internet or not interested
	in the use of technology). There is a risk of missing
	out the less 'inherent savvy' older patients, who are
	more likely to wear complete dentures.
	• May not change behaviour.
	They should be done in conjunction with other more
	traditional sources of information (e.g., leaflets).
	Should be a tailored service.
	Should be piloted (test the functionality and usability) to
	see its use/implementation.
Video on eating coping	Participants considered this as a good idea or tool for

strategies in Prosthodontics	increasing knowledge, particularly for some people, who
waiting room (capture those	may be too embarrassed to ask for help/advice when they
who are having most eating	are having eating problems.
difficulty). This could be	Some participants mentioned that video presentations on
online as well.	their own way may not change the behaviour and could
	make some of the patients anxious while they are waiting.
	Video presentations should address behaviour using 'the
	behaviour system' COM-B; Capability (how to cope),
	Opportunity (how best to plan to implement the coping
	strategies), and Motivation (the benefit of making the
	change).
	Using short, sharp and effective videos, and probably
	based on real patient stories.
	It could be run along an education event.
	If posted online, the link should be placed on a leaflet
	given to all patients, who receive new dentures.
A patient leaflet on eating	Most participants agreed that a patient leaflet is a good
with dentures.	way to provide information on eating with dentures for
	patients to absorb and digest the information at their own
	pace.
	Some of them mentioned that leaflets alone are poor
	methods for creating behaviour change. They can increase
	knowledge but no effect on behaviour.
	Combining the information in the leaflet with pictures in
	order to become more effective.
	Keeping it as short as possible.
	The dental team can talk through it with the patients and it
	should include a link to appropriate online forum/ website
	as advice coming from peers/ other denture wearers.
	The leaflet should not be an industry sponsored.
	Could be available in few different languages.
	Should include healthy nutritional tips.
Web-based intervention (to	It was highlighted as a very good idea by all participants

include online support	because they think that it is important in this digital age,
group/blog, video, and the	where everyone turns to the web for information and keep
leaflet) in addition to recipes	up to date.
and healthier eating	It would allow progressive development of additional
information.	information. However, some of them had concerns about if
	some of older people may not have an access to the
	internet.
	Should address behaviour change by using 'the behaviour
	system' COM-B; Capability (how to create healthy eating
	recipes), Opportunity (how best to plan to implement the
	change), and Motivation (benefits of making the change).
	Should be correctly tailored.
	Recipes should address vegetarians/ vegans special dietary
	requirements.
	It may include testimonials from the patients on how
	improving their diet improved their health and eating
	related quality of life.
	Collaboration with other organisations, which can help
	older people to easily access the internet.
	It is preferable for these web-based interventions to be
	accessible by wide range of people such as dietetics, care
	home managers, or perhaps community support nursing or
	carers.
CPD courses on the subject	Most participants mentioned that this is a good idea to
for the dentists and DCPs	keep all members of the dental team are up to date with
	current knowledge, resources and guidelines.
	This idea needs to be aligned with training in
	communication and behaviour change. In addition, need
	systems change to support/remunerate such behaviour.
	It needs to be integrated with other preventive and dietary
	advice in general.

 Table 7.5: Feedback on the Opportunities for Development from the Engagement Phase.

#### **Stage 4. Procedure and analysis**

The aim of this stage was to review feedback on Opportunities for Development obtained in the engagement phase and to use this to prioritise Core Concepts to take forward to the development phase. This stage involved holding a research team meeting to review data and prioritise the Core Concepts, which were drafted by the researcher based on the outcomes of the previous stages. The research team discussed and critically assessed the Core Concepts for consensus with the feedback received in phase 3. The team, also, considered the importance of these Core Concepts based on the practicalities of taking the concept forward as part of this PhD. Based on all these things, the team prioritised two Core Concepts: a patient leaflet and a linked website. Although some initial ideas for the website specification were drafted, during the timescale of this PhD, the idea was not taken forward to the development within the scope of this PhD study. Following the prioritisation exercise, it was decided to focus on developing the patient leaflet, but to do this a view to linking it to a website in the future.

# **Stage 4 Outcomes**

The outcome of this stage was defining list of Core Concepts for future development of dietary intervention (Table 7.6), which were developed to identify the concepts to take forward in this PhD. The prioritisation exercise identified the patient leaflet and website (interlinked) as a first priority. A mock up example of the potential website including some initial ideas for the website specification was drafted (Appendix L). This mock up examples or prototype could guide the building of a functioning web-based intervention or website on eating with complete dentures in the future. However, within the scope of the PhD study, it was difficult to continue developing the website, so the research team decided to focus on the leaflet with the view that the concepts developed in the leaflet would guide and underpin the content of a future website.

# **Core Concepts**

- > Producing a patient leaflet on eating with complete denture.
- > Developing a website or a web-based intervention on eating with complete denture.
- Including information on eating with dentures and providing dietary advice to patients in the undergraduate training curriculum of the dentists and the DCPs.
- Developing CPD training courses concerning advice on eating with complete denture for dental health providers.
- > Including advice on eating with denture in PHE toolkit.
- Developing online support group/blog for denture wearers relating to eating better with dentures.
- Developing videos on eating coping strategies to be displayed in the Prosthodontics waiting room.

# Table 7.6: The Core Concepts.

Patient leaflet selected as first priority and hand-drawn prototype of the content of the patient leaflet on eating with complete dentures was drafted (Table 7.7). The qualitative work indicated that a patient leaflet could be the most deliverable and appropriate format of providing advice to overcome functional problems associated with eating with complete dentures due to its relatively low cost. During the engagement phase, the dental health professionals supported this idea as a way of improving the knowledge of the denture wearers concerning eating with complete denture. This leaflet focused on the practical and function issues with eating faced by the denture wearers. It was based on patient's experience and linked to five eating-related problems (i.e.: I am having problems with biting and chewing foods; I am finding that foods stick to my dentures; My dentures move when I bite foods; It is painful when I eat with my dentures; and I find foods gets trapped underneath my dentures). As some dental health professionals in the engagement phase suggested that the patient leaflet should include healthy nutritional tips, the research team decided to build in the healthier eating messages by stealth. For example, adding many vegetables to the stew and slicing fruits will make them softer to eat. It could be argued that providing such advice could resolve the problem of chewing difficulty and increase intake of healthy foods (i.e., vegetables and fruits). The first draft of the patient leaflet informed the content of the next stage (Stage 5: Professional design of the leaflet).

# I am having problems with biting and chewing foods

# Tips I could try:

- In the beginning, you may find a difficulty in biting or chewing hard or tough foods; for example, meat, vegetables, and fruits, so when you eat such foods, eat them in different way (e.g., slice them, peel them or use smoothie etc.). Care should be taken not to chop the foods into very tiny pieces in order to avoid the possibility of choking.
- To make it easier to eat meat, try stewing or slow cooking it so it is more tender and soft.
- Try adding many vegetables to your stew as this will make them softer to eat.
- If you have soup, try dipping whole meal bread in it to soften the bread.
- You could also try replacing tougher red meats with other protein sources such as fish, chicken, eggs and legumes (pea, beans and lentils).
- If you are having problems eating hard cheese, you could try grating it or swapping it with a soft cheese.

# I am finding that foods stick to my dentures

# Tips I could try:

- Try eating whole grain bread instead of white bread because it is less sticky.
- Prepare your favourite sticky foods in a different way (e.g., put dates in a smoothie).
- Try toasting and baking bread slightly before eating or making a sandwich, as it will be less likely to stick to pallets.
- Toast toppings such as scrambled eggs may help to make the bread softer and easy to chew.
- If you have problems eating lettuce and leaves as these tend to stick to your palates, try shredded carrot or cabbage or slice peppers, cucumbers and tomatoes (with pulp and seeds removed).

# My dentures move when I bite foods

# Tips I could try:

- Try to balance the food evenly in your mouth when you chew so your dentures are more secure when you are eating.
- Try taking small mouthfuls, chewing more slowly on back teeth and try to avoid

biting down with your front teeth.

- Try using denture fixatives before eating.
- Some practical tips to apply denture fixatives suggested by the participants (denture wearers) in the focus groups:
  - ✓ Before putting fixative, ensure your mouth is dry by using a clean towel. So it is completely dry or as dry as possible.
  - ✓ *Put only a small amount of fixative on your dentures.*
  - ✓ *Take the towel out and straight away wear your dentures.*
  - ✓ Wait for 5 to 10 minutes for them to settle down, then brush your teeth to remove excess materials.
  - ✓ Enjoy your foods.

# It is painful when I eat with my dentures

# **Tips I could try:**

- Try to preserve, as things should settle down in a couple of weeks.
- If they do not settle down or you have sore patches, visit your dentist to get your denture adjusted.
- In the meantime, try to eat softer foods (e.g., soup, stewed meat, puree veg, porridge, milk puddings, milky drinks, smoothies, minced meat, and stewed fruits).

# I find foods gets trapped underneath my dentures

# **Tips I could try:**

- Try removing seeds from foods before eating them (e.g., buy seedless grapes, remove pulp from tomatoes, and avoid seeded breads).
- Some patients find using denture fixatives before eating helps to avoid food getting trapped.

# Table 7.7: A first draft of the content for the patient leaflet on eating with complete denture.

# 7.3.6 Stage 5: Professional design of the leaflet.

# **Stage 5. Procedure**

The aim of this stage was to produce a leaflet of professional standard. In order to achieve this aim, a graphic designer (EG) was identified and commissioned to work with the research team on a consultancy basis. The research team approached three designers on the list of the University's approved providers and selected the designer, who had most relevant experience

and was value for money. After that, the research team arranged a meeting with the designer to discuss the first draft of the potential patient leaflet on eating with complete dentures to design the overall layout and production of the leaflet that meet the desire of the target people (denture wearers). The idea being that the overall look for the leaflet would also translate into the future website. The team (the research team and the graphic designer) critically evaluated the title, language, content, length, colour and layout of the potential leaflet based on broad range of examples of other leaflets collected by the research student. The possibility of adding some quotes from the patient's data to the potential leaflet was considered and agreed. After selecting the appropriate quotes from the existing qualitative data, the graphic designer developed the first version of the leaflet and sent it via email to the research team to read and review it. After agreeing on the final layout of the leaflet, the graphic designer produced, printed and sent the first prototype of the patient leaflet on eating with complete dentures.

# **Stage 5 Outcomes**

The first prototype of the patient-centred leaflet on eating with complete dentures was produced as an outcome of this stage (Figure 7.6).



Figure 7.6: A prototype of patient leaflet on eating with complete dentures. Double click to open the figure or refer to (Appendix M) for a hard copy.

# 7.4 Discussion

The current study fills a gap in the literature regarding the steps necessary to informing eating advice and an intervention for denture wearers from methodological perspectives. It provides characterization of how to elicit evidence pertaining to eating with complete dentures from the literature including systematic reviews, qualitative and quantitative research, and other evidence relating to service users and providers engagement in a co-design or co-development process. Such an approach has never been done before to produce advice for edentulous patients. From methodological point of view, the study adopted contemporary co-design techniques to inform eating advice or intervention for denture wearers. Moreover, the study involved dental healthcare providers and experts (e.g., dental health professionals) as codesigners of a health intervention (i.e., advice or intervention on eating with dentures) as recommended by recent research (O'Brien et al. 2016). As the literature advocates the incorporation of user's point of view in intervention development (Yardley et al. 2012; Yardley et al. 2015), this co-design approach involved conducting a qualitative study with the users (i.e., denture wearers) and health providers (i.e., dentists and DCPs) to explore their views and opinions about the preferable format for delivering the eating advice or intervention. Service users and providers emphasised the importance of producing a patient leaflet on eating with dentures, and developing a patient-centred eating advice and intervention for complete denture wearers highlighting the importance of users and health providers in designing of eating advice or intervention.

The main outcome of this study was producing the Core Concepts for co-developed ideas for overcoming problems with eating with complete dentures. These ideas include producing a patient leaflet; developing a website (which could involve a web-based dietary intervention) on eating with dentures; developing online support groups/blogs for denture wearers; developing training CPD courses for dentists and DCPs, including information on eating with dentures in the dental undergraduate training curriculum, including advice on eating with dentures in PHE toolkit, and creating videos on eating coping strategies. However, based on the feedback received from previous stages relating to importance and practicalities, the research team prioritise two concepts; developing the patient leaflet as short-term aim and developing the website as a longer-term aim outside the scope of this PhD. The intention was to focus on the leaflet with the view that the concepts developed in the leaflet would guide

and underpin the content of the future website. Therefore, the main product of this research was the first prototype of the patient leaflet on eating with complete dentures.

The qualitative work indicated that patients wanted advice to overcome the physical problems they encountered with eating with complete dentures and did not want healthier eating advice. Therefore, the current approach to the leaflet did not use BCTs as the leaflet was providing practical advice to overcome denture wearer's problems as opposed to healthier eating advice to encourage them to change what they eat for health reasons. The approach focused on overcoming the eating problems (i.e., chewing and biting hard food, sticking of food to the dentures, movement of the dentures during eating, pain during eating with dentures, and trapping of food underneath the dentures) identified by the patients. Hence, the content of the leaflet included suggestions from denture wearers to help other edentulous people enjoy eating with dentures with regard to problems or difficulties related to eating with complete dentures. Dental professionals in the engagement stage suggested including nutritional material in any future leaflet about eating with dentures. A unique feature of this leaflet is not only enhancing the social and emotional perspectives of denture wearing, but that it might indirectly improving healthier eating because it was designed to provide healthier message to all readers through incorporating the principle of 'health by stealth'. Recently, this principle has been successfully used as indirect way in improving health. For example, reducing the price of fresh fruits and vegetables result in increasing their consumption and improving health (WHO 2016a). Similarly, imposing a tax on sugar can reduce childhood obesity (The Telegraph 2016), and decrease the incidence of dental caries (Briggs et al. 2017). However, it is difficult to compare these examples of national level policies, which used fiscal pricing to change behaviour to the present approach that aimed to produce a leaflet that helps overcome a concern of patients and to hide the health message within it. Whether the use of the leaflet actually changes the dietary behaviour of the patients in any way would need to be explored further. Verbatim quotations from denture wearers were included in the main themes of the leaflet to give participants a voice, and to enhance readability of the leaflet (Corden and Sainsbury 2006).

In addition to the patient leaflet, developing a website was also highlighted by the current study as a Core Concept. It is regarded as an appropriate way to providing information on eating with dentures, whereby the denture wearers could exchange information with each other. Despite the fact that some of the denture wearing cohort are currently not 'tech-savvy' (e.g. 75 years and over), producing a patient leaflet linked to a website appears to be an

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appropriate strategy to providing advice on eating with dentures. Therefore, the majority of the participants in the engagement phase supported the idea of developing a website on eating with complete dentures. According to the latest statistics from Office for National Statistics (2016), the number of people age 75 years and over, who have an internet access is increasing in the UK. It could be argued that in the near future, this internet access and information technology use will be commonplace for all age groups. The initial ideas of this website focus on overcoming the five functional problems related to eating with complete dentures underpinned by the patient leaflet. The patient could find some solutions for each problem through using certain computer features or tools such as plan my meal, meal ideas/recipes, downloading a leaflet or information and adding and watching videos about eating with dentures and holding online blogs/forums.

One of the Core Concepts identified in this study is developing online support groups/blogs for denture wearers. Dentists and DCPs suggested developing online forums, where edentulous patients can exchange information and knowledge with each other. Dental health professionals supported this idea in the engagement phase of the co-design approach. This kind of communication could increase social interaction and sharing useful information between edentulous people, particularly if these online blogs or forums integrated with the future website or web-based intervention on eating with complete dentures. Research reported that using online forum/blog or discussion could be advantageous in terms of well-being at individual and society level, particularly for stigmatised people (Pendry and Salvatore 2015). Fogelson et al. (2013) argued that by using online forums/blogs, individuals can communicate with each other via text, video, and audio in an open discussion. Therefore, developing online support groups/blogs for denture wearers as a part of a website or web-based intervention could be useful for the group of denture wearers.

The idea of developing training CPD courses on providing advice on eating with dentures for dentists and DCPs emerged from the lack of knowledge or training among this group of dental healthcare providers. It was one of the Core Concepts identified in this study, which could be taken forward. It is useful that such courses will be provided in accordance with guidelines of Public Health England (PHE 2016), and the National Institute for Health and Care Excellence (NICE 2016a), which emphasise on the role of the dental health providers in supporting patients to change their health behaviour. It is also preferable that the Public Health England develop such training courses and add them to the evidence-based toolkit of delivering better oral health. Inputs from experts (e.g., dieticians and nutritionists) should be

incorporated in these training courses, which could be delivered in face-to-face sessions or online. Training of dentists and DCPs could change their attitude towards adopting more holistic patient care including advice to overcome eating-related problems.

Likewise, including information about eating with dentures in the dentists and DCPs undergraduate training curriculum was highlighted as a Core Concept in this study. This idea came out because of a lack of knowledge and training about advice on eating with dentures among dentists and DCPs at undergraduate dental curriculum level. Thus, integrating information on eating with complete dentures as a part of nutrition education in the undergraduate dental curriculum is potentially useful for those under-graduate students, particularly if experts (e.g., dieticians and nutritionists) deliver such information or advice.

Finally, creating or developing videos on eating copying strategies (capture those who are having most eating difficulty) to be shown in the Prosthodontics waiting room was one of the Core Concepts identified in the present study. Displaying such videos may increase the knowledge of denture wearers, particularly if these videos based on real patient's experience. Moreover, they could motivate the patients to change their dietary behaviour through incorporating BCTs (e.g., Model/Demonstrate the behaviour). This technique includes "showing the person how to perform a behaviour e.g. through physical or visual demonstrations of behavioural performance, in person or remotely" (Michie et al. 2011c). According to the authors, cooking, recipes and personal experience are often demonstrated using 'Model/Demonstrate the behaviour' or 'Provide instruction on how to perform the behaviour' because 'demonstration' increase the likelihood of observing how to perform the behaviour change. Ultimately, these videos could be linked to the patient leaflet and integrated with future website or web-based intervention on eating with complete dentures. Considering all these Core concepts and how they will be approached in the future is important in terms of improving ERQoL of denture wearers.

This study adopted a co-development approach similar to that used by O'Brien et al. (2016), who combined evidence from different sources and involved stakeholders as co-designers of a web-based intervention for people in the retirement transition. The present approach is comparable to a co-design approach (Yardley et al. 2012), which used qualitative studies to inform intervention development, and similar to another co-design approach (Macdonald et al. 2012), which valued the inputs of older people and other key stakeholders in development of a prototype for an better-quality food and nutritional management system. These approaches

could highlight the importance of user's perspectives in designing health and improving health care services. However, it was not possible to compare our approach with approaches conducted with edentulous people due to a non-existence of such studies. This is the first codesign or co-development approach that integrated perspectives of users (i.e., patients and dental professionals) to inform eating advice or intervention for the complete denture wearers. Nonetheless, this study highlights an important new area for forthcoming research (i.e. to accomplish the present co-design or co-development method and process for the development of eating advice and intervention for complete denture wearers, and pilot or test the intervention on denture wearers community). This could determine whether co-design (involving users and no-users as co-designers for health intervention) is more effective than traditional approaches, which are relying on perspectives of intervention's designer to develop health interventions.

# 7.5 Strength and weakness of the study

The present study showed that the co-development approach can be applied to produce a patient leaflet and develop some initial ideas for the website on eating with complete dentures. It also, highlighted important new areas for future research (e.g., using co-design methods and processes for the development of dietary advice and intervention for complete denture wearers). One of the main strengths of this study is following the guidance of 'Medical Research Council' (Craig et al. 2008) for intervention development. This guidance emphasises the importance of collecting evidence from literature including systematic reviews to inform advice or intervention development. The present approach was in line with the MRC framework for development of advice or interventions, and possibly addressed the first phase of the fourth inter-related phases of the MRC framework: development, feasibility and piloting, evaluation, and implementation. Moreover, the present approach applied qualitative and co-design methodologies to facilitate active involvement of users (i.e., denture wearers) and health providers (i.e., dentists and DCPs) throughout the development process to generate new intervention ideas. The study applied more than one approach (i.e., compiling of evidence, conducting qualitative and quantitative studies and using co-design or codevelopment to develop eating advice or intervention for denture wearers). In addition, some of the essential steps of increasing the quality or effectiveness of health intervention developed by Wight et al. (2015) have been addressed and reflected in the present study. For instance, defining and understanding the problem of the negative impact of wearing dentures

on social and emotional issues around eating with complete dentures. Moreover, identifying modifiable causal or contextual factors such as eating difficulties (i.e., the five functional problems highlighted by the current research). Furthermore, deciding on the mechanisms of change, which are possibly denture replacement and providing eating advice for denture wearers. Finally, clarifying how these methods of changes will be delivered (i.e., patient leaflet and web-based information or intervention). It could be argued that producing the first prototype of the patient leaflet about eating with dentures is one of the unique areas of this research work. It is a patient-centred implying that it based on patient's opinions and experience during eating with complete dentures and does not rely on information from dentists or experts only.

This study; however, has some limitations. The co-design participants were unlikely to represent the full range of opinions in service users (i.e., edentulous patients and dental healthcare providers community); however, a 'representative consensus' was not the target of this study. The intention was to work with users as part of a team to produce a patient leaflet including useful information on eating with complete dentures, and in the future, inform the content of a website on eating with complete dentures. However, the content of the leaflet was based on data from a patient group, who lived in Northeast of England; therefore, the eatingrelated problems identified in the leaflet might differ across different nationalities and cultures indicating the importance of exploring whether the present leaflet is valid for other populations or not. One of the weaknesses of this approach was that it did not include patients in stage 2, 3, 4, and 5 to obtain their views about the outcome of each stage. It could be argued that potential reuse of focus group members in these stages could introduce a bias because those patients were the participants, who came with original ideas in the focus groups. If they were involved in these stages, they could only support ideas similar to their original suggestions and reject ideas that are not in agreement with their original suggestions. Practically, it was difficult to recruit new patients for each stage; therefore, the research team planned and tried to recruit some new patients (denture wearers) from the Voice North and SEARCH to take part in the potential co-design workshop to get their input and feedback on outcomes of all stages. Unfortunately, the research team did not manage to recruit any participant within the scope of this PhD project. Another weakness was that this co-design approach did not take all core concepts further due to limited resources and time of this PhD project. This approach was also difficult in terms of merging different opinions or views of different participants (i.e., denture wearers, dentists and DCPs). For example, whilst most

patients preferred the leaflet format as a simple source of information about eating, some dental professionals had concerns about the effectiveness of the leaflet in changing behaviour. Moreover, there were some contradictions between participants about the feasibility of using website by older denture wearers. The challenge of interpreting requirements from various viewpoints and evidence sources in conjunction with the main objectives and aims of the research project were overcome through decisions made by the research team in a realistic way. For example, the idea of using the principle of 'health by stealth' emerged during research team meeting; consequently, healthier eating message was incorporated in the content of the leaflet.

# 7.6 Implications of the approach

The main product of this study was producing of the patient-centred leaflet on eating with complete dentures. Therefore, after validation of the leaflet through user workshop with relevant stakeholders, clinicians, dental students and dental nurses in the Prosthodontics and oral rehabilitation departments will be able to use this leaflet in order to help denture wearers overcome eating related problems. In addition to providing advice on functional problems associated with eating with complete denture, this leaflet might promote the healthier eating among the denture wearers due to the 'health by stealth' messages within. Eventually, the leaflet could be used for educational purposes in the dentists and DCPs undergraduate training curriculum as an example of patient-based information on eating with complete dentures.

# 7.7 Conclusions

The study adopted a systematic and iterative approach involving service users, service providers and researchers co-designing a research to inform advice or intervention about eating with complete dentures for denture wearers. It defined several Core Concepts for future development of dietary intervention. The Core Concepts are: producing a patient leaflet; developing a website; developing online support group/blog for denture wearers; developing training CPD courses; including information about eating with dentures in the dental undergraduate training curriculum; including advice on eating with denture in PHE toolkit; and creating video on eating copying strategies in the Prosthodontic waiting room. Despite the importance of all these Core Concepts, the present study focused on the development of the patient leaflet taking into consideration that the concepts developed in the leaflet would guide

and support the design of a future website or web-based intervention on eating with complete dentures. The next chapter illustrates a general discussion and recommendations for future research.

# **Chapter 8. General Discussion and Future Research**

# 8.1 General discussion

This research aimed to explore the impact of wearing conventional complete dentures and denture replacement on social and emotional issues around eating or ERQoL. It also aimed to design a prototype or specification for patient-centric dietary intervention to help denture wearers eat-well and enjoy eating with dentures. After testing the psychometric properties of the ESIRE questionnaire against the McGill questionnaire, the ESIRE questionnaire was used in a cohort study on edentulous patients requiring new conventional complete dentures to determine any change in ERQoL after denture replacement and to obtain in-depth information about the effect of replacing complete dentures on social and emotional issues around eating with dentures. There was a significant improvement in ERQoL after denture replacement; however, some denture wearers had some eating related problems or difficulties highlighting the necessity to delivering a specific eating advice or intervention for this patient group. Therefore, a qualitative study (focus groups with denture wearers, dentists and DCPs) was conducted to explore their views about the potential methods of providing advice on eating with complete dentures. The qualitative study was a part of ongoing co-design or codevelopment approach to inform development of patient-centric dietary advice or intervention for denture wearers. The outcome of this approach was the defined Core Concepts for ideas for overcoming problems with eating with complete dentures. These ideas included producing a patient leaflet; developing a website on eating with dentures; developing online support groups/blogs for denture wearers; developing training CPD courses for dentists and DCPs; including information on eating with dentures in Public Health England's' Delivery Better Oral Health toolkit; and creating videos on eating coping strategies for use on a website and or dental practice waiting areas. Despite the evidence to support all these Core Concepts, the present study focused on developing a patient leaflet, taking into consideration that the concepts developed in the leaflet would guide and support the design of a future website that could include a web-based intervention on eating with complete dentures. In conclusion, the present study revealed the effect of denture replacement on social and emotional issues around eating or ERQoL, discussed these issues with service users and health providers in terms of providing advice about eating with dentures; and co-developed a patient-centred leaflet on eating with dentures along with initial ideas for the future website, which might include dietary intervention.

# 8.1.1 Deviations from the originally planned study

This research was originally designed to have two main phases, in addition to collecting some evidence pertaining to eating with complete dentures from the literature. The literature review, conducted at an initial stage of the research, disclosed a shortage of evidence in terms of the impact of replacing complete dentures on social and emotional issues around eating with dentures (e.g., enjoyment of eating, social interaction with other people and selfconsciousness or embarrassment). It also revealed a wealth of evidence in support of appropriate theories and BCTs used in dietary eating advice or intervention to increase its effectiveness. Such theories and BCTs should be used in the future dietary intervention for complete denture wearers. The clinical aspects of the study could not commence until a positive ethical opinion was obtained. The first phase was a semi-quantitative and qualitative investigation, which involved conduction of a cohort study of patients requiring new conventional complete dentures to determine how denture replacement influenced ERQoL. As a part of this cohort study, some psychometric properties of the ESIRE questionnaire were validated against the McGill questionnaire, on a sub-sample of the total sample of the cohort study. The second phase of this research was a qualitative and co-development stage to produce a prototype for eating advice and inform a website development (could involve a wnbased dietary intervention) for complete denture wearers. This phase involved holding focus groups with denture wearers, dentists and DCPs to explore their views and opinions on advice on eating with complete dentures. The focus groups were conducted as an integral part of codevelopment to produce a prototype for eating advice and intervention for denture wearers. The goal was that this model would be a person-centred and based on user-iterative approach. It was planned that could the co-development phase would involve seven stages based on published method (O'Brien et al. 2016). Stage 1 was collection of evidence from literature review including systematic reviews and meta-analysis, in addition to evidence from the current researches (i.e., the cohort and the qualitative study). Other stages were: stage 2 was research team meeting; stage 3: engagement with dental health professionals; stage 4: prioritisation exercise; stage 5: professional designing of the leaflet; stage 6: co-design workshop with denture wearers; stage 7: one to one interviews with dentists, DCPs and nutritionists). The intention was to hold a workshop with a sample of denture wearers from local public engagement groups. These were Voice North (the North East Regional Research and Engagement Panel, Newcastle University, UK) and SEARCH (a local support group for older people) to obtain feedback about the content, structure and language, and layout of the

patient leaflet and the initial ideas for the eating intervention. After the workshop, it was planned to hold one to one semi-structured interviews with a convenient sample of dentists and DCPs, in addition to some nutritionists from Newcastle University, to obtain further feedback about the amended versions of the patient leaflet and the mock-up examples of the eating advice or intervention. However, several factors such as difficulties in recruiting participants for the workshop and time limitations constrained the proposed plan. Therefore, as the PhD study progressed to the stage where the prototype of the leaflet was completed, the collaboration and research will extend beyond the PhD to ensure that the process is completed in accordance to the plan.

# 8.1.2 Key findings of the research

Adopting a holistic approach that stresses the use of a systematic diagnostic and therapeutic method, emphasizing on psycho-social influence and physical characteristics of oral conditions on human life is fundamental in the dentistry field (Sivakumar et al. 2015). Clinically, social and emotional issues related to eating with complete dentures are given little attention. This could be attributed to limited knowledge or perception of patient-based measures among dentists and other relevant dental care professionals. As relying on clinical measures to assess treatment outcomes are, sometimes, not enough (Corson et al. 1999), the stimulus for conducting the cohort study, therefore, was the idea to use the previously developed and validated patient-based instrument (the ESIRE questionnaire) to determine how denture replacement impact on social and emotional issues around eating or EROoL. However, before conducting such study, it was plausible to evaluate the psychometric properties of the ESIRE questionnaire. The literature review (See chapter 2, section 2.4.3) emphasises the importance of assessing the psychometric properties of any oral health measures; therefore, the psychometric properties of the ESIRE questionnaire were validated against the McGill questionnaire in a sample of conventional complete denture wearers. Although it was impractical to re-assess test-retest reliability, in this group of edentulous patients, the ESIRE questionnaire demonstrates a good acceptability, high internal consistency reliability and satisfactory construct validity (see chapter 4, section 4.4). Given the fact that most denture wearers were older people, in addition to the length and complexity of the questionnaires, particularly the ESIRE questionnaire, the findings of acceptability (i.e., response rate, missing data, floor and ceiling effects and the percentage of minimum and maximum scores) of the current study are possibly encouraging. The high internal consistency reliability of the ESIRE questionnaire is promising indicating that denture wearers were able

to provide consistent 'self-reports', and concurred with the original study that derived the ESIRE questionnaire (Kelly et al. 2012), which reported high internal consistency reliability of the ESIRE questionnaire. Most correlations between domains/scales, both between and within the two questionnaires supported the hypotheses of convergent and discriminant validity, and demonstrated a satisfactory construct validity of the ESIRE questionnaire. The lower than expected convergent validity correlations and the higher than expected discriminant validity correlations between some domains or subscales could be attributed to 'inherent psychometric weaknesses' in the ESIRE questionnaire or the validating instrument (i.e., McGill questionnaire). Hypothetically, the study did not expect the two questionnaires to be completely distinct from each other, and the whole point of using the McGill questionnaire as the 'reference' for establishing convergent and discriminant validity of ESIRE questionnaire was that it was expected that each questionnaire would be related to the other with respect to some domains. This could mean that the two questionnaires are measuring interrelated but different constructs. With the absence of other measures, that are primarily, designed to measure social and emotional issues around eating with dentures or ERQoL, the construct validation procedure of the ESIRE questionnaire could remain potentially limited. It could be argued that the ESIRE questionnaire is possibly the only existing available ERQoL measure that offers adequate psychometric properties. The ESIRE questionnaire, therefore, can determine any change in ERQoL after denture replacement.

Chapter 5, section 5.4 discusses the influence of optimising dentures on ERQoL. Although there were, some functional problems and eating-related difficulties reported by some patients, findings of the cohort study reveals that denture replacement can positively improve social and emotional issues around eating or ERQoL. In addition, the literature review (see chapter 2, section 2.1.5: psychosocial aspects, 2.1.7 and 2.1.14) discusses how social isolation and loneliness are linked to serious physical (e.g., increase the risk of NCDs such as cardiovascular diseases) and mental (e.g., depression) conditions, and early mortality amongst older people. Depression is regarded as a risk factor for dementia (Brommelhoff et al. 2009; Jacka et al. 2014); therefore, improving ERQoL may be important if it reduces social isolation and thereby prevents the occurrence of depression, dementia and other NCDs. For those patients, who had eating-related difficulties, a considerable effort such as establishing a good rapport between dental healthcare providers and providing dietary counselling or intervention is needed to help minimise the negative impact of social isolation on their life. Providing

dietary counselling is an effective way to reducing the incidence of depression among older adults (Stahl et al. 2014).

The literature review (see chapter 2, section 2.1.7 and 2.1.13) illustrates how diet and nutrition are key determinants for physical health, how poor diet can be a risk factor for many NCDs and how edentulism and subsequent prosthetic rehabilitation are associated with poor diet, undernutrition and obesity. The findings of the cohort study reveals that replacing dentures improves eating, indicating that optimising dentures could improve function with them. This could imply that if ERQoL improves at time of denture replacement, then this could make it an opportune moment to concurrently provide dietary advice or intervene to change diet as the patient may be in a more positive frame of mind and more receptive to change. Apparently, overcoming functional problems associated with poor fit or stability of the dentures are major concerns of the patients and main goals of the dentists in the focus groups due to its direct relationship to eating with dentures. Accordingly, the co-design (see chapter 7, section 7.3.5: Stage 4: Prioritisation exercise and section 7.4) addresses some aspects of specific BCTs such as 'barriers identification/problems solving' to put appropriate solutions for the problems. The study has identified barriers (functional problems during eating with dentures) and has come up with problem solving (producing a patient leaflet on advice on how to overcome the functional difficulties). Removing the barriers and overcoming eating problems is the first step in changing what edentulous patients eat. There would be no point doing a healthier eating intervention using BCTs if it did not address the problems faced by the patients and that is why producing the leaflet is so important. Such findings have led to a change in direction towards focusing on the practical issues denture wearers face when eating with dentures, and the 'health by stealth' (as opposed to an active approach using BCTs). The approach to produce a patient-centred advice (i.e., the patient leaflet) to overcome functional difficulties during eating with dentures was discussed in chapter 7 (see section 7.3). The leaflet developed included several domains including overcoming: problems in biting and chewing food; foods sticking to the dentures; dentures movement when biting; pain during eating; and foods getting trapped underneath the dentures. Using patient leaflets is often associated with increased knowledge, which can promote general health (Moerenhout et al. 2013), thereby improving quality of diet among complete denture wearers (Bartlett et al. 2013). Although there is no specific leaflet that could be applied to all denture wearers, producing the leaflet is possibly a relatively inexpensive idea of providing information on eating with dentures. It could be argued that informing denture wearers (using the current
leaflet that incorporates a healthy eating message) on how to overcome their problems with eating increases dietary self-efficacy. The incorporated health messages by stealth could inspire denture wearers to choose healthier lifestyle, but this would need to be confirmed in further research (see section 8.2.4 below). Therefore, this leaflet could be helpful for many denture wearers when given along with a brief explanation from the dental health care providers (e.g., dentists, dental students and DCPs) and moreover, if it is linked to a website, as suggested by the qualitative findings (see chapter 6, section 6.5.2) and identified Core Concept (see chapter 7, section 7.3.5). The present study also offers a realistic solution involving some initial ideas (based on the opinions of the patients and dental professionals) about developing a website (which could involve a web-based intervention) in which edentulous patients can exchange information about eating with dentures. By this approach, the denture wearers can hold online forums, download videos about the coping strategies, exchange experience, and learn new recipes, meal ideas and cooking strategies. Using an online forum/blog or discussion could be helpful for several denture wearers in sharing experiences and giving each other advice. Moreover, displaying videos on coping strategies in the Prosthodontics waiting room may be useful in increasing knowledge of denture wearers, particularly if these videos are based on real patient's experiences. In fact, these were Core Concepts identified in the present study. The future web-based intervention that compliments the leaflet will be produced and should enable the inclusion of BCTs that enhance dietary selfefficacy as recommended by many systematic reviews (see chapter 2, section 2.2.8). The intervention development could follow the recognised co-development process that was used to produce the leaflet.

In the qualitative study (see chapter 6, section 6.5.2), the finding that healthy eating advice in general practice was rarely performed with denture patients was discussed. This finding indicates that better training of dentists might be warranted. There may be knowledge issues; for example, dental professionals may not necessarily be aware of the 'gold standard' advice, and they are not educated in terms of up to date guidance on healthy eating. This means that they do not necessarily know what advice to give to the patients. Apparently, the patients' opinion is that dentists and DCPs are ill equipped to give eating advice as they have no personal experience of wearing dentures. Therefore, providing training CPD courses about advice on eating with complete dentures to the dental healthcare professionals is important, though it does not overcome the lack of personal experience in eating with dentures.

patients in the undergraduate training curriculum of the dentists and the DCPs is also important. Indeed, these were highlighted as Core Concepts for future development following the exhibition (see chapter 7, section 7.3.5). The current NHS contract does not allow the dentists and DCPs to spend additional time to provide dietary advice, particularly healthier eating advice, to patients. Consequently, it is fundamental that the NHS activates the commissioning system in dentistry and reforms of the current NHS dental contract to involve sufficient indemnification of dentists and DCPs for the time required to provide advice on eating with dentures in primary care centres. In accordance with the current NHS dental contract (which lacks provision of time and incentives), eating-related advice delivered by peer-to-peer might be a solution, particularly in a patient-led leaflet layout with a link to supporting website, where people can share information, knowledge, experience or practical assistance with each other. National Institute for Health and Care Excellence (NICE 2016a) recommended that the dental health providers must provide a tailored advice for all patients to change their behaviour basing on 'evidence-based toolkit of delivering better oral health' by Public Health England. Nonetheless, no advice is available about eating-related difficulties associated with wearing dentures, particularly conventional type. Again, including advice on eating with dentures in PHE toolkit was highlighted as a Core Concept for future development following the exhibition (see chapter 7, section 7.3.5). The patient-centred leaflet and the initial ideas of the future website that could involve a web-based intervention produced in the present research could help inform PHE on information to include advice on eating with complete dentures in the 'evidence-based toolkit of delivering better oral health.' The next section illustrates a summary of future research.

## 8.2 Recommendations for future research

The present research highlighted several suggestions for future research related to each of the four studies.

### 8.2.1 Validity study

The scaling failures or probable scaling failures of some items of the ESIRE questionnaire could indicate a need to conduct an item reduction analysis. However, the sample size was not sufficient to do such analysis. Therefore, item reduction analysis (by using factor analysis in a large enough sample or development) could be required to remove items, which performed poorly and development a short version of the ESIRE questionnaire. Moreover, the ESIRE questionnaire could be used to conduct another study to obtain further evidence of the construct validity (through confirmatory factor analysis in a large enough sample). Such analysis should be done after a discussion with the original ESIRE developers and some clinicians and patients to assess if there is need to remove items, which performed poorly (e.g., items marked for low response, potential floor effect and redundancy, and domains flagged for lack of construct validity). Similar to most other patient-based health outcome measures, the ESIRE questionnaire is appropriate for use in group comparisons rather than in an individual level. Therefore, it could be suggested that known-groups validity analysis is required. This could involve comparing the ESIRE scores for those, who do not use or, who complain about their conventional complete dentures with those, who seem to be using their dentures as planned. The expectation is that those having problems with their dentures have lower scores. Finally, it is recommended to use the ESIRE with other people in the UK to assess its generalisability; in addition, the ESIRE questionnaire could be translated to other languages and used in other countries to collect data on ERQoL. Indeed, a cross-cultural adaptation and the psychometric properties need to be re-evaluated in these languages and countries.

## 8.2.2 Cohort study

As the data of the present study are not necessarily generalizable for the whole community of complete denture wearers, further research is required to determine the impact of replacing dentures on ERQoL in other geographical areas in the UK and abroad. Moreover, although the results of this study revealed a highly significant improvement in ERQoL, one month after

denture replacement, it could be useful to conduct a similar study at different periods (i.e., three months, six months, and after one year) to monitor the changes in ERQoL. It would be recommended to repeat the cohort study using the same study design in conjunction with eating advice (e.g., a patient leaflet or dietary counselling) to evaluate the effect of both denture replacement and eating advice on ERQoL. As the results of this study concluded that this significant change in ERQoL has a clinical meaning, it is possible to use the data of this study to derive a power calculation for further studies. For instance, a comparative study could be conducted on adequate sample of patients wearing ISODs or CDs to determine the change in ERQoL after the treatment. This would enable comparison of the impact of different forms of prosthetic rehabilitation on ERQoL. Responsiveness of the ESIRE questionnaire could be calculated using other responsiveness measures such as the minimal importance difference, and Guyatt's responsiveness index (Guyatt et al. 2002) on sufficient sample size of denture wearers. Ultimately, it would be beneficial to conduct a similar study on edentulous patients requiring either conventional complete dentures or ISODs from other countries such as Iraq (the researcher's home country) to state to test cross-cultural differences. Such study requires translation of an Arabic version of the ESIRE questionnaire using back-translation method, and then, validation of the ESIRE questionnaire on Iraqi edentulous patients. However, before translating the ESIRE questionnaire, it is fundamental to conduct a qualitative study with edentulous patients to explore if the impacts of wearing ISODs or CDs on social and emotional issues are the same for the Iraqi population. This will provide the literature with information about the cultural differences in the impact of wearing different types of dentures on EROoL.

## 8.2.3 Qualitative study

Further research is required to explore the views and opinions of denture wearers and dental health providers about advice on eating with complete dentures in other geographical areas in the UK and abroad. Moreover, it may be advantageous to conduct a qualitative study on patient perspectives of how ISODs and CDs influence eating within other countries and cultures; for example, with in the population of Iraqi edentulous patients. Those people have different cultural ambitions, socio-economic status, attitudes towards eating and foods. Therefore, it will be interested to obtain in-depth details on the impact of edentulism and denture wearing on social and emotional issues surrounding eating among those people to see if the ESIRE questionnaire is appropriate (i.e., covers the issues in different cultures). A similar qualitative study using focus groups or semi-structured one to one interview could be

conducted on Iraqi denture wearers and dentists to explore their views and opinions about advice on eating with complete dentures.

## 8.2.4 Co-design study

The present study identified several Core Concepts. These were producing a patient leaflet; developing a website on eating with dentures; developing online support groups/blogs for denture wearers; developing training CPD courses for dentists and DCPs, including information on eating with dentures in the dental undergraduate training curriculum, including advice on eating with dentures in PHE toolkit, and creating videos on eating coping strategies. Further development of these Core Concepts is required to fully address the issue of supporting edentulous patients to eat well with dentures and inform a dietary intervention for them. The following sections discuss future directions of these Core Concepts:

## 1. The patient leaflet

In addition to obtaining feedback on the Core Concepts identified, an interactive session (a workshop with denture wearers) could be held to brainstorm for feedback on the content and design of the patient leaflet on eating with dentures to validate the information and identify anything that is missing/superfluous. Moreover, additional feedback on the leaflet should be obtained through one to one semi-structured interviews with denture wearers, DCPs, and nutritionists to provide input on the mock up for the leaflet. This feedback will inform of any appropriate modifications to the patient leaflet in the future. Furthermore, appropriateness of the leaflet for different populations and cultures could be tested in the future. For example, the final version of the patient-based leaflet could be translated to the Arabic language and validated on other edentulous patients from Iraq (the researcher's home country).

## 2. The future web-based information

As determining the degree of end user input into the final intervention is necessary for every co-design study (Donetto et al. 2014), it is recommended to involve denture wearers in any future step or stage that aims to complete the present work. Similarly, involving stakeholders as co-designers of health interventions is fundamental in maximizing the acceptability and possible effectiveness of any health intervention (Bowen et al. 2013; Craig et al. 2013; O'Brien et al. 2016). Therefore, it is recommended to engage other stakeholders in specific phases of the future website development to have their input about the feasibility, relevance,

and usefulness of the future web-based intervention for the group of denture wearers. Additional work is required to accomplish this web-based eating intervention design and would need the holding of co-design workshop and one-to-one interviews with denture wearers, DCPs, and nutritionists. Feedback from the workshop and the one to one semistructured interviews might provide a useful input to the plans for web-based information. This feedback will inform of any appropriate modifications to the specification for the webbased material. It is envisaged that any future intervention on eating with dentures would be a patient-centred web-based intervention and follow the development criteria of O'Brien et al. (2016) in which the intervention has to be tailored, scalable, sustainable, interactive, digital, and visually and functionally engaging. Although some preliminary ideas for the website specification were prepared (see chapter 7, section 7.3.5), this was not taken forward due to the timescale of the project. The participants in the engagement phase mentioned that any future intervention should be tailored, accessible, digital, utilising effective BCTs to start and maintain change. A principle idea behind developing a website would be to provide general information on eating with dentures by sharing and exchanging information between the denture wearers. However, in addition to providing information on overcoming the practical problems of eating with dentures, this website could include a web-based intervention that incorporates BCTs (e.g., 'goal setting', 'barriers identification/problems solving', and 'prompt self-monitoring of behaviour', and 'stress management/emotional control training') to encourage and support healthier eating through enhancing self-efficacy among edentulous people (a population that stands to benefit from a healthier diet). Systematic reviews show that dietary intervention studies that incorporate BCTs result in enhancing dietary selfefficacy and increase the effectiveness of these interventions (Michie et al. 2009; Michie et al. 2011c; Bhattarai et al. 2013; Lara et al. 2014a; Prestwich et al. 2014a). It is likely that 'selfregulatory process' is considered as a key factor to enhance health behaviour change, which requiring participant's active engagement in the intervention (Michie et al. 2009). The idea of developing a website about eating with dentures is supported by the literature, which suggests that web-based interventions are possibly an appropriate way to reach older people, who are increasingly using the internet frequently (Harte et al. 2014). Applying a web-based information on eating with complete dentures could have positive effects on lifestyle behaviours among a rapidly expanding older adult population. As oral health is directly linked to general health in terms of quality of life (Walls and Steele 2004a; Moynihan 2007;

Gerritsen et al. 2010a), implementing such eating advice or intervention for older edentulous people could have a positive impact on their general health.

## 3. Other Core Concepts

NHS or other relevant organisations such as PHE could develop training CPD courses about advice on eating with dentures. PHE could consider the findings of the current study and include advice on eating with dentures in the updated version of delivering better oral health toolkit. Dental schools around the UK could include information about eating with dentures in the dentists and DCPs undergraduate training curriculum. The future website could include online support groups/blogs for denture wearers and videos on eating coping strategies. Such videos could be shown in the Prosthodontics waiting room. It could be argued that addressing all above-mentioned suggestions could increase our understanding of ERQoL and advice about eating with dentures, which could help denture wearers improve and enjoy eating with dentures and indirectly adopt healthier eating style. The next chapter illustrates the main conclusions of this PhD study.

# **Chapter 9. Conclusions**

This thesis aimed to assess the impact of denture replacement on ERQoL and inform the development of a prototype of patient-centred eating advice or intervention for denture wearers. Four separate but related research studies that addressed four objectives were conducted to achieve the aims.

## 9.1 Validity study: testing the psychometric properties of the ESIRE questionnaire

- The ESIRE questionnaire demonstrated good psychometric properties (i.e., acceptability, internal consistency reliability and construct validity) in a sample of denture wearers from Northeast of England, supporting its use for assessing aspects of quality of life related to eating.
- The ESIRE scores were superior in comparison to the McGill scores in terms of overall internal consistency reliability, acceptability and convergent validity.

## 9.2 Cohort study: determining the impact of denture replacement on ERQoL

- There was a significant improvement in the total ESIRE scores following intervention with conventional complete dentures. Equally, there were significant difference in each of the domains.
- Denture replacement can directly improve ERQoL highlighting the importance of using a conventional complete denture as a treatment option for edentulous patients.
- The magnitude of change in ERQoL that has been measured by the effect size shows the effect of denture replacement on ERQoL is 'clinical meaningful'
- The qualitative data revealed some eating related problems among some denture wearers highlighting the importance of delivering eating advice or intervention.
- The ESIRE questionnaire was responsive to changes in ERQoL after denture replacement among a population of conventional complete denture wearers in the UK. Evidence on responsiveness of the ESIRE questionnaire implies that the ESIRE questionnaire can be used as an outcome measure for future clinical studies.

# **9.3** Qualitative study: opinions of dentists and DCPs about advice on eating with dentures

- Currently, the dentists are seemingly focused on adjusting dentures, rather than advising to modify diet of denture wearers.
- The denture wearers do not think the dentist is the most appropriate person to advise them on eating and their main priority was to eat what they ate prior to wearing dentures
- Peer delivered advice might be useful especially in a leaflet format with a link to website, where people can share information.
- Patience, perseverance, adjustment of the dentures, and preparing and eating foods differently were the main advice recommended by patients.
- Findings of this study are being used to formulate appropriate eating advice for the denture wearers.

# 9.4 Co-design study: development of a prototype of patient-centred advice or intervention on eating with complete dentures)

- An iterative co-design process engaging both patients and dental professionals produced a patient-centred leaflet on overcoming functional eating problems with complete dentures.
- The co-design approach also developed initial ideas for a future website or web-based intervention on eating with complete dentures.
- The approach identified several Core Concepts such as producing a patient leaflet; developing a website; developing online support group/blog for denture wearers; developing training CPD courses; including information about eating with dentures in the dental undergraduate training curriculum; including advice on eating with denture in PHE toolkit; and creating video on eating copying strategies in the Prosthodontic waiting room. These Core Concepts could be developed further in the future to fully address the issue of supporting edentulous patients to eat well with dentures.

# Appendices

Appendix A: Denture satisfaction scale (McGill questionnaire).



# **Denture Satisfaction Scale**

Study Centre- University of Newcastle upon Tyne

We would like to know how satisfied you are with your present prosthesis. Read each of the following questions and draw a vertical line on the horizontal line, where you think your answer best fits. In the case where a question doesn't apply to you, for example if you don't eat a certain type of food, write a brief explanation on the line.

Thinking about your current dentures:-

1. Ease of cleaning

Please indicate how difficult it is to clean your lower prosthesis and mouth? (Please, place a cross on the line below).

Extremely difficult Not at all difficult

|-----|

2. General satisfaction

In general, are you satisfied with your lower prosthesis?

Not at all satisfied Extremely satisfied I------I

3. Ability to speak

Please indicate how difficult it is for you to speak because of your lower prosthesis?

Extremely difficult Not at all difficult

4. Comfort Are you satisfied with the comfort of your lower prosthesis?

Not at all satisfied Extremely satisfied

## 5. Aesthetics

Are you satisfied with the appearance of your lower prosthesis?

Not at	all satisfied	Extremely satisfied

6. Stability Are you satisfied with the stability of your lower prosthesis?

Not at all satisfied Extremely satisfied

7. Ability to chew

A/ In general, do you find it difficult to chew food because of your lower prosthesis?

Extremely difficult Not at all difficult

B/ Please indicate how difficult it is for you to eat fresh white bread because of your lower prosthesis?

Extremely difficult Not at all difficult

C/ Please indicate how difficult it is for you to eat hard cheese because of your lower prosthesis?

Extremely difficult Not at all difficult

D/ Please indicate how difficult it is for you to eat raw carrots because of your lower prosthesis?

Extremely difficult Not at all difficult

E/ Please indicate how difficult it is for you to eat dry salami because of your lower prosthesis?

Extremely difficult Not at all difficult

F/ Please indicate how difficult it is for you to sliced steak because of your lower prosthesis?

Extremely difficult	Not at all difficult	

G/ Please indicate how difficult it is for you to eat raw apples because of your lower prosthesis?

Extremely difficult Not at all difficult

H/ Please indicate how difficult it is for you to eat lettuce because of your lower prosthesis?

Extremely difficult Not at all difficult

8. Function

A/ In general, is your food well chewed before swallowing?

Badly chewed Very well chewed

B/ Are pieces of fresh white bread well chewed before swallowing?

Badly	chewed	Very well chewed

C/ Are pieces of hard cheese well chewed before swallowing?

Badly chewed	Very well chewed

D/ Are pieces of raw carrot well chewed before swallowing?

Badly chewed Very well chewed

E/ Are pieces of dry salami well chewed before swallowing?

Badly chewed	Very well chewed

F/ Are pieces of sliced steak well chewed before swallowing?

Badly chewed Very well chewed

G/ Are pieces of raw apple well chewed before swallowing?

Badly chewed Very well chewed

H/ Are pieces of lettuce well chewed before swallowing?

Badly chewed Very well chewed

9. Oral condition

In general, are you satisfied with your oral condition?

Not at all satisfied

**Extremely satisfied** 

 -

Do you believe that your oral condition has a negative effect on your general health?



If yes, why?



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Patient Number:





**Appendix B: ESIRE questionnaire.** 



# Denture Satisfaction Scale

## Study Centre- University of Newcastle upon Tyne

# Enjoyment of Eating with your Dentures

This questionnaire is about your opinions on the way your dentures (false teeth) affect your experience of eating and quality of life. We would very much value your opinions. Please, take your time and complete as much of the questionnaire as possible.

The questionnaire was designed with questions to be answered using a scale. Below, there is some example on how to answer the questions using this scale.

Example 1: If you were very dissatisfied then your line be over to the left hand side as illustrated in the example below.

Very dissatisfied	Very satisfied	
-	-	

Example 2: If you were very satisfied then your line be over to the right hand side as illustrated in the example below.

Very dissatisfied Very satisfied

I-----I

Thinking about your current dentures:-

A/ Enjoyment of food/eating

1a. How satisfied are you with your ability to chew food? (Please, place a cross on the line below).

Very dissatisfied Very satisfied

|-----I

1b. Why are you satisfied or dissatisfied with your ability to chew food? (Please, describe fully below and give examples where possible).



Very dissatisfied

Very satisfied

|-----|

2b. Why are you satisfied or dissatisfied with your ability to taste food? (Please, describe fully below and give examples where possible).

3. How enjoyable is eating and drinking with your current dentures in each of the following situations?

3a. At home on your own? (Please, place a cross on the line below).

Not at all enjoyable

Very enjoyable

|-----|

3b. With other family members? (Please, place a cross on the line below).

Not at all enjoyable Very enjoyable

|-----|

3c. With friends? (Please, place a cross on the line below).

Not at all enjoyable Very enjoyable

I-----I

3d. In public places? (Please, place a cross on the line below).

Not at all enjoyable

Very enjoyable

|-----|

**3e. What affects your enjoyment of eating and drinking? (Please, describe fully below and give examples where possible).** 

3f. How does your enjoyment of eating and drinking affect your life? (Please, describe fully below and give examples where possible).

4a. When you are eating in public, how often do you choose foods that are easy to eat because of your dentures?

Never Always

4b. If you choose different foods to eat in public how does this affect your life? (Please, describe fully below and give examples where possible).

5a. Do you ever find that because of your dentures you have to chop or slice food in order to eat it? (Please, place a cross on the line below).

Never

Always

|-----|

5b. If you have to chop or slice food to eat it, how does this affect you? (Please, describe fully below and give examples where possible).

6a. Are there any foods you would like to eat but cannot at all because of your dentures? (Please, describe fully below and give examples where possible).

6b. What do you miss about these foods? (Please, describe fully below and give examples where possible).

**B/ Self-consciousness/embarrassment** 

7. Are you ever self-conscious or embarrassed because of your dentures while you are eating or drinking?

7a. At home on your own? (Please, place a cross on the line below).

Never Always

7b. With other family members? (Please, place a cross on the line below).

Never Always

|-----|

7c. With friends? (Please, place a cross on the line below).

Never Always

7d. In public places? (Please, place a cross on the line below).

Never

Always

|-----|

7e. Why are you self-conscious or embarrassed? (Please, describe fully below and give examples where possible).

7f. How does self-consciousness or embarrassment when eating or drinking with your dentures affect your life? (Please, describe fully below and give examples where possible).

8a. Are you concerned about your dentures moving when you are eating? Please, place a cross on the line below).

Never

Always

|-----|

8b. If you are concerned about your dentures moving, how does this affect you? (Please, describe fully below and give examples where possible).

9a. Are you ever concerned that your dentures might fall out while you are eating? Please, place a cross on the line below).

Never Always

9b. If you are concerned, how does this affect you? (Please, describe fully below and give examples where possible).

10a. Do you ever hide your face or mouth when you are eating because of your dentures? Please, place a cross on the line below).

Never

Always

|-----|

10b. Why do you hide your face or mouth? (Please, describe fully below and give examples where possible).

10c. How does hiding your face or mouth affect you? (Please, describe fully below and give examples where possible).

11a. Do you worry about what other people think when you are eating with your dentures? Please, place a cross on the line below).

Never

Always

|-----|

11b. What do you worry about? (Please, describe fully below and give examples where possible).

11c. How does worrying about what other people think affect your life? (Please, describe fully below and give examples where possible).

12a. Does noise from your dentures ever bother you while you are eating? Please, place a cross on the line below).

Never

Always

|-----|

12b. Why does the noise bother you? Please, describe fully below and give examples where possible).

13a. Do you ever avoid cooking meals because of your dentures? Please, place a cross on the line below).

Never

Always

|-----|

13b. If you avoid cooking meals how does this affect your life? Please, describe fully below and give examples where possible).

C/ Interruption to meals

14a. Do you ever have to interrupt meals to clean foods or liquids from your dentures? Please, place a cross on the line below).

Never

Always

14b. How does this affect you? Please, describe fully below and give examples where possible).

D/ Confidence when eating

15. How confident are you about eating and drinking in each of the following situations?

15a. At home on your own? Please, place a cross on the line below).

Not at all confident Very confident

I-----I

15b. With other family members? Please, place a cross on the line below).

Not at all confident Very confident

|-----|

15c. With friends? Please, place a cross on the line below).

Not at all confident Very confident

|-----|

15d. In public places? Please, place a cross on the line below).

Not at all confident Very confident

15e. What affects your confidence about eating and drinking? Please, describe fully below and give examples where possible).

15f. How does your level of confidence when eating or drinking with your dentures affect your life? Please, describe fully below and give examples where possible).

E/ Time for eating or preparation of meals

16. How satisfied are you with the time it takes to eat a meal in each of the following situations?

16a. At home on your own? (Please, place a cross on the line below).

Very dissatisfied Very satisfied

16b. With other family members? (Please, place a cross on the line below).

Very dissatisfied Very satisfied

|-----|

16c. With friends? (Please, place a cross on the line below).

Very dissatisfied

Very satisfied

16d. In public places? (Please, place a cross on the line below).

Very dissatisfied

Very satisfied

|-----|

16e. What concerns do you have about the time it takes to eat a meal? Please, describe fully below and give examples where possible).

16f. How does the time it takes to eat a meal affect you? Please, describe fully below and give examples where possible).

17a. If you are going out for a meal do you have to take anything with you in order to eat adequately with your dentures? Please, describe fully below and give examples where possible).

F/ Functional ability to eat

18a. How satisfied are you with your ability to bite into an apple? (Please, place a cross on the line below).

Very dissatisfied

Very satisfied

|-----|

18b. If you are not satisfied, why not? Please, describe fully below and give examples where possible).

19a. How satisfied are you with your ability to eat foods with pips or seeds in? (Please, place a cross on the line below).

Very dissatisfied

Very satisfied

|-----|

19b. If you are not satisfied, why not? Please, describe fully below and give examples where possible).

20a. How satisfied are you with your ability to eat steak? (Please, place a cross on the line below).

Very dissatisfied

Very satisfied

20b. If you are not satisfied, why not? Please, describe fully below and give examples where possible).

21a. How satisfied are you with your ability to eat nuts? (Please, place a cross on the line below).

Very dissatisfied

Very satisfied

|-----|

21b. If you are not satisfied, why not? Please, describe fully below and give examples where possible).

22a. How satisfied are you with your ability to eat sticky or chewy foods? (Please, place a cross on the line below).

Very dissatisfied

Very satisfied

|-----|

22b. If you are not satisfied, why not? Please, describe fully below and give examples where possible).

23a. How satisfied are you with your ability to eat lettuce? (Please, place a cross on the line below).

Very dissatisfied

Very satisfied

|-----|

23b. If you are not satisfied, why not? Please, describe fully below and give examples where possible).

24. Do you have any other comments about how your dentures affect your experience of eating and quality of life? Please, describe fully below and give examples where possible).

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Patient Number:



Appendix C: A positive ethical opinion from the National Research Ethics Services (NRES) committee London-Westminster.



#### NRES Committee London - Westminster

4 Minshull Street Manchester M1 3DZ

Telephone: 0161 625 7827 Fax: 0161 625 7299

20 August 2015

Prof. J Mark Thomason Professor of Prosthodontics & Oral Rehabilitation Newcastle University School of Dental Sciences Framlington Place Newcastle upon Tyne NE2 4BW

Dear Prof. Thomason

 

 Study title:
 Assessment of the Impact of Wearing Complete Dentures (CDs) on Eating Related Quality of Life (ERQoL), and development of patient-centric dietary intervention.

 REC reference:
 15/LO/1299

 IRAS project ID:
 168815

Thank you for your submission of 18 August 2015. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 14 August 2015. The Chair has confirmed that as R&D cannot suggest a suitable database to register the study on that this condition can be waived.

#### Documents received

The documents received were as follows:

Document	Version	Date
Other [Response letter to the Conditional favourable ethical opinion]		18 August 2015
Participant information sheet (PIS) [Appendix 8 Participant information sheet for Dental Care Professional DCPs (phase II, stage 2, 3, and 4) ]	version 3	18 August 2015

### Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	Varsian	Data
	version	
evidence of sponsor insurance or indemnity (non NHS Sponsors only) [Evidence of insurance and indemnity]		17 June 2015
Interview schedules or topic guides for participants [Interview schedules or topic guides for participants]	1.6	15 May 2015
Letter from sponsor [A written approval from clinical director (letter).]		
Other [Dr James Field CV ]		15 May 2015
Other [GCP of PhD student: Hassan Al-Sultani]		17 November 2014
Other [Caldicott approval e-mail]		28 April 2015
Other [CV of member of assistant moderator]		15 May 2015
Other [Panel progression report]		
Other [Our response to the progression report (Peer review)]		
Other [Responsibilities of CI or PI]		
Other [Appendix 3 Case Report Form (CRF) for all participants.]	1.6	15 May 2015
Other [Application clarification]		09 July 2015
Other [e- mail to the adminstrator of Voice North]		11 August 2015
Other [Response to the provisional opinion of REC committee]		11 August 2015
Other [Response letter to the Conditional favourable ethical opinion]		18 August 2015
Participant consent form [Consent forms (tracked changes version)]	version 2	11 August 2015
Participant consent form [Consent forms (clean version)]	version 2	11 August 2015
Participant information sheet (PIS) [Partcipant Information Sheets (tracked changes version 2)]	version 2	11 August 2015
Participant information sheet (PIS) [Partcipant Information Sheets (clean version 2)]	version 2	11 August 2015
Participant information sheet (PIS) [Appendix 8 Participant information sheet for Dental Care Professional DCPs (phase II, stage 2, 3, and 4) ]	version 3	18 August 2015
REC Application Form [REC_Form_08072015]		08 July 2015
Research protocol or project proposal [Research protocol version 1.6]	1.6	15 May 2015
Summary CV for Chief Investigator (CI) [Prof J Mark Thomason CV]		15 May 2015
Summary CV for student [Dr Hassan Al-Sultani CV]		15 May 2015
Summary CV for supervisor (student research) [Prof Paula Moynihan CV]		15 May 2015
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Outline of the study]	1.6	15 May 2015
Validated questionnaire [Validated questiooaires]		
Validated questionnaire [The ESIRE questionnaire]	version 2	11 August 2015

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

15/LO/1299

Please quote this number on all correspondence

Yours sincerely

Rachel Katzenellenbogen REC Manager

E-mail: nrescommittee.london-westminster@nhs.net

Copy to: Prof J Mark Thomason, Newcastle University Mrs Joanna Ho, The Newcastle upon Tyne Hospitals NHS Foundation Trust Appendix D: Research and Development (R and D) approval from Newcastle upon Tyne Hospitals (NHS Foundation Trust).

# The Newcastle upon Tyne Hospitals

Regent Point Regent Farm Road

Newcastle upon Tyne

Tel: (0191) 233 6161

Gosforth

NE3 3HD



18 September 2015

Professor Mark Thomason School of Dental Sciences Newcastie University Framlington Place NE2 4BW

Dear Professor Mark Thomason,

7515
Assessment of The impact of Wearing Complete Dentures (CDs) on Eating Related Quality of Life (ERQoL), and
Development of Patients-centric Dietary Intervention
Professor Mark Thomason
98
Iraqi Ministry of Higher Education and Scientific Research (MoHESR
The Newcastle upon Tyne NHS Hospitals Foundation Trust
15/L0/1299
168815
18 October 2015

After completing the necessary risk and site assessments for the above research project, The Newcastle upon Tyne Hospitals NH5 Foundation Trust grants NHS Management Permission for this research to take place at this Trust dependent upon:

- (i) you, as Principal Investigator, agreeing to comply with the Department of Health's Research Governance Framework for Health and Social Care, and confirming your understanding of the responsibilities and duties of Principal Investigators by signing the Investigator Responsibilities Document. A copy of this document will be kept on file within the Joint Research Office.
- (ii) you, as Principal Investigator, ensuring compliance of the project with all other legislation and guidelines including Caldicott Guardian approvals and compliance with the Data Protection Act 1998, Health and Safety at Work Act 1974, any requirements of the MHRA (*eg* CTA, EudraCT registration), and any other relevant UK/European guidelines or legislation (*eg* reporting of suspected adverse incidents).
- (iii) where applicable, you, as Principal Investigator, should also adhere to the GMC supplementary guidance Good practice in research and Consent to research which sets out the good practice principles that doctors are expected to understand and follow if they are involved in research – see http://www.gmc-uk.org/guidance/ethical\_guidance/5991.asp

The NIHR requires NHS organisations to recruit patients to CLRN Portfolio studies within 30 days from the date of this letter. The 30 day deadline for recruiting the first patient is therefore 18 October 2015.

Please note: the Department of Health 70 day bench mark requires recruitment within 70 days of a valid SSI submission. Therefore, recruiting within the NIHR 30 day target will ensure compliance with both targets.

#### Sponsorship

Approval Letter version 1.1 05.12.14 1
The Newcastle upon Tyne Hospitals NHS Foundation Trust will act as Sponsor for this project, under the Department of Health's guidelines for research in health and social care.

In addition, the Trust has a Research Governance Implementation Plan, agreed with the Department of Health, in order to fully comply with Research Governance and fulfil the responsibility of a Sponsor.

As the Trust is acting as Sponsor for the research and where some of the research is taking place outside of Newcastle upon Tyne, then all costs must be met for research governance audit visits to those sites. It is the responsibility of the PI to provide confirmation to the Trust of who will pay these costs. Audit is required under the Research Governance Framework for health and Social Care. (Please note that the Trust randomly audits 10% of approved research projects annually.)

NHS Permission applies to the research described in the protocol and related documentation as listed on the favourable ethical opinion(s) from NRES Committee London- Westminster, dated 20 August 2015. Specifically, the following versions of the key documents are approved:

Document	Version	Date
Research Protocol or project proposal [Research protocol version	1.6	15 May 2015
1.6]		
Participant Information Sheet (PIS) [Appendix 8 Participant	Version 3	18 August 2015
Information Sheet for Dental Care Professional DCPs (phase II,		
Stage 2, 3, and 4)		
Participant Information Sheet (PIS) [Participant Information Sheets	Version 2	11 August 2015
(Clean Version 2)]		
Participant Consent Form [Consent forms (clean version)]	Version 2	11 August 2015
Interview Schedules or topic guides for participants [Interview	1.6	15 May 2015
schedules or topic guides for participants]		-
Other [Appendix 3 Case Report Form (CRF) for all participants.]	1.6	15 May 2015
Other [ e-mail to the administrator of Voice North]		11 August 2015
Validated questionnaire [The ESIRE questionnaire]	Version 2	11 August 2015

Any changes to these documents, or any other amendments to the study must be submitted to the Research Ethics Committee and MHRA (if relevant) for review – see <a href="http://www.nres.npsa.nhs.uk/applications/afterethical-review/amendments/">http://www.nres.npsa.nhs.uk/applications/afterethical-review/amendments/</a> for guidance). All amendments must be submitted to the R&D office for review in parallel with ethical and regulatory review so that implications of the amendment can be assessed. You must send a copy of all amendment documents to the R&D office and if the changes or amendments to the study have implications for costs or use of resources, you must also submit details of these changes.

It is the Principal Investigator's responsibility to ensure that all staff involved in the research have Honorary Research Contracts or the necessary Letters of Access. These must be issued prior to commencing the research.

In addition, unless otherwise agreed with the Trust, the research will be covered for negligence under the CNST (Clinical Negligence Scheme for Trusts), however cover for no-fault harm is the responsibility of the Principal Investigator to arrange if required.

Please also note that for any NHS employee who generates Intellectual Property *in the normal course of their duties*, it is recognised that the Intellectual Property Rights remain with the employer and not the employee.

Yours sincerely

Andrew Johnston

Andrew Johnston Research Management & Governance (RM&G) Manager

Approval Letter version 1.1 05.12.14 2

**Appendix E: Participant information sheet for denture wearers from Newcastle dental hospital.** 



#### Participant Information Sheet for Denture Wearers from Newcastle Dental Hospital<sup>2</sup>

Study title: Enjoyment of Eating with your Dentures.

We would like to invite you to take part in our research study about eating with dentures, but before you decide whether or not to take part, it is important to know that:

- Joining the study is entirely up to you, before you decide if you want to take part we would like you to understand why the research is being done and what it would involve for you.
- One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and to answer any questions you may have.
- Please feel free to talk to others about the study if you wish.
- The first part of the information sheet explains the purpose of the study and what will happen to you if you take part.
- The information sheet then provides you with more detailed information about the conduct of the study. Do ask if anything is unclear.

#### What is the purpose of this study?

We are doing some research into eating with dentures as we want to help denture wearers to be able to eat better and enjoy eating with their dentures. We have developed a questionnaire on eating with dentures and we need to test it out. This will be done by asking a number of questions relating to your current dentures (false teeth) using two different paper questionnaires.

At the same time, the study will look at the effect of your new dentures on your experiences of eating, including different foods and in different situations. We aim to find out the social and emotional issues related to eating with your dentures. We will ask you to complete one of the questionnaires again, a few weeks after your new dentures have been fitted. This follow up questionnaire will allow us to see if there is any difference in your eating experience before and after having new dentures.

We **will** invite you to a group discussion to share your views on the eating advice that is given to people like you who wear dentures, and to explore barriers towards eating better with your dentures.

<sup>&</sup>lt;sup>2</sup> Participant information sheet for denture wearers from Newcastle dental hospital, version 2, 11th of August 2015.

This research will form a part of a PhD thesis titled 'Assessment of the Impact of Wearing Complete Dentures on Eating Related Quality of Life and Development of Patients- centric Dietary Intervention', which is seeking to help denture wearers eat better.

#### Why have I been invited?

We need the help of patients with old or no dentures and who are about to have new dentures made.

#### 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. If you agree to take part, we will then ask you to sign a written consent form with one of the research team.

#### What would taking part involve?

Taking part in the study would involve completion of questionnaires and, if attended, participation in a group discussion.

We would you like to fill in two different questionnaires; the first questionnaire will be completed on one occasion before you get your new dentures; while, the second questionnaire will be completed on two occasions (the first copy will be completed before you get your new dentures, and the second (follow up) questionnaire will be completed after you have receive your new dentures. You can complete these questionnaires in your own home at a time convenient to you.

The questionnaires contain a range of questions related to eating experiences. Each question gives an answer scale on which we would like you to mark your opinion. The first questionnaire contains 9 questions and takes approximately 10-15 minutes to complete; while, the second questionnaire includes 24 questions and takes approximately 30-40 minutes to complete.

#### How will I get my questionnaires?

The researcher will give you a copy of the study questionnaires during one of your visits to the Dental Hospital. The researcher will provide you with a stamped, addressed envelope to send the questionnaires back to us by post or if you prefer you could bring the completed questionnaires to your next visit and the researcher will collect them from you.

#### What should I do when I get the second questionnaire?

The follow up questionnaire will be sent to you approximately one month after you receive your new dentures. You will be asked to complete it and post it back in the stamped addressed envelope provided.

#### What do I have to do if I am attended to take part in group discussion?

If you are invited to take part in a group discussion, it will be around the time of getting your new dentures and it will last approximately 45- 90 minutes. The group discussion will involve approximately 5-8 patients both; men and women, who also wear dentures. It will take place in a meeting room in the Dental Hospital or in the School of Dental Sciences. Refreshments such as beverage (e.g. tea, coffee, water) and light snack (e.g. sandwiches, fruit platter) will

be provided free of charge. You will be encouraged to talk about advice for eating with your dentures and will be asked some questions related to this topic.

#### What are the possible benefits of taking part?

Although there are no direct benefits to you personally, we hope that you will find our questionnaires interesting and that taking part will give you an insight into some of the things dentists and other health professionals think about regarding dentures.

If you participate in a group discussion, we hope that you will find it interesting and that taking part will give you an insight into some of the opinions and views on advice for eating with dentures of other denture wearers. The information that you provide during this study will help us to gain a better understanding of how wearing dentures affect eating experiences, and in the future, this study will allow us to give appropriate dietary advice to help people with dentures eat better.

#### What are the possible disadvantages and risks of taking part?

It will take up some of your time to complete the questionnaires to return them back to us and to take part in a group discussion (if you attended). However, we will give you the questionnaires during your scheduled dental appointment. If you do participate in a group discussion, you will be told the date in advance and we will provide you with as much notice as possible. It is unlikely that this study will lead to distress; however, in the unlikely event that you do become upset by discussion, the discussion will stop and you will be able to leave the discussion.

#### Who will pay any travel expenses?

In completing the questionnaires you should not incur any additional travel expenses as you will be invited to take part in the study during your usual visits to the Dental Hospital and the questionnaires can be return by post (stamped addressed envelopes will be provided). However, we will reimburse reasonable travel expenses incurred for any visit not associated with your usual visits (e.g., attending the group discussion).

#### How will my information be kept confidential?

Everything you tell us in person (discussion) or on paper (questionnaires) is completely confidential. The discussion 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 anonymised through the use of a code number unique to you. Any document or report written from the information you have provided will be anonymised and will only refer to your age, gender, occupation and the number of years you have worn a denture, but will not be linked to your name in any way. However we will keep a separate record of your name, age, gender, contact details, occupation and period of time you worn dentures against your individual code number in a separate secure 'master coding sheet' to be held along with your consent form in a secure locked filing cabinet that can only be accessed by the research team. Your data will be analysed by the research team of this study only and the results of this study may be published in academic journal or presented at a research conference or we may use data or results for future educational and teaching practice, possibly with quotes from yourself, however your identity will be kept anonymous. In either case your name will not be mentioned as part of the publication, and your opinions will not at any time be attributed to you by name.

#### Can I withdraw from the study at any time?

If you agree to take part in this study you can still withdraw at any time and without giving a reason and your ongoing dental treatment will not be affected in any way. Any data that we have previously obtained would be retained in the study. The research 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 up to the time when the data are analysed.

#### What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with the principal investigator: Prof J Mark Thomason (0191 208 8189) or the researcher: PhD student (Hassan Al-Sultani) (01912088433), who will do their best to answer your questions.

#### **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.

#### Who is organizing and funding this research?

This work is a part of a PhD project and is being governed by the Institute of Health and Society and the School of Dental Sciences, Newcastle University, and funded from PhD bench fees by Iraqi Ministry of Higher Education and Scientific Research (MoHESR). It will take place under the supervision of Prof. Paula Moynihan, Dr James Field and Prof. J Mark Thomason.

#### Who has reviewed this study?

A review of this study has been carried out by the National Research Ethic Committee (NRES) to protect your interests. It has also been subject to review by the postgraduate student's PhD supervisors and an independent assessment by academic staff.

#### If I would like to take part in the study, what should I do next?

You can contact the researcher (PhD student) Hassan Al-Sultani, who will arrange an appointment to meet you during your next visit to the Dental Hospital for the purpose of signing the consent form and getting the questionnaires and arranging the date and time for group discussion.

#### Further information and contact details:

If you require any further information, please contact:

**The principal investigator: Prof. J Mark Thomason** School of Dental Sciences Framlington Place Newcastle upon Tyne NE2 4BW Phone no. +44 (0) 191 208 8189 Email: j.m.thomason@ncl.ac.uk

#### **Prof. Paula Moynihan**

Institute of Health and Society Newcastle University Newcastle upon Tyne NE2 4BW Phone no. 0191 208 8241 E- mail: <u>paula.moynihan@ncl.ac.uk</u>

#### **Dr James Field**

School of Dental Sciences. Newcastle University Newcastle upon Tyne NE2 4BW Phone no. 0191 208 8515 E- mail: james.field@ncl.ac.uk

#### The researcher: Hassan Al-Sultani (PhD student)

School of Dental Sciences, Level 4, Neil Jenkins Wing, room 4.025. Newcastle University Framlington Place Newcastle upon Tyne, NE2 4BW Phone no. 01912088433 E- mail: <u>h.f.f.al-sultani@ncl.ac.uk</u> 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.

#### Appendix F: Consent Form for Denture Wearers from Newcastle Dental Hospital.

Study Number:

Participant Identification Number for this Study:



Consent Form for Denture Wearers from Newcastle Dental Hospital<sup>3</sup>

#### Study title: Enjoyment of Eating with your Dentures.

Name of the researcher: Hassan Al-Sultani

#### Please **<u>INITIAL</u>** all boxes

- 1. I confirm that I have read and understand the Patient Information Sheet (dated .....,version......) for the above study. I have had the opportunity to consider the information. If needed, I have asked questions and have had these answered satisfactorily.
- 2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason and without any dental care or legal rights being affected.
- 3. I understand that I am free to withdraw my data from the study up to the time when the data are analysed.
- 4. 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 to me.
- 5. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.
- 6. I understand that other researchers will have access to these 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. I give permissions for those individuals to have access to my records.
- 7. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the study (The Newcastle upon Tyne Hospitals NHS Foundation Trust) or their representatives and from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- 8. The use of the data in research, publications, teaching, sharing and archiving has been explained to me.
- 9. I consent to completing the first questionnaire on one occasion and the second one on two occasions and to return these back to the researcher.
- 10. I consent/ do not consent (delete as appropriate) to participate in a group discussion.
- 11. I agree to any discussion conducted with me being audio recorded and I understand that transcripts of my discussion will be anonymised, but that I may be anonymously quoted verbatim in published literature.
- 12. I agree to take part in the above study.

Patient name (Print):	Signature:	Date:	
Researcher (Print):	Signature:	Date:	

When completed 1 for participant; 1 for researcher site file.

<sup>&</sup>lt;sup>3</sup> Consent form for denture wearers from Newcastle dental hospital, version 2, 11th of August 2015.

Appendix G: Participant information sheet for dentists and DCPs from Newcastle dental hospital.



#### Participant Information Sheet for Dentists and DCPs<sup>4</sup>

#### Study title: Dietary advice for eating with dentures.

We would like to invite you to take part in our research study regarding eating with dentures, but before you decide whether or not to take part, it is important to know that:

- Joining the study is entirely up to you, before you decide if you want to take part we would like you to understand why the research is being done and what it would involve for you.
- Declining to participate or a decision to withdraw at any time requires no reason to be given and would have no effect on one's professional status.
- One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and to answer any questions you may have.
- Please feel free to talk to others about the study if you wish.
- The first part of the information sheet explains the purpose of the study and what will happen to you if you take part.
- The information sheet then provides you with more detailed information about the conduct of the study. Do ask if anything is unclear.

#### What is the purpose of this study?

We are doing some research into eating with dentures as we want to help denture wearers be able to eat better and enjoy eating with their dentures. We want to develop some guidance for providing dietary advice for denture wearers.

You are invited to focus group discussion to share your views on the dietary advice that is given to people, who wear dentures, and to explore barriers towards eating more healthily.

Once you have taken part in the focus group discussion on eating with dentures, you will be invited at a later date to attend a workshop at Newcastle University or another venue in Newcastle, where we will present our initial ideas on how to help denture wearers eat better and ask you for your input and feedback on these ideas.

We will also invite you back at a later date to take part in a one to one discussion with a researcher to ask you more questions on your views on the ideas (dietary intervention) we have for helping people who wear dentures eat better.

If you agree to participate in the initial focus group, you do not have to attend the subsequent workshop or take part in one to one interview if you do not wish to.

<sup>&</sup>lt;sup>4</sup> Participant information sheet for dentists and DCPs, version 3, 18th of August 2015.

This research will form a part of a PhD thesis titled 'Assessment of the Impact of Wearing Complete Dentures on Eating Related Quality of Life and Development of Patients- centric Dietary Intervention' which is seeking to help denture wearers eat better.

#### Why have I been invited?

We are looking for the help of Dental Care Professionals, who should be familiar with the above mentioned topic, known for their ability to respectfully share their opinions, and willing to volunteer about 45-90 minutes for the focus group, up to half a day for the workshop and one hour for the one to one interview.

#### 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. If you agree to take part, we will then ask you to sign a written consent form with one of the research team.

#### What would taking part involve?

Taking part in the study would involve participation in focus group, and if attended participation in workshop and/or a one to one interview. If you agree to participate you will be asked to sign a written consent form. In agreeing to participate you will be invited to a focus group discussion with the research student named below. The discussion will take approximately 45- 90 minutes and it will be held in seminar room at Newcastle Dental Hospital or in the School of Dental Sciences.

If you are take part in the workshop at a later date, it will last approximately up to half a day. Refreshments such as a beverage (e.g. tea, coffee, water) and light snack (e.g. sandwiches, fruit platter) will be provided. The workshop will be held in Newcastle University or another venue in Newcastle.

If you take part in a one to one interview, it will last for approximately one hour and it will be held in a seminar room at Newcastle Dental Hospital or in the School of Dental Sciences.

The focus group, workshop, and one to one interview are explicitly not intended to critique your practice. You will be encouraged to talk about your experiences and views regarding this topic. We will ensure that we obtain information on all relevant topics by occasionally asking specific questions related to the topic.

#### What are the possible benefits of taking part?

Although there are no direct benefits to you personally, we hope that you will find participation in the focus group, and the workshop (if attended) and one to one interview (if attended) interesting and that taking part will give you an insight into some of the things dentists and other health professionals think about regarding eating with dentures. We hope to gain a better understanding of how wearing dentures affects eating experiences, and in the future, the information gained from this study will allow us to design appropriate dietary advice or intervention to help denture wearers.

#### What are the possible disadvantages and risks of taking part?

The only disadvantages in this voluntary work is the time it takes for participation in the focus group, workshop (if attended) and one to one interview (if attended). We will try to arrange these activities at times convenient for you. It is unlikely that this study will cause you

distress; however, in the unlikely event that you do become upset by the discussion, it will be ceased.

#### Who will pay the travel expenses?

We will pay reasonable travel expenses where incurred.

#### How will my information be kept confidential?

Everything you tell us in person or on paper is completely confidential. The workshop will be audio recorded digitally and visually recorded (photographs, videos); while the focus group and one to one interview will be audio recorded only. Audio recordings will be transcribed verbatim by a professional company, once transcribed the recordings will be wiped from the recorder and the computer. Any report written from the information you have provided will be anonymized and will only refer to age, gender, occupation and years in practice, and will not be linked to your name in any way. However, we will keep a record of your name, age, gender, contact details, occupation and years in practice against your code number in a separate secure 'master coding sheet' to be held along with your consent form in a securely locked filing cabinet that only the research team has access to.

Your data will be seen by the research team of this study, and the results of this study may be published in academic journal or presented at a research conference or we may use data or results for future educational and teaching practice, possibly with quotes from yourself, however your identity and practice will be kept anonymous. In either case your name will not be mentioned as part of the publication, and your opinions will not at any time be attributed to you by name.

#### Can I withdraw from the study at any time?

Yes, if at any time you wish to withdraw just let us know. Any data that we have previously obtained would be retained in the study. The research 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 up to the time when the data are analysed.

#### What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with the principal investigator: Prof J Mark Thomason (0191 208 8189) or the researcher: PhD student, Hassan Al-Sultani (01912088433), who will do their best to answer your questions.

#### **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.

#### Who is organizing and funding this research?

This work is a part of a PhD project and is being governed by the Institute of Health and Society and School of Dental Sciences, Newcastle University, and funded from a PhD funded by the Iraqi Ministry of Higher Education and Scientific Research (MoHESR). It will take place under the supervision of Prof. Paula Moynihan, Dr James Field and Prof. J Mark Thomason.

#### Who has reviewed this study?

A review of this study has been carried out by the National Research Ethics Committee (NRES) to protect your interests. It has also been subject to review by the postgraduate student's PhD supervisors and an independent assessment by academic staff.

#### If I would like to take part in the study, what should I do next?

The researcher (PhD student) Hassan Al-Sultani will contact you to arrange an appointment to meet you for the purpose of signing the consent form and arranging the date and time for the focus group, and workshop and one to one discussion (if you have agreed to participate in these activities).

#### Further information and contact details:

If you require any further information, please contact:

#### Principal Investigator: Prof. J Mark Thomason

School of Dental Sciences

Framlington Place

Newcastle upon Tyne

NE2 4BW

Phone no. +44 (0) 191 208 8189 Email: j.m.thomason@ncl.ac.uk

#### **Prof. Paula Moynihan**

Institute of Health and Society

Newcastle University

Newcastle upon Tyne

NE2 4BW

Phone no. 0191 208 8241 E- mail: paula.moynihan@ncl.ac.uk

#### **Dr James Field**

School of Dental Sciences.

Newcastle University

Newcastle upon Tyne

NE2 4BW

Phone no. 0191 208 8515 E- mail: james.field@ncl.ac.uk

#### The researcher (PhD student): Hassan Al-Sultani

School of Dental Sciences, Level 4, Neil Jenkins Wing, room 4.025.

Newcastle University

Framlington Place

Newcastle upon Tyne

NE2 4BW

Phone no. 01912088433 E- mail: <u>h.f.f.al-sultani@ncl.ac.uk</u>

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.

#### Appendix H: Consent Form for dentists and DCPs from Newcastle dental hospital.

#### **Study Number:**

Participant Identification Number for this Study:



Consent Form for Dentists and (DCPs) <sup>5</sup>

#### Study title: Dietary advice for eating with dentures.

Name of the researcher: Hassan Al-Sultani

#### Please **INITIAL** all boxes

- 1. I confirm that I have read and understand the Participant Information Sheet (dated....., version......) for the above study. I have had the opportunity to consider the information. If needed, I have asked questions and have had these answered satisfactorily.
- 2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason and without any legal rights being affected.
- 3. I understand that I am free to withdraw my data from the study up to the time when the data are analysed
- 4. I understand that all the information related to my identity will be kept strictly confidential. The procedure regarding confidentiality of my data have been clearly explained to me.
- 5. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.
- 6. The use of the data in research, publications, teaching, sharing and archiving has been explained to me.
- 7. 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. I give permissions for those individuals to have access to my records.
- 8. I understand that data collected during the study, may be looked at by individuals from the study (The Newcastle upon Tyne Hospitals NHS Foundation Trust) or their representatives and from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- 9. I consent to participate in focus a group discussion.
- 10. I consent/ do not consent (delete as appropriate) to participate in a workshop.
- I consent/ do not consent (delete as appropriate) to participate in a one to one interview.
- 11. I agree that the focus group discussion conducted with me be audio recorded.
- 12. I agree to my participatning in he workshop (if attended) being recorded with audio/ visual recording.
- 13. I agree to the one to one interview (if attended) conducted with me be audio recorded.
- 14. I understand that transcripts of the any recordings made of my participation in this study will be annonymised, but that I may be anonymously quoted verbatim in published literature.
- 15. I agree to take part in the above study.

Patient name (Print): \_\_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Researcher (Print): \_\_\_\_\_Signature: \_\_\_\_ Date: \_\_\_\_

When completed, 1 for participant; 1 for researcher site file.

<sup>&</sup>lt;sup>5</sup> Consent Form for dentists and DCPs from Newcastle dental hospital, version 2, 11th of August 2015.

Appendix I: Topic guide for focus groups with denture wearers from Newcastle dental hospital.

#### **Topic Guide for focus groups with denture wearers** <u>Focus group instruction</u>

#### Welcome

Thank you for agreeing to be part of the focus group. Your willingness to participate is appreciated.

#### Introductions

Introducing the moderator and assistant moderator to the participants.

Introducing the participants to each other.

#### **Purpose of focus groups**

The general aim of this group discussion is to explore your opinions and views on advice for eating with dentures. We would like to hear from you about how, when and where you would like to receive an eating advice. We need your input and want you to share your honest and open thoughts with us. For today, we (the moderator or the assistant moderator) are going to facilitate the session, guide the discussion and help you share your views. We are not here today to give you our opinions.

#### **Ground rules:**

#### 1. We want you to do the talking.

- We would like everyone to participate.
- We may call on you if we haven't heard from you in a while.

#### 2. There are no right or wrong answers.

- Every person's experiences and opinions are important.
- Speak up whether you agree or disagree.
- We want to hear a wide range of opinions.

#### 3. What is said in this room stays here.

• We want you to feel comfortable sharing when sensitive issues come up.

#### 4. We will be audio recording the group.

• As we mentioned in the patient information, we have the option to record the session today.

- This makes it easier to capture everything faithfully and verbatim which can help us make an accurate analysis afterwards. The recording would be erased afterwards.
- We want to capture everything you have to say, so please **remember "only** one person can talk at once because this is being audio-recorded".
- Before you speak, you need to say your name in order to make the process of transcription easier.
- We don't identify anyone by name in our study. You will remain anonymous.

#### 5. The time.

- The group discussion may last for about 45- 90 minutes. Help yourself to coffee, tea, water, and some beverages and light snacks.
- Complete the travelling and related expenses claim form.
- Does anyone has any questions about the procedures that we could answer before we start?
- ➢ Start RECORDING .....

#### **Topic Guide Themes**

• **Opening Question:** Some dentists and dental practice staff give advice on eating with dentures for their patients, other are not. Please, could you tell me a little bit in your own words about receiving any advice on eating with your dentures (I mean your long life experience about eating advice not only at Newcastle Dental Hospital, but everywhere)?

#### **Indicative probes:**

- ✓ Who gave you it?
- ✓ When was this given and where?
- ✓ What specifically was advised?
- ✓ Was this useful for you? Why?
- ✓ How did you feel about this advice?
- ✓ What do you like best about this advice?
- ✓ If you didn't receive any eating advice, according to your point of view, why those dentists or dental staff didn't give such eating advice? Why you didn't ask them? Why you didn't look for such eating advice elsewhere?
- Do you really think that you want such eating advice to help you eat well and enjoy what you eat? Why?
- In an ideal world, if you get some advices to help you with eating, how you would like to receive such eating advice?

#### **Indicative probes:**

- ✓ What sort of information you would like; for example, do you just want facts, do you want meal or snack ideas or recipes to help you eat well and enjoy eating?
- ✓ Do you want someone to give you some practical advices in order to overcome the limitation of dentures?

- ✓ In what form you would like to receive such eating advice; for example, in form of website with notice board, internet forum, video, mobile application, booklet or leaflet. Why?
- ✓ In a form of verbal explanation by the dentist, dental assistant or may be nutritionist or dietician. Why?
- ✓ Anything else? Examples?

#### • Where you would like to receive this eating advice?

#### **Indicative probes:**

- ✓ At home.
- ✓ Any public place such as dental clinics, hospitals and community centres (e.g., support group). Why?

#### • When you would like to receive eating advice?

#### **Indicative probes:**

- ✓ During the period of teeth extraction. Why?
- ✓ During the period of denture construction. Why?
- ✓ After wearing the dentures. Why?
- What advice do you have for other women and men who are facing eating-related problems? Examples?

#### **Indicative probes:**

- ✓ Is the idea of starting with soft foods then gradually change to hard foods is useful?
- ✓ Is the idea of preparing or eating food 'differently' is helpful?
- ✓ Are the ideas of visiting the dentist regularly to adjust dentures, be patience, and it is a matter of 'trial and error' are practical to adapt to dentures?
- **Closing questions:** Is there is anything else you would like to tell me about any advice you have received for eating with dentures or anything on the type of eating advice you would like to receive?

That's all the questions we have for you, Thanks very much. These are very interesting and useful data...

Stop RECORDING....

Appendix J: Topic guide for focus groups with dentists and DCPs from Newcastle dental hospital.

#### Topic Guide for focus groups with dentists and DCPs

#### **Focus Group Instructions**

- ✓ Room,
- ✓ Agenda,
- ✓ Time ( one hour),
- $\checkmark$  Record settings,
- ✓ Consent,

#### **Focus group introduction:**

#### Welcome

Thank you for agreeing to be part of the focus group. Your willingness to participate is appreciated.

#### Introductions

Introducing the researcher and moderator to the participants

Introducing the participants to each other

#### Purpose of focus groups

The general aim of this group discussion is to help us understand your opinions and views on dietary advice for eating with dentures. We need your input and want you to share your honest and open thoughts with us.

#### **Ground rules:**

#### 1. We want you to do the talking.

- We would like everyone to participate.
- I may call on you if I haven't heard from you in a while.

#### 2. There are no right or wrong answers.

- Every person's experiences and opinions are important.
- Speak up whether you agree or disagree.
- We want to hear a wide range of opinions.

#### 3. What is said in this room stays here.

• We want you to feel comfortable sharing when sensitive issues come up.

#### 4. We will be audio recording the group.

- We want to capture everything you have to say, so please remember only one person can talk at once because this is being audio-recorded.
- We don't identify anyone by name in our study. You will remain anonymous.

#### 5. The time.

- The group discussion may last for about 45- 90 minutes. At the mid time of this discussion, there will be a break and some beverages and light snacks.
- > Do you have any questions about the procedures that I could answer before we start?
- Start RECORDING .....

#### **<u>Topic Guide Themes</u>** Theme 1: Dietary Advice for Eating with Dentures:

• Opening question: Please, could you think back over all the years that you have managed edentulous patients and tell us your view and opinion regarding giving an eating advice for denture wearers?

#### **Indicative probes:**

- ✓ Do you give out any information? If not. Why?
- ✓ Does this information include information about diet?
- ✓ What sort of information do you provide? (Content?)
- ✓ Was it a simple eating advice or more advanced healthy eating advice to change eating behaviour towards a healthier one?
- ✓ Was it a specific advice for specific group or general advice?
- ✓ In what form you provided this type of information? When and where?
- ✓ Do you think it was helpful?

### Theme 2: Barriers against providing an eating advice or a healthy eating advice to change eating behaviour:

• In your opinion, what are the barriers for providing a simple eating advice or may be a specific dietary advice for denture wearers to change their dietary behaviour?

#### **Indicative probes:**

- ✓ Is it an economic, practical, and social or time barrier?
- ✓ Personal views?
- ✓ Do you think that giving eating advice for denture wearers is your responsibility or not? If not, why and who is the responsible for raising the awareness of those people?

#### Theme 3: Methods of providing eating advice for denture wearers.

• According to your experience, what are the potential methods of providing an eating advice or a dietary advice for denture wearers to help them eat well and enjoy eating?

#### **Indicative probes:**

✓ Verbal information given by dentists, dental nurses, hygienists, and therapists. When and where? For example, during their treatment visits or review visits?

- ✓ Verbal information given by nutritionist or dietitian in people's homes, nursing homes or other community centres.
- ✓ Leaflets, a website or Mobile application, website with notice board, internet or web based forum, and may be other ways we have not even thought of yet?
- ✓ Do you think that holding support groups with denture wearers is effective in raising the awareness of this group of people?
- ✓ What sort of information you would like to give to denture wearers e.g., facts, meal or snack ideas or may be recipes to help them eating a healthier foods?
- ✓ Advice on how they prepare their food differently?
- $\checkmark$  Do you think that using fixative or paste is important to improve eating?

### Theme 4: Do you think that it is practical to provide a healthy eating advice is sufficient to change eating behaviour for denture wearers?

- ✓ If yes, How?
- ✓ Could you give us an example?
- ✓ If not, Why?
- **Closing question:** Is there is anything else you would like to tell me about the dietary advice for eating with dentures? *You are Free to make comments*.

That's all the questions I have for you, Thanks very much. These are very interesting and useful data...

Stop RECORDING....

#### Appendix K: Postcards distributed to the participants in the Engagement phase.





Your thoughts and suggestions about the role of the Public Health England (PHE) in providing guidance or a toolkit on eating with dentures.



# Write here

DCPs	
Primary care dentist	
Specialist/ consultant	

Please do not forget to pick up your free raffle entry for each comment card you submit.







Your thoughts and suggestions about displaying a video on coping strategies in the waiting room and online.

## Write here

DCPs Primary care dentist

Specialist/ consultant

Please do not forget to pick up your free raffle entry for each comment card you submit.







Your thoughts and suggestions about improving or enriching Continuing Professional Development (CPD) for the dental team relating to eating with dentures.



# Write here

DCPs Primary care dentist Specialist/ consultant

Please do not forget to pick up your free raffle entry for each comment card you submit.



Appendix L: A mock up example of the potential web-based eating advice or intervention.



Appendix M: A prototype of patient leaflet on eating with complete dentures.



### I am having problems with biting and chewing foods...



In the beginning, you may find a difficulty in biting or chewing hard or tough foods; for example, meat and vegetables and fruits, so when you eat such foods, eat them in different way (eg. slice them, peel them or use smoothie etc.). Care should be taken not to chop the foods into very tiny pieces in order to avoid the possibility of choking.

To make it easier to eat meat, try stewing or slow cooking it so it is more tender and soft.



Try adding lots of vegetables to your stew as this will make them softer to eat.



If you have soup, try dipping whole meal bread in it to soften the bread.



You could also try replacing tougher red meats with other protein sources such as fish, chicken, eggs and legumes (pea, beans and lentils).



If you are having problems eating hard cheese, you could try grating it or swapping it with a soft cheese. You can still eat the same foods but you tend to eat them differently...

## I am finding that foods stick to my dentures...



Try eating whole grain bread instead of white bread because it is less sticky.



Prepare your favourite sticky foods in a different way (eg. put dates in a smoothie).



Try toasting and baking bread slightly before eating or making a sandwich as it will be less likely to stick to pallets.



If you have problems eating lettuce and leaves as these

tend to stick to your palates, try shredded carrot or cabbage or slice peppers, cucumbers and tomatoes (with pulp and seeds removed).

> I have got quite used with chewing sticky foods so long as I take a small mouthful I manage.

> > 16

11Stba

#### • My dentures move when I bite foods



#### It is painful when I eat with my dentures

Try to persevere as things should settle down in a couple of weeks.

If they do not settle down or you have sore patches, visit your dentist to get your denture adjusted.

In the meantime, try to eat softer foods (eg. soup, stewed meat, puree veg, porridge, milk puddings, milky drinks, smoothies, minced meat, and stewed fruits).

> ...things will get better but they'll not be an instant fix.

> > 100

## 6 I find **foods gets trapped** underneath my dentures.



Try removing seeds from foods before eating them (eg. buy seedless grapes, remove pulp from tomatoes, and avoid seeded breads).

Some patients find using denture fixatives before eating helps to avoid food getting trapped.

> When a food gets stuck...drink...and take a quick swill around.

Appendix N: International conferences presentations.

1. International Association for Dental Research (IADR), 95th General Session and Exhibition 2017, San Francisco, Calif., USA.
# The Impact of Replacement Conventional Dentures on Eating Experience

HF AL-Sultani<sup>1,2</sup>, JC Field<sup>1</sup>, Thomason JM<sup>1</sup>, PJ Moynihan<sup>1</sup>

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### **Introduction & Aim**

For some patients, wearing a conventional complete denture is a complex issue in terms of food selection, and social and emotional perspectives (1).

Despite much research on the impact of edentulism and prosthetic rehabilitation on intake of foods and nutrients, there is less information on how wearing dentures impacts on the social and emotional issues around eating or Eating Related Quality of Life (ERQoL)

- To determine if replacing complete dentures impacts on ERQoL
- To evaluate the responsiveness of the ESIRE questionnaire to changes in ERQoL

### Method



Sequential Bonferroni: minimise probability of Type 1 error
 SRM (standaridsed response mean) & Cohen's D: Responsiveness of ESIRE to changes in ERQoL

### Results

- $\circ~$  77 Participants → 50 (65%) completed the study → Age range 52085, 42% male, 58% female
- $\circ\,$  High significant improvement in total ESIRE score after provision of new conventional complete dentures
- All ESIRE domains showed significant improvements



Percentage (%) of pre- and post-treatment ESIRE scores categorised as levels (low, medium, and high).

# **Discussion**

- This is the first study to longitudinally follow the effect of wearing new conventional complete dentures on ERQoL.
- There was a significant improvement in the total ESIRE scores following intervention.
- Equally, there were significant difference in each of the domains.
- This improvement could be explained by the fact that majority of participants of had been referred by from general dental practices, and most of them were suffering from particular difficulties in wearing their complete dentures. Therefore the patients might have experienced a positive impact on their ERQoL after denture renewal possibly resulting from enhanced retention, stability, and occlusion.
- It is not uncommon to have a response bias in studies involving completion of self-administration questionnaires.
- The large effect size after treatment with new conventional complete dentures indicates the magnitude or strength of this clinical outcome (the positive clinical effect of denture renewal on ERQOL). The intervention with new conventional complete dentures not only improves the functional ability to eat among denture wearers, but also enhances enjoyment of food during eating.



Pre- and post-treatment ESIRE scores (presented as mean and SE of mean), paired sample statistics and effect size of all outcome measures.

# Conclusion

- Denture replacement can directly improve ERQoL.
- The results of this study provide the first evidence of the responsiveness of the ESIRE questionnaire to changes in ERQoL among a population of conventional denture wearers in the UK.

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#### Acknowledgment

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Q<sup>-</sup><sup>®</sup> SCIENCEPOSTERS

# # 0800

**Newcastle** University

# 2. Continental European Division of International Association for Dental Research

(CED-IADR) of Oral Health Research Congress 2017, Vienna, Austria.

# Patient's Opinions on Advice about Eating with Complete Dentures

HF AL-Sultani<sup>1,2</sup>, JC Field<sup>1</sup>, JM Thomason<sup>1</sup>, RD Holmes<sup>1</sup>, MD Breckons<sup>1</sup>, PJ Moynihan<sup>1</sup> <sup>1</sup>Newcastle University, UK <sup>2</sup>Babylon University-College of Dentistry, Iraq





# 0374

#### Introduction

Previous researches showed that rehabilitation of edentulous people with complete dentures is not enough to achieve adequate enjoyment of food (1).

Therefore, providing eating advice for denture wearers is warranted (2) to increase enjoyment of food, and implementing dietary counselling might be linked to dietary and health benefits among the denture wearers (3).

However, the content of most previous dietary advice for denture wearers has been based researcher/clinician led; there has been little patient-centred research regarding eating with complete dentures.

#### Aim

The aim of this study was to explore views of denture wearers about advice on eating with complete dentures

#### Methods

- A series focus groups were held each with five patients from Newcastle . Dental Hospital, UK
- Group discussions were transcribed verbatim and analysed independently by two investigators using Framework analysis (4)
- The framework analysis included five key stages: familiarization: construction of initial thematic framework; indexing and sorting; reviewing data extracts, and data summary and display using framework.
- □ At each stage, the data were sent to a third independent reviewer to assess and triangulate the emergent themes.
- □ Inductive and iterative approaches, and constant comparative analysis were applied until data saturation was reached.

#### **Results and Discussion**

Data saturation was reached after two focus groups with ten participants. The emergent themes were:

#### Advice received about eating with dentures

The advice received from dentists was very simple or general. The denture wearer's main priority was to eat what they ate prior to wearing dentures. Most participants believed that they were more experienced than the dentists in terms of what and how to eat with dentures indicating that peer advice might be more appropriate than that from a dental health professionals.

# "No, I've never been given eating advice from any dentist, not that I've been for a long time." (P02, M65)

"But, as regards the dentist, I cannot see how a dentist can give you advice on your eating habits, when they're not on this side of your teeth, you know what I mean? I don't think they really could give you a lot. You know. You could tell you what, as I said before, tell you what foods to eat, which is good for ya, but whether you could cope with that, whether your denture stays, is another matter." (P04, M69)

The advice recommended by the participants were: perseverance and patience, preparing and eating foods differently, and using denture fixatives occasionally - highlighting the importance of denture fit and stability during eating with dentures. However, the denture fixatives were not useful in all instances.

Advice recommended by the

denture wearers

"Don't give up on it, you've got to persevere that little bit." (P02, M65) You see, you can still eat the same foods but you tend to eat them differently." (P07, M59) "Now I've got to chop an apple up slice it up into pieces and the sam (P08, M85)

(P08, M85) "Erm, I eat a lot of fruit, and I find when J put the paste on, I can manage to eat some foods but you know the one's that actic because it just takes the paste straight off. So halfway through an orange the teeth are moving all over the place again. You know, so it depends on, I still haven't found a paste thet'r and/u acod' "(202 E65) paste that's really good." (P03, F65)

#### The concept of denture fit and stability

Most participants thought that getting properly fitting dentures can improve eating and could help the denture wearers eat what they choose. This could be achieved through continuous perseverance and visits to the dentist to adjust the dentures

> "Everybody can eat the same thing here, but they'd have a different effect, effect on, depending how your teeth fit...., the leeth themselves stopping, and stopping them from moving, it makes it easier for me to eat anything more or less that I choose". (P02, M65)

> "..., and the secret of it is getting them to fit properly, if you've got good fitting dentures that's the se of it...." (P01, F74). secret "I've done adjustment to the

dentures about five times, I've got one, one more but I think it's about six or seven times now. So that makes it easier from the eating side. (P02, M65)

Acknowledament This study was supported by a scholarship from Iraqi Ministry of Higher Education and Scientific Research

#### Preferred format of receiving eating advice

A leaflet format with a link to a website for further information about eating with dentures was proposed as the preferred mode for delivering advice pertaining eating with complete dentures

"You might, you might sit if you pull advice down. Where before you used to eat an apple biting it, you might not be able to bight it now with your new dentures but you can still eat if if you just slice it up. You know, things like that. Just-General, erm, a general thing....and therefore, for a dentist, that if there is executed by the second just if they're in coming here, the dentist here, instead of having a lot of paraphernalia sent out, just a little leaflet, as X said, 'You might have problems eating this but this, we suggest, is how you could cope with it." (P08, M75)

"I would say a leaflet and have something on the internet, because most people are on the internet nowadays." (P09, F66)

1423 🚆 2002 Carl

#### Conclusion

- Peer delivered advice might be useful especially in a leaflet format with a link to website, where people can share information
- Patience, perseverance, adjustment of the dentures, and preparing and eating foods differently were the main things recommended by patients
- Currently, dentists only give simple and general advice on eating, and the denture wearers did not think the dentist was the most appropriate person to advise them on eating
- Findings of this study are being used to formulate appropriate eating advice for the denture wearers

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3. International Association for Dental Research 96th General Session and Exhibition and Pan European Regional Congress (IADR/PER) 2018, London, UK.



al, 2015). Providing eating advice for denture wearers is beneficial in terms of overcoming functional problems associated with eating with complete dentures. However, there is few patient-centred research regarding eating with complete dentures. Therefore, the objective of this study was to use an iterative co-design process to integrate scientific evidence from literature including systematic reviews, and working together with service users (i.e., denture wearers) and health care providers (i.e., dentists, and DCPs) to inform eating advice and intervention for complete denture wearers.

#### Aims

The aim of this study was to produce patient-centred eating advice and inform intervention development for complete denture wearers.

#### Methods and Results

The study adopted a co-deign approach similar to that used by O'Brien et al. (2016). Results of each stage determined the methods for the next; therefore, this section is a combined methods and results, figure 1.

Stage 1	Figure 1: Stages of co-	design for producing of	a patient-centred leaflet	on eating with complete dentures.
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Literature review including existing systematic review, meta-analysis and met-regressions	Qualitative study (focus groups with denture wearers, dentists and DCPs)	Cohort study on patients (complete denture wearers)				
	Outcomes: Evidence statements					
Stage 2						
	Research team meeting					
Outcomes: Opportunities for Development						
Stage 3						
Engagement with dental health professionals (n=30)						
Outcomes: Feedback (in form of oral explanation and comments on postcards) about the Opportunities for Development						
Stage 4						
	Prioritisation exercise					
Outcomes: Core Concepts (CCs) for future development of eating advice and web-based information defined. CCs included producing patient leaflet and developing initial ideas for a website on eating with dentures. Patient leaflet was selected as first priority. Hand-drawing prototypes produced.						
Stage 5						
Professional design of the leaflet						
Outcomes: The first prototy	pe of a patient-centred leaflet on eating with compl	ete dentures produced				

#### Conclusions

This iterative co-design process engaged service users to:

- Produced a patient-centred leaflet on overcoming eating problems with complete dentures.
- Identified Core Concepts to fully address the issue of supporting edentulous people to eat well with dentures.
- \* Developed initial ideas for the future website, which might include a web-based dietary behavioural change intervention for denture wearers.

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