Investigating parental attitudes to randomised controlled trials in primary dental care: The IMPACT Study

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Abstract

BACKGROUND: Evidence-based practice is of increasing significance within dentistry, with randomised controlled trials (RCTs) regarded as the gold standard. There is however, uncertainty regarding parental understanding of RCTs, and the emotional effects of their child's participation.

AIMS: To quantify whether their child's participation in a RCT impacted on parents' dental anxiety (MDAS), oral health related quality-of-life (OHIP-14) and attitudes (dental health beliefs (DHB) and sense of coherence (SOC-13)) to their own dental care and that of their children, and whether these constructs were associated with socio-demographic characteristics. To investigate parents' views, knowledge and experience around their child participating in dental research.

METHODS: A mixed methods approach was adopted. A longitudinal survey (questionnaires at baseline and 18 months) was conducted of parents whose children were FiCTION RCT participants or had been screened for FiCTION but did not participate. Semi-structured face-to-face qualitative interviews were completed with a subsample of these parents.

RESULTS: 261 parents completed a baseline questionnaire; of these, 55 were parents of FiCTION RCT participants. 192 parents also completed a follow-up questionnaire and were included in an analysis of change over time. Quantitative analysis showed no difference at baseline in MDAS, OHIP-14, DHB or SOC-13, between FiCTION participant parents (Mean (SD) score 11.8 (6.3), 6.7 (6.1), 9.2 (1.6), and 63.7 (7.8) respectively) and FiCTION non-participant parents (10.9 (4.8), 6.7 (6.5), 9.4 (1.9), and 62.9 (7.0) respectively). Nor was there a difference between groups for the very limited change in scores over 18 months. Socio-demographic variables were not significant predictors of change over time for any outcomes. The 18 parents who participated in qualitative interviews indicated positive attitudes towards research in primary dental care, but there was no noticeable differences in their definitions of good dental health or perception of the facilitators and barriers thereof.

CONCLUSION: There was no difference at baseline or over time between FiCTION participant parents and non-participant parents for dental health outcomes. Parents valued dental research in primary care, but perceived it as complex and challenging. Further research should explore the effect of parental education on the perceived importance of primary dental care research.

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List of Abbreviations

ADHS	Adult Dental Health Survey
ANCOVA	Analysis of covariance
BDA	British Dental Association
CCT	Clinical Controlled Trial
CDHS	Dental Health Survey of Children and Young People
CQC	Care Quality Commission
CRC	Clinical Research Collaboration
CSO	Chief Scientific Office
DA	Dental anxiety
DAS	Dental Anxiety Scale instrument
DBS	Dental Beliefs Survey instrument
DFS	Dental Fear Survey instrument
DHB	Dental Health Beliefs (DHB) instrument
DHRSU	Dental Health Services Research Unit
DIDL	Dental Impact on Daily Living instrument
DPB	Dental Practice Board
EIDM	Evidence-informed decision-making
FCEs	Finished Consultant Episodes
FFS	Fee For Service
FiCTION	Filling Children's Teeth: Indicated or Not?
GDP	General Dental Practitioner
GDS	General Dental Service
GOHAI	General Oral Health Assessment Index instrument
GP	General Medical Practitioner
HEIs	Higher Education Institutions
HRA	Health Research Authority
IMPACT	Investigating Parental Attitudes to Randomised Controlled Trials in Primary Dental Care
JLA	James Lind Alliance
KT	Knowledge translation
LCRN	Local clinical research networks

MDAS	Modified Dental Anxiety Scale instrument
MHRA	Medicines and Healthcare Products Regulatory Agency
MRC	Medical Research Council
n	Number
NECS	North of England Commissioning Support
NHS	National Health Service
NIHR	National Institute for Health Research
NRES	National Research Ethnics Service
NRS	NHS Research Scotland
OHIP	Oral Health Impact Profile instrument
OH-RQoL	Oral Health-Related Quality of Life
OIDP	Oral Impact on Daily Performance instrument
PI	Principal Investigator
PSP	Priority Setting Partnerships
R&D	Research and Development
RA	Research associate
RCPCH	Royal College of Paediatrics and Child Health
RCT	Randomised Controlled Trial
REB	Research Ethics Board
REC	Research Ethics Committee
SAOHS	Scottish Adult Oral Health Survey
SCPMDE	Scottish Council for Postgraduate Medical and Dental Education
SDPBRN	Scottish Dental Practice Based Research Network
SES	Socioeconomic status
SOC	Sense of Coherence
SPSS	Statistical Package for Social Sciences
SSI	Site-Specific Information
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
SWAT	Study Within a Trial
UDA	Unit of Dental Activity
UK	United Kingdom
UKCRN	UK Clinical Research Network
USA	United States of America
WHO	World Health Organisation

Chapter 1: Introduction – dentistry and dental research in England and Scotland

The focus of this thesis is the views of parents on their child participating in research within primary dental care and the impact on parents of such participation. The dental landscape is evolving with changes in the prevalence of disease as well as in patient expectations. With devolution having occurred in Scotland in 1997, the National Health Service (NHS) dental models in Scotland and England continue to diverge. The need for evidence-informed decision-making within healthcare is, nonetheless, consistent. Whilst England and Scotland may be approaching the challenge independently, there is recognition of a common goal of improving dental services in primary care, since the overwhelming majority of dental care is provided in that setting. One key area of mutual interest is in reducing inequalities in dental health, including for child patients.

1.1. Introduction

Many changes have taken place within dental services in the United Kingdom (UK) since the formation of the NHS in 1948. Although dental health continues to improve, demand for dental health care is rising for several reasons; the population is increasing, more people are living longer, often with multiple long-term conditions and technological advances mean that new treatments are increasingly available (Steele 2009). As a result, health services are treating more people than ever before (Steele 2009). The pattern of oral disease has changed since the NHS began, and continues to change, with a decrease in prevalence of some dental health problems e.g. dental decay but an increase in others such as moderate tooth wear (Steele et al. 2012). Patient demand, as opposed to need, has also increased and changed in nature as newer generations aspire to higher standards of dental care and aesthetics (Steele et al. 2012).

Despite differences in NHS dental services between Scotland and England, both jurisdictions have finite resources and share the same goal of making decisions to ensure the best possible outcome for all patients (Illingworth 2013). Decisions must be made in a systematic, consistent and transparent way, with the aim of fair and rational distribution of these resources across different patient groups, and across competing demands (Illingworth 2013). The emphasis and importance placed on evidence-based practice and policy is key; it is difficult to justify the funding of novel treatments with outcomes that are either unproven or unclear, especially when many

proven interventions and important elements of healthcare remain either unfunded or cannot be fully accessed by sections of the population (Illingworth 2013). The need for commissioning decisions that lead to improved dental health, by utilising the best available evidence for the prevention and management of oral diseases, is an essential aspect of local delivery of dental services (Illingworth 2013). A critical aspect of this process involves “building, testing, adapting and adopting” evidence-based, best practice, to achieve quality health improvement and cost efficiency (Illingworth 2013). The National Institute for Health and Care Excellence (NICE)’s role is to improve outcomes for people using the NHS and other public health and social care services by: producing evidence-based guidance and advice for health, public health and social care practitioners; developing quality standards and performance metrics for those providing and commissioning health, public health and social care services; and providing a range of information services for commissioners, practitioners and managers across the spectrum of health and social care.

This introduction is presented in four main sections to highlight the need for research in primary dental care in the UK. It commences with an overview of dental health in the UK and how the population’s dental health has changed in recent decades. The second section briefly explores how NHS dental services for adults and children in England and Scotland are provided “on the high street”. The third section explains the role of evidence-informed decision-making and research within dentistry and includes an overview of recent changes in the funding and infra-structure of research. The fourth section includes an overview of current randomised controlled trials (RCTs) in primary dental care before concluding with a summary of the thesis content by chapter.

1.2. Dental health in the UK

1.2.1. *Disease aetiology and historical context*

Dental caries, also known as tooth decay, is a process of destruction of tooth tissue by toxins produced by bacteria living in the mouth metabolising sugars in the diet. Its negative clinical consequences include pain and infection and the need for dental treatment (Ricketts et al. 2013).

Periodontal disease, also known as gum disease, destroys the ligaments and bone that support teeth. Susceptible patients develop the disease because their immune system reacts to the accumulation of bacterial plaque (Van Dyke and Sheilesh 2005). Bacteria and their products within the plaque cause inflammation in the tooth's supporting tissues and the consequences can lead ultimately to tooth loss (Preshaw 2015). It is a chronic silent disease until at an advanced stage (Tervonen and Knuuttila 1988).

As far as the UK is concerned, in the 17th and 18th centuries there was no distinct profession of dentistry although some barber-surgeons became known as 'operators for the teeth' (Bishop 2014). The British Dental Association (BDA) was founded in 1880 when dentistry became recognised as a profession (British Dental Association, Gelbier 2005a). However, it was not until the 1921 Dentists' Act that the profession was closed to anyone who had not trained at a school of dentistry recognised by the newly created Dental Board (HM Government 1921). The School Medical Service, established in 1907, led to compulsory medical inspections in public- and elementary schools. At some point thereafter, these inspections were extended to include the teeth and oral sepsis and, whilst originally carried out by doctors, responsibility subsequently shifted to dentists (Gelbier 2005c). Over time, some dental care was also provided for pre-school children, expectant and nursing mothers (Gelbier 2005b). In the early-mid 20th century, only about 6% of the 13 million working population of the UK utilised the benefits made available under the National Health Insurance scheme (Levitt et al. 1999). The NHS was established in 1948 as a publicly-funded service which to this day remains "free at the point of need" with a few notable exceptions (one being primary care dental services) (Gorsky 2008).

Prior to the founding of the NHS, the general state of dental health in the UK was very poor; many people had no natural teeth, dental decay was widespread and infection was common. Understandably, with such a backlog of untreated disease the initial demand on NHS dental services was huge, and in the early years of the service, millions of sets of complete dentures were made to alleviate pain and return people's mouths to function (Steele 2009). In 1952, as demand and costs for the NHS were rising, charges were introduced for dentistry, prescriptions and glasses. The NHS continues to have unwavering support amongst the public which

endures across generations (Evans and Wellings 2017). Nonetheless, Wanless (2002, 2004) has raised a number of core issues which are as pertinent to dentistry as they are to any other sector of the NHS; the need for safe, high quality, patient-centred health care with fast access to meet rising expectations.

1.2.2. *Dental health trends in the UK*

The improvement in population dental health in the UK over the last 40 years can be seen from the UK Adult and Child Dental Health Surveys (Steele et al. 2012, Murray et al. 2015). The first UK Adult Dental Health Survey (ADHS) was conducted in 1968 with subsequent decennial surveys in 1978, 1988, 1998 and 2009 (Steele et al. 2012). The ADHS investigates the current state of adults' dental health, their experiences of dental care and their access to dental services; it also measures how this has changed over time since 1968. The first Dental Health Survey of Children and Young People (CDHS) was conducted in 1973 in England and Wales (Murray et al. 2015) and subsequent surveys have taken place every ten years. Scotland and Northern Ireland were included in the CDHS from 1983. Both the adult and child surveys were commissioned by the UK Health Departments to help health authorities/boards effectively plan local dental services and to show the extent to which government dental health targets were being met (Steele et al. 2012). Unfortunately, Scotland decided not to take part in the 2009 ADHS survey (Steele et al. 2012) or the 2013 CDHS (Murray et al. 2015) making full within-UK comparisons impossible. Instead, from 2008 onwards, data on dental health in Scotland has been under the same umbrella as the Scottish Health Survey (Marcinkiewicz 2014) which does not include a dental examination and focusses only on adults. The Scottish Adult Oral Health Survey (SAOHS) was carried out as a pilot project (SAOHS Report Writing Group 2017) in 2015/16 with the principal aim being to assess the feasibility of conducting a survey of adults' (aged 45 years or older) dental health across Scotland. Whilst the pilot study was deemed successful (SAOHS Report Writing Group 2017), it is unclear at this stage when the SAOHS main study will be completed. Prior to this pilot study, the most recent epidemiological survey which included a professional oral examination of the dental health of Scotland's adult population was carried out as part of the 1998 UK ADHS (SAOHS Report Writing Group 2017).

These epidemiological surveys show that the North of England, covering an area from the Scottish Borders to Merseyside and north-east Lincolnshire, has the highest proportion of children and adults in England attending an NHS dentist (NHS Digital 2017a). This area has previously been found to deliver the largest number of courses of dental treatment (12.8 million, a 32% share) in England (Health and Social Care Information Centre 2015). This exceeds the national average by 14.5%. The reasons for such a north:south difference are unclear, but it could be postulated that this may be due to regional differences in the proportional split between NHS and private dental care provision.

The most important trend shown in the recent ADHS is a decrease in caries experience, shown by a decrease in the average number of teeth per individual with signs of disease or disease experience (fillings).

> "*The prevalence of dental caries and the need for restorative treatment may have peaked for young adults in the 1980s and is now in sharp decline, but many older adults require complex treatment just to maintain their dentate state after the effects of higher decay rates in their past. The reasons for the continued reduction in dental caries are not clear, welcome though they are, and understanding the reasons may be important if we hope to maintain the trajectory*" (White et al. 2012, p. 572).

The CDHS provides information on the dental health of children in the UK, measures changes in dental health since the last survey and provides information on children's experiences of dental care and treatment and their oral hygiene. Since 1983, this has involved 5-, 8-, 12- and 15- year olds. The 2013 survey provided statistical estimates of the distribution and severity of oral diseases and conditions of 5, 8, 12 and 15-year-old children in England, Wales and Northern Ireland, using data collected during dental examinations conducted in schools on a random sample of children (Holmes et al. 2016). The decay experience of children has decreased considerably in the whole of the UK since 1973 (Murray et al. 2015) and decay into dentine in 5-year-olds is increasingly found within only a minority of children (Murray et al. 2015). Direct comparison between data collected in the UK in 1973, 1983, 1993 and 2003 is difficult due to improvements and changes in the diagnostic criteria used to assess dental decay by researchers, and with Scotland's decision not to take part in future

ADHS or CDHS. Although improvements in children's dental health have been seen at every survey, the rate of improvement in England, Wales and Northern Ireland slowed between 2003 and 2013 (Murray et al. 2015). In 2013, 46% of 15 year olds and 34% of 12 year olds in England, Wales and Northern Ireland had "obvious decay experience" in their permanent teeth (Health and Social Care Information Centre 2015). This represented a reduction from 2003 when the comparable figures were 56% of 15 year olds and 43% of 12 year olds in England, Wales and Northern Ireland. The surveys have also confirmed that children from lower income families (eligible for free school meals) in England, Wales and Northern Ireland continue to be more likely to have oral disease than other children of the same age, and that the extent of their tooth decay is also greater (Health and Social Care Information Centre 2015). In Scotland, more than two thirds (71%) of primary one (P1) children (4-5 years old at start of the school year) had no obvious decay experience in their primary teeth in 2018; a huge improvement from 45% in 2003 (Information Services Division 2018b). In 2018, the average number of teeth affected by obvious decay experience in P1 children was 1.14, less than half of the average number of teeth affected in 2003 (2.76) (Information Services Division 2018b). However, even with the introduction of Childsmile in Scotland (Scottish Government 2005), a national programme to improve the dental health of children and reduce inequalities in dental health and access to dental services, national inequalities remain, with only 56% of P1 children having no obvious decay experience in the most deprived areas compared to 86% in the least deprived areas (Information Services Division 2018b).

In England, the rate of tooth extractions for decay per 100,000 population for 0 to 10 year olds is calculated annually. This figure is derived from the number of Finished Consultant Episodes (FCEs) for admitted patients for extraction due to decay of one or more decayed primary or permanent teeth, recorded as either surgical removal or simple extraction along with a primary diagnosis of dental caries (tooth decay or cavities). This indicator captures those who have most likely been missed in primary care dentistry as the tooth decay is severe enough that they need hospital treatment. It is therefore likely that they have not regularly attended the dentist as if they had gone to the dentist their dental caries should have been picked up earlier and not reached the stage of extraction. Treatment occurring in secondary care implies children are having their teeth extracted under general anaesthetic and means that

decay in the tooth has reached extreme levels. In 2015/16, the rate was 425 per 100,000 population (NHS Digital 2017c). This is significantly lower than all previous years since the start of the time series in 2011/12. There is, nevertheless, on-going regional variation in England in the level of hospitalisation for tooth extractions; rates for most regions fell significantly in 2015/16 compared to the previous year but exceptions were evident in the North East, East and South West of England where the rates remained the same as in previous years (NHS Digital 2017c).

1.3. NHS Dental Services in the UK

Whilst dental health needs in the UK are changing, overall, health services still adhere to the primary principles of the NHS as set out in 1948. Since devolution in 1997, however, administrations in Edinburgh, Cardiff and Belfast have taken different political directions with regard to health (Morphet and Clifford 2018). England has continued on the path to more patient choice and transparency; the Welsh Government has re-affirmed its rejection of a private or mixed economy in health care; the Scottish Government has interfered little in its healthcare system (Cylus et al. 2015) while in Northern Ireland, there has been very little change in the NHS. Politicians often defend differentiation across the NHS as a way to make health care more responsive to local needs, yet there is some concern that the emphasis on uniqueness may increasingly undermine mutual learning between devolved nations, making it more difficult to compare performance and outcomes between the four constituent services (Bevan et al. 2014).

In the UK, dental care is provided through three services: (1) General Dental Services (GDS) in the community; (2) secondary and tertiary dental services in acute hospitals for procedural and/or patient complexities, often requiring a specialist clinician; (3) Salaried Dental Services (England, Wales, Northern Ireland) or Public Dental Services (Scotland) for patients (both adults and children) who cannot access general dental services due to additional special needs. Throughout the UK, the majority of dental treatment for adults and children is provided by the NHS GDS and it remains the first point of contact for patients to access NHS dental treatment. The majority of GDS care is provided by independent contracted dentists (“High Street dentists”).

It is beyond the scope of this thesis to cover the nuances between NHS dental services across the UK, as there are a number of differences in how these services are organised and managed. Nonetheless, since the current study involved recruitment of participants from England and Scotland, the main differences in GDS care between these two jurisdictions are summarised below.

1.3.1. *General Dental Services*

Prior to 2006, dentists in England and Scotland worked under a GDS contract, largely unchanged since 1951, in which dentists were reimbursed for each item of treatment they provided (Fee For Service (FFS)). This model of payment led to concerns, by the late 1980s, that dentists may have been over treating patients (Schanschieff 1986) since, despite a population emerging with better dental health than previous generations, there was no financial incentive to keep patients disease-free. As a direct result, an element of capitation for registering and maintaining patients was introduced in 1990 (Steele 2009) in an effort to encourage more prevention of disease. Dentists were still remunerated largely on a fee per item basis but with additional capitation payments for children and a relatively small financial reward for providing adult continuing care and NHS commitment payments. This proved to be extremely popular with dentists and patients in England and Scotland. After 1990, resources were held centrally and administered through the Dental Practice Board (DPB) with dentists submitting claims for reimbursement to the DPB once a course of dental treatment was completed. With this system, local NHS organisations had relatively little control over the distribution and location of NHS primary care dental practices, resulting in dental services being driven by historic demand and dentists' geographical preferences rather than clinical need (Landes and Jardine 2010) which in turn often resulted in inequalities of access for local populations (Harris and Haycox 2001, Drugan et al. 2007). Nonetheless, due to a higher than expected expenditure and earnings, in 1992 the government implemented a 7% fee cut in the fee-for-service items for 1992/3, in order to claw back some of the "overpayments" made in 1991/92 (Bloomfield 1992). Unsurprisingly, this was unpopular with dentists who regarded this not as an "overpayment" but as proof that they had been successful in delivering NHS dental care and resulted in a significant movement of dentists away from NHS provision to private dentistry in both England and Scotland. In a 1993 BDA survey 75% of GDS

dentists said that they received at least three quarters of their earnings from the NHS and just 12% received less than one quarter but by 1999 those figures had changed to 58% and 18% respectively (HM Government 2001).

1.3.1.1. General Dental Services in England

Under the arrangements of the 2006 contract, a new measure of dentist activity – the Unit of Dental Activity (UDA) – plus an associated banded set of patient charges were introduced in England and Wales. The UDA system ended the traditional non-cash-limited fee per item arrangement and introduced a cash-limited system based on delivering agreed levels of dental activity for an agreed price per UDA. The number of UDAs received by a general dental practitioner (GDP) for a course of treatment awarded can be 1, 3 or 12, depending of the complexity of the treatment received and the number of UDAs for a given level of complexity is the same across all practices, yet the actual financial value of each UDA varies and is specific to each practice. Activity undertaken during a 12-month 'test' period during 2004–2005, prior to the introduction of the current dental contract in 2006, was used as the basis for calculating dental practices' contract values and activity thresholds. Differences in the volume and type of dental treatment activity conducted during this reference period is the reason for the financial value of a UDA varying between dental practices. The implication of this is that individual GDPs receive different financial amounts for completing the same types of treatment on their respective patients. Dental contracts are agreed locally by an area team of NHS England responsible for that region and can differ even within that area depending on the commissioning intention and delivery expectation (NHS England 2016). As a general rule, NHS England will not renegotiate or recalculate a practice's UDA rate (NHS England 2016). Unsurprisingly, practitioners have highlighted the unfairness of variable UDA rates between practices. Variation in the annual UDA targets contracted to individual practices, difficulty in achieving the annual UDA targets for children and adults, and anxiety resulting from the financial implications of underperformance (Chestnutt et al. 2009, Hudson 2007) have been identified as key reasons for the need for further fundamental reform of GDS in England.

The government commissioned an independent review into NHS dental services in England in 2008/9 which recommended a series of major changes in NHS primary

dental care delivery. A new dental prototype contract has been trialed since 2016, building upon previous dental contract pilots in 2011 and 2013, but given the analysis of the data collected and the feedback and views of the dental practices involved in the prototype contract, it has been recommended that further work and adjustments are needed before the new contract should be widely implemented (Department of Health & Social Care 2018).

In the interim, the unpopular 2006 contract remains in place. Over half of young (up to 10 years post-graduation from first dental degree) NHS dentists have indicated they plan to turn away from NHS dentistry in the next five years, with 42% stating intentions to move into private practice (British Dental Association 2018). In the 24 month period ending 30 September 2017, 22.1 million adult patients in England were seen by an NHS dentist, representing 51.3% of the adult population (NHS Digital 2017b). The number of children seen by an NHS dentist in England in the 12 months to 30 September 2017 was 6.8 million which equates to 58.5% of the child population (NHS Digital 2017b). Given that there is a clear need to reduce inequalities between patients in access to and outcomes from healthcare services and to ensure services are provided in an integrated way to try to reduce health inequalities, this highlights the challenges for both adults and children accessing dental care in England.

1.3.1.2. General Dental Services in Scotland

Since 1999, responsibility for the organisation and budget for the NHS in Scotland is a matter for the devolved administration (Robson 2016). NHS GDS in Scotland are provided by general dental practitioners (GDPs) contracted with, or employed by, their local NHS Board to provide general dental care and treatment. These GDPs are independent contractors who can choose whether to join or resign from a NHS Board's dental list. Within NHS general dental practice in Scotland, all patients, regardless of age or other socio-demographic characteristics, are entitled to free check-ups. Treatment costs to patients are subsidised by the health service with the patient contributing 80% of the cost of NHS treatment, up to a maximum of £390 per course of treatment. Scotland continues to operate under the 1990 GDS contract (Scottish Government 2019), within a remuneration model of fee per item of service, capitation payments and continuation fees (where dentists are rewarded financially per month for maintaining a continuing care arrangement with adult and child

patients). The GDS accounts for 75% of all NHS dental services spending in Scotland (Padilla 2014). Whilst it has long been accepted that the current contract in Scotland is flawed, given the challenges faced with implementing successful contract reform in England, there is wariness to make changes. Likewise, despite confidence that Scotland can formulate solutions to the current and increasing difficulties in delivering and funding NHS dentistry, it has been suggested that they can learn lessons from the English pilots and other such initiatives (Scottish Government 2005).

In Scotland, 'registration' is defined as 'any patient registered with a practicing NHS dentist'. Change in registration policy between April 2006 and April 2010 has impacted the registration rates: before April 2006, anyone who was registered but did not attend the dentist within 15 months was de-registered from the dentist. This 'grace period' was extended to 36 months in April 2006, 48 months in April 2009 and then 'lifetime registration' i.e. the patient will remain registered with that dentist unless they move to another dentist, or upon death was introduced in April 2010. As of 30 September 2017, 92.5% of the Scottish population of 5.4 million was registered with an NHS dentist; children were more likely to be registered with an NHS dentist than adults (93.8% and 92.2% respectively); 96% of adults living in the most deprived areas were registered with an NHS dentist compared to 86.5% in the least deprived areas (Information Services Division 2018a). Registration rates between children living in the most and least deprived areas are similar, suggesting fewer challenges for children accessing dental care in Scotland than in England.

As of 30 September 2017, 70% of the 3.5 million registered patients had seen an NHS dentist within the last two years: children were more likely than adults to have seen an NHS dentist within the last two years (84.5% compared to 67.4%); with those from the most deprived areas less likely to have seen their dentist within the last two years than those from the least deprived areas (80.5% compared to 89.5% of children and 62.9% compared to 73.5% of adults) (Information Services Division 2018a). This suggests that whilst children living in the most and least deprived areas are equally likely to be registered with an NHS dentist, more work is required in Scotland to support the further reduction of health inequalities in GDS.

1.4. Knowledge production

Research on the effects of healthcare treatments often overlooks the shared priorities of patients, carers and clinicians (Partridge and Scadding 2004). The pharmaceutical and medical technology industries and academia play essential roles in developing and testing new treatments, but their priorities are not necessarily the same as those of patients and clinicians. Many areas of potentially important research are therefore neglected, and there is often a mismatch between the research being carried out and the research evidence needed by patients and clinicians every day (Tallon et al., Crowe et al. 2015). This can lead to an avoidable waste of precious research funds (Chalmers and Glasziou).

In 2004, the James Lind Alliance (JLA), a non-profit making initiative, was established to bring patients, carers and clinicians together in Priority Setting Partnerships (PSPs). PSPs aim to help these various stakeholders work together to agree the most important treatment uncertainties affecting their particular interest, to influence the prioritisation of future research in that area and to address uncertainties about the effects of a treatment in order to determine if it should be accepted as a routine part of clinical practice (Partridge and Scadding).

The National Institute for Health Research (NIHR) was created in 2006 with the vision ‘to improve the health and wealth of the nation through research’ in the NHS (National Institute for Health Research 2019c). The NIHR is a ‘virtual’ organisation, funded by the UK Department of Health, and designed to fund leading-edge scientific research, to drive faster translation of basic science discoveries into tangible benefits for patients and to create the best possible conditions for inward investment by the life-sciences sector (National Institute for Health Research 2019c). The NIHR covers all health and care therapeutic areas and funds the infrastructure of the JLA to oversee the processes for PSPs.

1.4.1. *Patient public involvement*

It has been argued that the EIDM model is not as patient-centered as it is sometimes assumed to be and that it should embrace patient involvement in research (Greenhalgh et al. 2015). INVOLVE was established in 1996 to support active public involvement in NHS, public health and social care research (INVOLVE 2019) and is

now part of NIHR and one of the few government funded programmes of its kind in the world. As a national advisory group its role is to bring together expertise, insight and experience in the field of public involvement in research, with the aim of advancing it as an essential part of the process by which research is identified, prioritised, designed, conducted and disseminated (Hayes et al. 2012). When the Health Research Authority (HRA), an executive non-departmental public body, sponsored by the Department of Health and Social Care, was set up in 2011 in England, a strong commitment was made to involve patients and the public in health research (Elliot 2013). INVOLVE, NIHR and the JLA work together to support integrated learning and development opportunities for researchers and members of the public.

1.5. Knowledge translation

EIDM involves the integration of the best available research evidence in the context of community preferences, local health issues and available public health resources (Armstrong et al. 2013), and requires an unbiased assessment of the evidence-base. While decision-makers are under increasing pressure to use research evidence to inform their decisions, significant barriers have been identified, ranging from lack of relevant research, having no time or opportunity to use research evidence, policymakers and other users not being skilled in research methods, and the costs of providing appropriate healthcare (Campbell Collaboration 2014, Oliver et al. 2014). In attempts to address these barriers, a range of strategies, known collectively as Knowledge Translation (KT), have been identified. KT has been defined as “The synthesis, exchange, and application of knowledge by relevant stakeholders to accelerate the benefits of global and local innovation in strengthening health systems and improving people’s health”(World Health Organisation 2019).

Translational research looks at how best to translate research into practice and/or policy e.g. research that addresses particular gaps in translation (Davidson 2011). The translation of research findings into practice is unpredictable and can be a slow and haphazard process (Clarkson et al. 2010, National Institute for Health and Clinical Excellence 2011).

1.5.1 *The Cochrane Collaboration*

Archibald Cochrane championed using RCTs throughout most of his professional career and strongly criticised the lack of reliable evidence behind many commonly accepted healthcare interventions at the time (Shah and Chung 2009). His call for systematic reviews of the evidence led to the creation of The Cochrane Collaboration in 1993. This not-for-profit organisation works in more than 120 countries to produce credible, accessible health information free from commercial sponsorship and other conflicts of interest, and is internationally recognised as providing the benchmark for high quality information on the effectiveness of health care (Warner 2013). The Cochrane Collaboration has defined KT as: “the process of ensuring that health evidence from our high quality, trusted Cochrane Reviews is used by those who need it to make health decisions” (Cochrane Collaboration 2018).

1.6. Improving dental care through research

1.6.1. *The dental research policy agenda in the NHS*

It is mandated in the NHS Constitution in England that 'the NHS aspires to the highest standards of excellence and professionalism’ and has a ‘commitment to innovation and to the promotion, conduct and use of research to improve the current and future health and care of the population’ (Department of Health 2015, p. 3). It also states that the NHS commits *“to inform you of research studies in which you may be eligible to participate”* (Department of Health 2015, p. 8).

In January 2014, dentists in Scotland were notified of new arrangements for clinical audit beginning in the 2013-2016 clinical audit cycle, and informed that participation in research was eligible for up to five hours audit credit (Scottish Practice Based Research Network 2014). These arrangements remain in place in the 2016-2019 clinical audit cycle. Eligible research has been defined as that which informs and supports the delivery of the three quality ambitions (person-centred, effective, safe care) for dentistry in Scotland (Scottish Government 2019). Four main categories of research projects are potentially eligible for research audit hours:

- Rapid Evaluation Practitioner practice-based dental research projects conducted by the Scottish Dental Practice Based Research Network (SDPBRN);
- Practice-based dental research projects conducted by Higher Education Institutions (HEIs) or NHS Health Boards;

- Practice-based dental research projects awarded research funding by NHS Education for Scotland, and;
- National, practice-based, dental quality improvement initiatives that include a reflective research component.

In contrast, in England, the Care Quality Commission (CQC) expects providers of primary care dental services to conduct clinical and other relevant audits to demonstrate good governance, deliver care and treatment safely and to ensure premises and equipment are clean are suitably maintained (Care Quality Commission 2015). Currently, there is no option that participation in research, as in Scotland, would count towards CQC requirements and there is no funding allowance available. However, this may soon change with the recent partnership between NIHR, the HRA and the Medicines and Healthcare Products Regulatory Agency (MHRA), together with the CQC, which plans to develop new research indicators for use as part of CQC's monitoring and inspection programme (National Institute for Health and Clinical Excellence 2018).

1.6.2. *Funding for dental research*

The total amount of health-relevant research funding from UK organisations remained relatively stable between 2004 and 2014 for the Oral and Gastrointestinal health category (UK Clinical Research Collaboration 2015), which includes dental health.

For many years, the Research Councils (of which the most relevant to dental research is the Medical Research Council (MRC)) were seen as the most prestigious funders, using a state allocation of taxpayers' money to support selected high quality research and researchers. More recently, the NIHR (established in 2006), has also provided direct grants for clinical projects and the MRC is now more focussed on up-stream determinants of public health. Establishment of the NIHR has been considered a major catalyst for primary care based research with this being a key domain in its activities (National Institute for Health Research 2019d). As many people's first point of contact with the NHS is with primary care services, this seems a rational move.

1.6.3. *Clinical research networks*

Clinical research networks have been established in each of the four UK nations funded by the UK Health Departments. Together these national networks form the UK Clinical Research Network (UK CRN), strategic oversight for which is provided by the UK Clinical Research Collaboration (UK CRC). The structure of the networks varies between the four nations of the UK, but all share the common goal of providing the infrastructure to support high quality clinical research studies for the benefit of patients. There is a commitment to ensure that the clinical research networks across the UK work together in an integrated manner to share experiences, develop joint initiatives and promote partnership and UK-wide working wherever possible (UK Clinical Research Collaboration 2019).

Since 1st April 2014, NIHR has evolved 15 local clinical research networks (LCRNs) across England, each with 30 specialities including a specific oral and dental health theme and practice based research theme. The responsibility of each theme lead is to: “maintain an overview of the national NIHR CRN portfolio in the speciality group; to provide the NIHR CRN link for the specialty with external specialty-specific NIHR CRN Stakeholders (e.g. charity funders); and to support collaboration of the NIHR CRN in relation to the specialty with other parts of the NIHR” (Soteriou 2016).

The NIHR Clinical Research Network Oral and Dental Health Specialty Group, Dental Schools’ Council and Public Health England, came together to form the Oral and Dental Health Priority Setting Partnership with the JLA. This means that for the first time, members of the public, patients, carers and dental health professionals worked together to identify the most pressing unanswered research questions about how we can improve oral and dental health for individual patients, communities and the whole population. In December 2018, the “Top 10” (National Institute for Health Research 2018) most important questions for future research were agreed with lay people and dentists.

In 1998, a partnership was formed with representatives from the Scottish Council for Postgraduate Medical and Dental Education (SCPMDE) and the three Scottish dental institutions at Dundee, Edinburgh and Glasgow Universities. The need to develop primary dental care research was identified and it was recognised that dentists

interested either in participating in or in developing research in dental primary care in Scotland needed to be better supported (Clarkson et al. 2000). In order to support dentists better and generate high quality research in dental primary care, the SDPBRN was created (Clarkson et al. 2000). The aim of SDPBRN was, and remains to this day, to promote the implementation of evidence-based practice in Scotland through the partnership and participation of all providers of primary dental care in the conduct of high quality research and the dissemination of the increasing body of evidence relevant to dental primary care (Scottish Practice Based Research Network 2017).

In 2008 the Scottish Government, through the offices of the Chief Scientist and the Chief Dental Officer, commissioned a review of dental health research in Scotland (Bagg et al. 2010). The timing coincided with the withdrawal, by the Chief Scientific Officer, of core funding for the Dental Health Services Research Unit (DHRSU) at the University of Dundee. The DHRSU, which had been created in 1979, is a research centre designed to:

> "*contribute to improving oral health and effective dental healthcare in Scotland and beyond by undertaking and facilitating collaborative health-related research and development which is delivered and implemented to international quality standards (Pitts et al. 1991, p. 2)".*

The "Strategy for Oral Health Research In Scotland" (Bagg et al. 2010) led to a refinement of dental research strategies and centralisation of resources in Scotland. Greater emphasis was also placed on primary care based research. NHS Research Scotland *(*NRS) is a partnership involving Scottish NHS Boards and the Chief Scientist Office (CSO) of the Scottish Government that provides funding to the NHS to ensure that NHS Scotland provides the best environment to support clinical research. The CSO provides NRS funding to the NHS to support this aim. 'Oral and Dental' research is recognised as a research area with NHS Scotland and has a recognised specialty lead (NHS Research Scotland 2019). The SDPBRN is provided with administrative and performance management support from NRS.

1.6.4. *RCTs in Primary Dental Care*

Despite the vast majority of dental services being provided in primary dental care, very few NIHR funded national RCTs in primary dental care have taken place or are underway. Currently there are three underway; INTERVAL (Dental recalls trial), INCENTIVE (Dental contracting) and REFLECT (Effectiveness of prescribing high dose fluoride toothpaste). The FiCTION Dental Trial (Fillings in children's teeth) and IQUAD (Improving the Quality of Dentistry), both NIHR funded, have been completed. Further information about each of these studies can be found in the NIHR website (National Institute for Health Research 2019b).

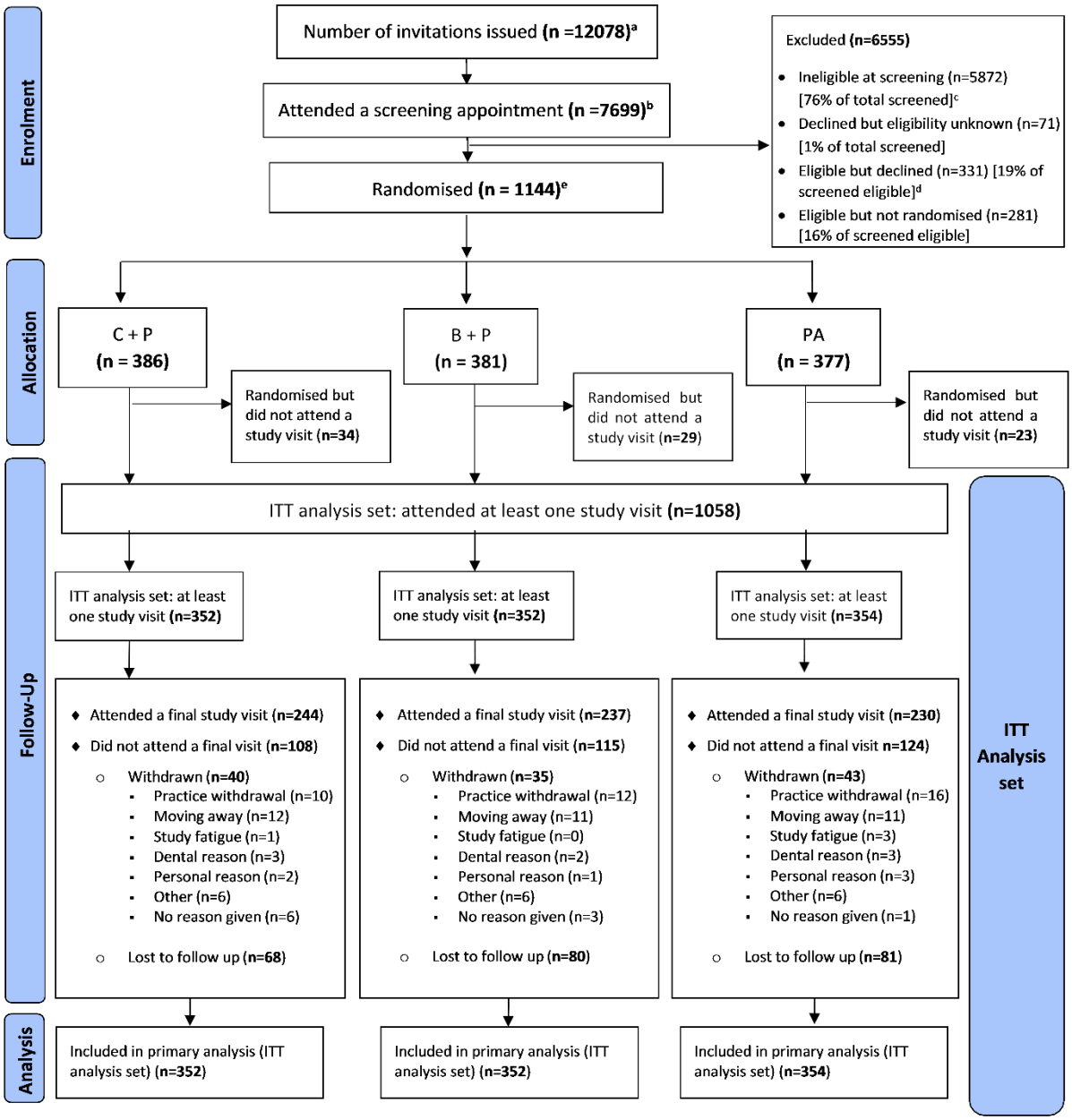
The NIHR-HTA FiCTION Trial - Filling Children's Teeth: Indicated or Not? (Innes et al. 2013) was a multi-centred 3 arm, parallel group, patient-randomised trial to compare three treatment strategies used to manage decay in children with dental caries in primary teeth. The three treatment methods were: conventional management of decay with best practice prevention, biological management of decay with best practice prevention and best practice prevention alone (i.e. no fillings). Many RCTs report challenges with recruitment (Bower et al. 2007, McDonald et al. 2006, Prescott et al. 1999) and this was echoed with the FiCTION RCT (Keightley et al. 2014). Recruitment remains an important area to address, if dental research is to flourish and help answer the key dental health research questions arising in primary care, the environment where the majority of dental care is delivered.

1.6.4.1. The FiCTION Trial

For young children with decay, the FiCTION trial compared the difference between three treatment strategies over 3 years in NHS dental practices in Scotland, England and Wales. Children aged 3–7 years with one or more holes in their baby molar teeth, but without pain/infection, were recruited and placed at random into one of three groups: (1) conventional treatment: tooth numbing, removing decay and filling(s) with preventative treatment; (2) biological treatment: sealing in decay with fillings or caps and preventative treatment but no numbing; or (3) preventative treatment alone. Recruitment opened on 1 October 2012; the first child was randomised on 12 October 2012. The trial closed to recruitment on 30 June 2015; the last child to enter the trial was randomised on 18 June 2015. Recruitment and retention of dental practices and children was challenging but achieved. In the end, a

total of 72 dental practices were recruited; 7699 children were screened, of whom 1144 were randomised (conventional arm, n = 386; biological arm, n = 381; prevention alone arm, n = 377) (Figure 1). The primary reason for ineligibility was the lack of identified decay into dentine in one or more primary molar teeth. However, not all children who were randomised attended a study visit; those who did not attend were not included in the final analysis; 1058 randomised children (conventional arm, n = 352; biological arm, n = 352; prevention alone arm, n = 354) attended at least one trial visit. Children were followed up over the 3 years following randomisation and children lost to follow up or withdrawn from the study were also reported. It was reported that there was no evidence of differential attrition between trial arms, with 67% of children attending a final trial visit (Maguire et al. 2020).

Figure 1: Consort flow diagram of participant journey through the FiCTION RCT (Maguire et al. 2020).



[a] Prior to the start of the study, it was estimated that 18717 children would be invited
[b] Prior to the start of the study, it was estimated that 65% of children invited would attend a screening appointment; 64% attended.
[c] Prior to the start of the study, it was estimated that 85% of children screened would be ineligible; 76% were ineligible and 1% declined screening.
[d] Prior to the start of the study, it was estimated that 20% of children screened and found eligible would decline to take part in the trial; 19% of those eligible declined.
[e] Prior to the start of the study it was estimated that 12% of children screened would be randomised; 15% of those screened were randomised.

1.7. Summary

Clinicians and policymakers who want to improve the quality and efficiency of healthcare services find help in research evidence. To be both evidence-based and clinically useful, clinical policy must balance the strengths and limitations of all relevant research evidence with the practical realities of the healthcare and clinical settings, including how care is organised and remunerated. This can be problematic in the UK within dentistry because of the limitations in both the evidence that is available and in policy-making, with different and increasingly divergent organisational and funding challenges in both Scotland and England.

1.8. Overview of thesis layout

This introductory chapter has provided an overview of the dental health in the UK followed by an exploration of how the populations' dental health has changed in recent decades. It has discussed the organisation, delivery and remuneration of NHS dental services in England and Scotland. The role of EIDM and research within dentistry was then highlighted with an overview of recent changes in the funding and infra-structure of research in the UK. In the concluding section, a brief overview of current NIHR-funded RCTs in UK primary dental care was provided.

This thesis continues with a critical appraisal of the literature around the recognised barriers and facilitators to research involvement, summarised into two general categories: patient-related and health professional-related. In the third chapter, the aims and objectives of this PhD are outlined. Chapter four provides an overview of the research methodology utilised. The fifth chapter gives a detailed account of the quantitative research approach utilised, recruitment of participants into the study, data collection and analysis and the quantitative study findings. Chapter six gives a detailed account of the qualitative research approach utilised, recruitment of participants into the study, data collection and analysis and the qualitative study findings. The seventh chapter triangulates the findings from the quantitative and qualitative studies. Following on, the thesis concludes in the eighth chapter with a suggestion for future research and overall discussion.

Chapter 2: Literature Review

2.1. Literature search strategy

To locate relevant studies relating to the impact on parents of their child participating in research, Ovid MEDLINE® without Revisions and Cochrane Database of Systematic Reviews databases were searched using a combination of search terms. Since both quantitative and qualitative studies were relevant, both types of studies were included in the review but it was restricted to English language publications. The search strategy was widened to include non-dental healthcare studies due to the paucity of literature within dental research. Findings of relevant literature are reviewed and appraised in this chapter.

2.2. Introduction

Despite the large role general dental practitioners (GDPs) play in providing dental care for children in primary care (Clarkson 2005), many aspects of paediatric clinical dental practice still lack a robust evidence base (Bagg et al. 2010). RCTs remain the gold standard research approach, however the number of RCTs within primary dental care is low (see Section 1.6.4). It is widely acknowledged that, whilst a range of settings can be utilised for conducting clinical dental research, including specialised secondary care facilities, it is critical that research involving primary care patients happens in the pragmatic, real world setting of general dental practice (Heasman et al. 2015).

However, major barriers to the successful conduct of clinical trials include site and participant recruitment and retention (Ross et al. 1999). Reducing barriers to participation in research can: lead to more reliable study data (McDonald et al. 2006); make the research more patient-centric (Fayter et al. 2007); and provide an overall better participant experience (Mann et al. 2018).

> *"The consequences of poor recruitment are: premature closure of trials; trials that are underpowered to answer the main research questions (and the dangers associated with this (Altman and Bland 1995)); wasting of resources; and the end-users of research (patients and clinicians) not benefiting from the intended outcomes of the trial"(Das Nair et al. 2014).*

According to the results of a recent survey (Hunn 2017), most people did not believe or were not aware of research taking place in their local NHS hospital, suggesting

that, as a consequence, patients may not ask their physician to include them or their families into research studies. However, it is important to consider whether it should be down to the patient to ask to participate in research or whether their clinician should ask them in the first place. In the UK, only a small proportion of trials actually recruit successfully to time and target (McDonald et al. 2006, Martin-Kerry et al. 2015). Many clinical trials are stopped or extended due to issues surrounding recruitment and retention (Tooher et al. 2008). Primary care is a clinical setting that faces particular recruitment challenges with common barriers to general practice trial recruitment including time constraints, lack of funding, lack of interest in research, and a perception that patients need to be protected (Colwell et al. 2012). Of all the RCTs conducted between 1994 and 2003 (n = 114) and funded by the Medical Research Council (MRC) or Health Technology Assessment (HTA) Programme, fewer than one third recruited their original target within the time originally specified (Campbell et al. 2007). Bower (2007) and colleagues also found that fewer than a third of UK primary care trials recruited to their original timescale. Therefore, recruitment to trials is clearly a big challenge and although often having access to larger participant pools, recruitment to primary care trials is no exception (Bower et al. 2007, Tognoni et al. 1991).

The way in which research is funded has had a major influence on where it is conducted and the research questions being posed and answered (UK Clinical Research Collaboration 2015). In 2005, only 2% of published dental research was based in primary dental care settings (Clarkson 2005). Since 2005, the increasing number of dentists working in primary dental care, who have undertaken master's degrees which include a research project, has led to an increasing interest and involvement in research in primary dental care (Farbey et al. 2010). With 23,947 dentists in England providing 39.6 million courses of NHS treatment to 30 million patients in primary care in 2014–2015 (Health and Social Care Information Centre 2015) and over 4.1 million courses of NHS General Dental Service treatment provided to adults and 506,000 in children in Scotland in 2016/17 (Information Services Division 2017), it is clear that, with appropriate funding and trained resource, there is an immense wealth of opportunities for dental research to expand further into primary care.

Despite about 27% of the world's population being children, paediatric trials constituted only 16.7% of the total number of trials registered on the World Health Organisation (WHO) portal in 2015 (Joseph et al. 2015). There has been a general reluctance to involve children in trials, particularly among parents and doctors, exacerbating the challenges in recruiting children to research studies (Caldwell et al. 2004). Children are not small adults (Ungar et al. 2006) and their recruitment involves greater complexity, such as gaining proxy consent from a parent or guardian. When recruiting children to research, it is important to ensure that the study is conducted in a way that is appropriate to families and clinicians whilst remaining robust (Marshman et al. 2007). Ideally, especially for older children, the assent of the children themselves should also be obtained (Waligora et al. 2014).

In medical paediatric RCTs the recruitment of children is more difficult than for adults due to the smaller pool of potential participants because of the relatively lower burden of disease, coupled with the high fixed costs of trial set-up and the higher ethical demands in paediatric trials, making it less economically attractive for funders (Caldwell et al. 2004). In addition, child compliance with the drug or treatment can be difficult due to a child's developmental abilities and acceptability and tolerability of the treatment on offer (Joseph et al. 2015). Children can be fearful of injections, while certain dose forms e.g. tablets and capsules, can also be problematic (Abdel-Rahman et al. 2007). This all increases the burden for clinicians in recruiting and retaining children in research studies.

Trial discontinuation is also a common problem in paediatric clinical trials, driven predominantly by poor patient accrual and problems with their conduct, including technical difficulties and logistical issues, leading to children being enrolled into trials that were never completed (Pica and Bourgeois 2016). Robinson (2016) reported that research into the reasons for participation and non-participation in child-focused RCTs warranted investigation separate to adult populations. It has been recognised that the majority of research studies investigating recruitment and retention challenges in RCTs are focused on adult populations (Eiser et al. 2005). As parents are potential gatekeepers who can facilitate or obstruct children participating in research, it is important to consider the impact on parents when their child is being considered a subject for research. Examination of the existing literature around

parents' thoughts about involvement in a primary dental care-based trial identified a pattern in a range of literature which is critically appraised in this chapter. This literature comprised quantitative, qualitative and mixed methods research studies that could be summarised into two general categories of barriers and facilitators to involvement in research: patient- and parent-related and health professional-related. The gaps in the literature formed the basis for the aims and objectives of this thesis, described in Chapter 3.

2.3. Parent-related barriers (and facilitators) associated with their child's recruitment and retention in a trial and influencing factors

Parent, family and child factors can be important in determining whether a family chooses to participate in research (Tromp et al. 2016). Failure to recruit children into research studies may be due, in part, to parental misconceptions about the research process (Cheah and Parker 2014). Thus, it is essential for researchers to understand parental fears, concerns and preconceived ideas. Decision-making on behalf of a child is recognised as a different experience to the adult making a decision for themselves (Shilling and Young 2009). Children are unable to give full informed consent and thus have to rely on their parents to make decisions on their behalf. Parents, on the other hand, feel the obligation to protect the child from potential harm and may refuse to enroll their children in a research study on this basis (Tromp et al. 2016). The perception of a study's risks and benefits is amongst the most important determinants of a parent's decision to allow his or her child to participate in a medical research study (Tait et al. 2004). It is not only the burden for the participating child that may influence a decision for recruitment and retention in a clinical trial, but also burden for parents and the rest of their family (Wulf et al. 2012).

There has been growing recognition that children are experts on their own lives who can contribute knowledge and unique insight in research (Barron 2000), but a systematic review by Marshman et al. (2007) reported that, between 2000 and 2005, dental research was mostly conducted "on children" rather than "with children". Marshman et al. (2015) repeated this systematic review to include papers published between 2006 and 2014, once more limited to studies published in the child dental literature, using a clearly specified and comprehensive search strategy, and multiple reviewers were involved in screening and sifting identified papers. The vast majority

of papers, n=1984, had still children used as objects; not listened to or heard. This updated systematic review highlighted a 12.6% increase in the use of proxies to gain the child's perspective and it was concluded that proxies were being overused, especially with older children. This is noteworthy, as parents acting as proxies for their children is clearly complicated and we need to take care not to conflate parental proxy consent (which is legally required for minors) with parental proxy-reporting of outcomes. Associations between socio-demographic characteristics such as the age, gender or ethnicity of the child and parent and the level of involvement of children in research were not explored in this review.

In summary, it is clear that decision-making on behalf of a child is a different experience to an adult making a decision for themselves. Whilst we are moving more towards research conducted "with children" rather than "on children", parents legally need to retain at least some degree of proxy control for their children. It is unclear whether the degree of proxy control desired is influenced by socio-demographic characteristics such as the age, gender or ethnicity of the child and parent.

A systematic review, restricted to English language publications, by Tromp (2016) identified 42 articles, involving 26 quantitative studies (number of participants per study ranging from 20 to 448) and sixteen qualitative studies (number of participants per study ranging from one to 81), which considered the factors that motivated or discouraged children (sixteen studies) and their parents (37 studies) in decisions regarding participation in clinical drug trials. The age range for 'children' was from six to 21 years, though most focused on those aged under 18. The included studies were very diverse with regard to research population and setting. Studies concerning oncology patients were most common. Although some studies involved hypothetical scenarios, the majority related to factors influencing participation in specific clinical trials. Four of the 42 identified studies were omitted from data synthesis because of their low quality. Within this systematic review (Tromp et al. 2016), 33 of the included studies reported motivating factors mentioned by parents in respect of their child's participation in clinical drug research, while ten considered motivating factors for the children themselves; for discouraging factors, 24 studies related to parents' views and six to children's perceptions. The most frequently mentioned motivating factors for parents were: health benefit for their individual child, altruism, a trust in research

in general and in respect of the specific researchers (Tromp et al. 2016). The most common discouraging factors for parents were: fear of the risks; general distrust in research; the logistical demands of study participation, including disruption to daily life; burden for the child. The possibility that no direct benefit would accrue to the individual child, which is a key tenet in RCTs, was mentioned in five studies addressing discouraging factors. Interestingly, the systematic review identified five studies, all within an oncology setting, where parents reported participating because they “felt as the only option” available to them, with three of these studies being defined as studies with no prospect of having direct benefit to the individual child (Tromp et al. 2016). Associations between socio-demographic characteristics, such as the age, gender or ethnicity of the child and parent and perceived facilitators of, and barriers to, trial participation were not considered in this systematic review. This was a high quality review, with a clearly specified and comprehensive search strategy, and multiple reviewers involved in screening and sifting identified papers. However, the focus was solely on studies related to participation in medical drug trials and therefore the findings may not be generalisable to dental research studies.

A systematic review, restricted to English language publications and limited to children from 0-12 years old, by Robinson (2016) identified 23 RCTs with randomisation at an individual level and five cluster trials, which considered the predictors for recuitment and retention in RCTs involving children. Hypothetical trials, qualitative studies and articles without a clear definition of recruitment or retention were excluded. From the 28 studies, 11 considered predictors for recruitment, 13 considered predictors for retention and four considered predictors for both recruitment and retention. Twelve of the studies were community-based, 11 were located in a health setting (hospital centres, university centres, health centres and a dental practice) and three were carried out between community and healthcare settings; information on setting was unavailable for two studies. The majority of the studies were conducted in the USA (17 studies) or Canada (four studies) and all articles were from high income countries. The majority of the studies (24 studies) were published in 2000 or later. The 23 individually randomised trials covered a range of medical conditions of varying medical severity. Twelve of the 28 studies were classifed as medical; the remaining 16, including two dental RCT studies (one relating to dental disease management and the other to dental caries prevention

strategies), were considered non-medical. Within this systematic review (Robinson et al. 2016), a wide range of parent, child, family and neighbourhood-related predictive factors were identified; 155 of these variables were included in analyses across the 28 papers. Of the 155 variables reported, 45 parent, 19 child, four family and two neighbourhood variables were found to be significant predictors in at least one study of recruitment and retention to RCTs involving children and families. Nine parental factors, two child factors, two family factors and two neighbourhood characteristics were identified as predictors for more than one study across the 28 papers. The nine parent characteristics found to be predictive were: ethnicity (n=17 studies), parental age (n=16), parental education (n=16), income (n=10), socioeconomic status (SES) and parental depression (n=9), single parent status (n=9), marital status (n=6) and employment (n=5). A measure of parent/caregiver education was found to be a significant predictor in some (n=4 out of 7) of the recruitment trials but different measures to assess education were used across studies, limiting comparability. Likewise, indicators of SES used were varied with no common measure used in the recruitment and retention studies. Parental age and income gave more conflicting results with regard to recruitment. Being young, less educated, of an ethnic minority and having low SES were associated with lack of willingness to participate in some RCTs, although there was little agreement between studies and, as these characteristics were not always considered, the studies' findings could not be generalised to all RCTs. There was no evidence that setting or severity of the child's illness influenced participation rates. Likewise 17 different definitions of "retention" were identified across the studies, increasing the difficulty in generalising the review's findings. This review only identified studies from higher-income countries, due to an absence of available studies, with Caucasian-dominated populations being common. This was a moderately high quality review, with a clearly specified and comprehensive search strategy, and multiple reviewers involved in screening and sifting papers. However, the focus was solely on quantitative studies in the English language and the method used for quality assessment of the included studies were not standardised due to the lack of a suitable tool available. The review team reported that, due to the diversity of the studies and outcomes included in the studies, traditional quality assessment tools were difficult to adapt to the assessment of studies and therefore they needed to specifically adapt two existing checklist tools,

even though one had been recommended not to be used as a quality assessment tool, as there was nothing else suitable.

Wulf et al. (2012) conducted a systematic review, limited to English language publications, to identify studies that examined participation in paediatric clinical trials from the perspective of the young patient, their families and their physicians. From the 67 papers identified, there were 23 quantitative studies (number of participants per study ranging from 12 to 505), 39 qualitative studies (number of participants ranging from one to 307) and five mixed method designed studies (the number of participants ranging from fourteen to 305). Across all included studies, the age range for children was diverse, from 0-18 years. The included studies were also very diverse with regard to research population and setting. Although some studies involved hypothetical scenarios, the majority related to factors influencing participation in specific clinical trials. Within this systematic review it was reported that the factors that motivated parents to allow their child to participate in a clinical trial included the chance for individual benefit, altruism, hopefulness, a feeling of obligation, and the potential for better care. Frequently cited perceived harms were side effects, family burden, and randomisation with placebo. The review also discussed common comprehension challenges experienced by parents in distinguishing between trial participation and clinical treatment, as well as poor parental recall of the risks and study design concepts, especially randomisation and placebo. However, it should be noted that this systematic review was about advanced understanding of determinants of patient participation in paediatric clinical trials, specifically addressing the consent and participation stages in clinical trials from the perspective of the young patients, their families and their physicians. Clinical trials were excluded if “they enrolled only adults or mothers in the decision process as participants and if they stated that they only gained the approval of the ethics committee.” As such it is highly possible additional factors influencing participation in clinical trials research were not captured.

These systematic reviews (Tromp et al. 2016, Robinson et al. 2016, Wulf et al. 2012) identify several factors that potentially influence participation of children in research as reported by parents. However, the focus of these studies was primarily in the medical field and therefore the findings may not be generalisable to dental research

studies. The quality of the studies incorporated in the systematic reviews were highly variable with different outcome measures used, making comparison between studies difficult.

A narrative review by Shilling and Young (2009), who have a wealth of experience in this field, discussed how parents experienced being asked to enter their child in a RCT. This discussion paper drew primarily on qualitative studies in medical settings but it is unclear regarding why certain studies were selected for review. The age range for children was not stated. Although a few studies considered hypothetical scenarios, the majority related to factors reported in specific clinical trials. A wide range of factors were highlighted as to how parents made sense of trials, with suggestions made regarding how to improve further research with children. It was reported that the sense of responsibility associated with making decisions for their child may make parents more vulnerable, especially if it was associated with living with the “wrong” decision or “failing to protect” their child. An interesting finding reported was that the process of agreeing consent could be enpowering to parents where there is an absence of parental role in day-to-day management of the child’s condition due to the severity of the illness. Rather unsurprisingly, it was reported that the seriousness of the child’s condition and the urgency surrounding trial entry may be important in influencing parents’ experience of being recruited into a trial, their sense of vulnerability and their ability to ask questions or ask for additional information. Parents with chronically ill and terminally ill children were prepared to take greater risks as they perceived that the potential benefits outweighed the risk. Interestingly, it was noted that simply discussing trial participation may have lasting effects for declining participants with some non-participants subsequently reporting inaccurate understanding about the nature and purpose of the research itself or harmful misconceptions, leading to distrust in healthcare professionals after being approached to participate in research. Socio-demographic characteristics were also considered in this narrative review. It was recognised that little research had investigated how parents from different social and ethnic groups experienced being asked to consider a trial for their child and the authors were not aware of any studies from developing countries. Whilst this was only an opinion paper, it had a clear aim and objectives. The focus of the paper was solely on medical RCTs and therefore the findings may not be generalisable to dental research studies.

A narrative review by Cheah and Parker (2014), who have published extensively on ethical issues arising from conducting research and working with vulnerable populations, outlined key factors that they believed should be taken into account to assent children to research studies in low-income settings. Whilst recognising that low-income settings exist in low-, middle- and high-income countries, Cheah & Parker (2014) primarily focused on low-income countries. For this reason they adopted a practical set of criteria for low-income settings i.e. the income in the community was below the country average, there was a general lack of basic healthcare and educational facilities, and there was a high prevalence of diseases of poverty. They reported that lack of formal education and high illiteracy rate and/or earlier maturity could result in different decisions being made in comparison with children from high-income settings. Cheah and Parker (2014) also reported that children from low-income families may have had more opportunity than their parents had to be educated, with more exposure to technology, leading them to being more informed about research than the parents. Furthermore, it was reported that families from low-income settings found it more difficult to distinguish between medical research and routine clinical care.They reported there can be additional familial challenges from families in low-income settings: final decisions may lie with the head of the (extended) family who may not be the child's parent and complex family relationships make it less clear who has parental responsibility for a child. Communities in low-income settings may struggle with the concept of formally signing a consent/assent form as signing documentation in the past has been linked to loss e.g. loss of land because they signed a document (Creed-Kanashiro et al. 2005). Cheah & Parker (2014) argued that children who are competent should consent for themselves, but acknowledged that care would be necessary to prevent abuse and, where children lacked competence, both the child's assent and parental/local relevant alternative consent should be obtained. They concluded that further work was required to explore the ways in which issues in consent and assent arose differently in different places. Whilst this was an opinion paper focussed on low-income settings, it is important to consider that some families in the UK may present with similar cultural backgrounds and attitudes and these findings, whilst not automatically generalisable, may have cross-cutting relevant themes.

In summary, enabling their child to participate in research comes with a high sense of parental responsibility. Simply discussing trial participation may have lasting effects for some declining participants with inaccurate or harmful misconceptions evident after being approached about research. It is unclear whether there is likely to be a greater risk associated with certain study designs or research participants.

Using a qualitative approach, Woolfall (2013) explored parental perspectives and decision-making in clinical trials to compare what was said during trial recruitment discussions with subsequent parental interpretation. This qualitative interview and observational study (called RECRUIT) ran alongside four placebo-controlled, double blind RCTs of medicines for children. For logistical reasons, sites for inclusion in RECRUIT were generally selected from Northwest England. Participants were identified using a mix of consecutive and purposive sampling and 95 families were approached to participate in the qualitative study; 60 families participated and a further 30 declined by direct refusal or by not arranging or cancelling appointments and not responding to further contacts from the research team. Five families with recorded trial discussions were not approached for interview due to bereavement or contact difficulties (e.g. as they had been transferred to another hospital or did not respond to invitations). Both recorded trial discussion and interview data were available and could be matched for 41 of the 60 participating families. Of these 41, 33 were randomised (though one later withdrew), four consented to randomisation but were ineligible, two were ineligible for the trial at consent and two declined to participate in the trial. Nine doctors and two research nurses were involved in the audio recorded trial discussions. The number of families recruited from each of the four trials ranged from six to 15 families. Of the 41 families, the range of deprivation was compared for 38 families; 3 families from Northern Ireland where deprivation scores are not directly comparable were excluded. Twenty-four of the 38 families were in the lowest quintile (higher deprivation) using the Index of Multiple Deprivation (2007); only three were in the highest. The most common topics raised as important in making a decision about their child's participation in a clinical trial were: desire for their child to benefit from participation and not be harmed, the practicalities of participation, potentially benefiting children in the future and other altruistic reasons. Parents often spoke of having a sense of confusion or poor recollection about their trial which they linked to their emotional situation or being overloaded with

information at the time of recruitment. Some parents were confused with how randomisation worked, even when this had been explained clearly, with parents commonly not seeking clarification from clinicians or expressing their queries/concerns. This study predominantly included mothers rather than fathers, although the specific numbers are unclear, meaning that gender differences could not be explored. The study team identified that the sample also predominantly came from areas with higher material deprivation level meaning differences in understanding/themes could not be fully explored with parents from less deprived areas. The study team reported that data saturation was not reached in relation to misunderstanding; they considered this to be a potentially significant limitation with this study. The low numbers of parents who were ineligible, had declined or withdrew from the trial also limited the interpretation of the findings.

2.3.1. *Economic status, cultural barriers and ethnicity*

It is commonly suggested that ethnic minorities, as well as lower income, poorly educated or lower socioeconomic status groups are less likely to participate in research and therefore are underrepresented; these assumptions, however, generally appear to be based on the analysis of single trial datasets (Robinson et al. 2016). The population of England, Wales and Scotland has become increasingly ethnically diverse. In the 2011 England and Wales Census around one in five people (19.5% of the population overall) identified with an ethnic minority group (defined as all other ethnic groups outside of White British) (Office for National Statistics 2014). In 1993, the UK Department of Health identified that in key health areas, including cancer, improvements in mortality and morbidity could be achieved and an essential element in achieving this related to identifying and responding to the needs of black and minority ethnic people (Bahl 2001).

By my examination of the literature in the healthcare field, economic status, cultural barriers and ethnicity are generally reported together. Parental experiences in paediatric trials have been investigated in Western countries, but are relatively unexplored in developing countries which have different economic, cultural and practical barriers to their participation in clinical trials (Nabulsi et al. 2011). Given the increase in ethnic minorities in the UK in recent decades, parental perceptions and attitudes to their child participating in research from a range of countries were considered potentially important. Nabulsi et al. (2011) identified the need to explore

the attitudes of parents in Lebanon, a developing country, and conducted 33 in-depth interviews; 13 parents whose children (aged 2-20 years old) enrolled in a vaccine clinical trial were interviewed to explore their feelings about, perceptions of, and attitudes towards paediatric clinical research based on their experiences and 20 parents with no experience of clinical experience but whose children were receiving medical care were included to explore their responses when presented with a hypothetical clinical trial scenario. The themes generated from analysis of interviews from both groups of parents were quite similar and the findings from the Lebanese parents were similar to results from the Westernised world. A main barrier to parental consent to children's enrolment in clinical trials was parental fear of possible harm to their child from the study and fear of associated painful procedures. Interestingly, only six of the parents approached about the hypothetical clinical trial comparing the effectiveness of alternating oral antipyretics versus monotherapy in children aged between 1-13 years old were willing to consent to participate in the trial. The concepts of consent and randomisation were identified as barriers, especially for parents from a lower social position or those who were less educated. Signing a consent form was felt to be a potential cultural barrier as, in the Arab context, signatures are not required except for formal transactions and these are binding. This study identified a need to replace the term "randomisation" as in Arabic this translates to "happening in a haphazard way" to enhance parental understanding and children's enrolment in research studies. Perception of direct benefit to the child, trust in the physician or institution, financial gains and having a positive previous experience in research were recurrent factors that were associated with facilitating research participation. Whilst this was a single qualitative study, it had an appropriate strategy to address a clear study aim, with a clear statement of findings which highlighted one of the challenges of including subjects where language translation services may be required.

Whatever arm of an RCT or Clinical Controlled Trial (CCT) parents think is better for their child, their preference shows that the idea of clinical equipoise held by the expert medical community is not directly transferable to the parent setting and parents do not often perceive the different arms of a trial to be in equipoise (De Vries et al. 2011). Kingori et al. (2010) investigated the fears of mothers whose children were involved in a malnutrition study conducted by an international team of

researchers in Zambia, Southern Africa. The trial carried out was designed to determine whether liquid, milk-based foods would allow easier absorption and cause fewer hypersensitivity problems than the standard nutritional rehabilitation approach (involving a gradual switch to solid soy/maize porridge in the second week of treatment) in severely malnourished children. In order to understand the mothers' perceptions and reactions to the trial, face-to-face in-depth interviews (n=25; 12 mothers of children recruited into the trial & 13 mothers of children ineligible for inclusion in the trial) and focus group discussions (n=2) with mothers were held during the study. In addition, face-to-face in-depth interviews (n=5) were conducted with some (50%) of the research nurses collecting data for the trial. Many negative rumours about the trial were reported by the mothers whose children were approached by the research nurses. Almost 20% of mothers who were approached declined to participate, or agreed and then withdrew or failed to comply with the intervention, and cited 'rumours' as their reason for not giving their consent. The main concerns expressed through rumours were that:

1. Recruitment was really an indicator that the medical and nursing staff knew that the child was HIV-infected.
2. The trial was a disguise for witchcraft or Satanism.
3. The children's blood and body parts would be removed and sold, presumably for use in witchcraft.
4. The liquid, milk-based food given as part of the study would worsen the condition of the child because it was believed that a child simply could not survive on liquid food only.

The severity of the cases referred to the hospital meant that the mortality rate on the ward was high and 39 of the 200 children recruited during the course of this study died (19.5% fatality rate). The anxiety levels in the mothers were understandably typically raised as a consequence and many mothers feared the outcome of interventions carried out on the ward. Kingori et al. (2010) reported that the concerns raised by the parents were not unique and have been reported in countries where historical, socio-economic and cultural conditions communicate anxiety by rumours. They suggest that rumours should be interpreted as a quest for clarification and a means of expressing understandable concerns about research. Socio-demographic characteristics, such as the age, gender or ethnicity of the child and parent were not factors associated with the facilitators of or barriers to trial participation identified in

this study. This was a high quality retrospective examination of one aspect of a trial, with a clearly detailed discussion relating to challenges associated with conducting a trial based in a developing country because of deep-seated suspicions. However, given the high mortality rate associated with this study, which may worsen the likelihood of rumours, the findings may not be generalisable to dental research studies, even in developing countries, where the risk of harm is likely to be lower.

Based on their experiences in clinical trials in children in low-income countries over many years Molyneux et al. (2012) stated that clinical trials in these populations were necessary for many reasons: disease problems in this group are vast; the problems differ from those prevailing elsewere; and solutions feasible in other environments are commonly not feasible where resources are in short supply. Whilst it was stated that consulting with the community before trial protocols were finalised could be beneficial for recuitment and retention of participants in clinical trials, the extent of this impact on trial participation recruitment and retention rates was not quantified.

Only one study (Bentley and Thacker 2004) has assessed the effects of risk and payment on subjects' willingness to participate, and examined how payment influences subjects' potential behaviours and risk evaluations. Students enrolled at one of five US pharmacy schools read a recruitment notice and informed consent form for a hypothetical study, and completed a questionnaire. A total of 789 questionnaires were handed out and 326 were returned. Nine responses were discarded because of missing data, and seven because the respondent’s self-rated health was not excellent, very good or good, yielding a usable response rate of 39.3%. To simplify analysis and interpretation of the results, respondents were randomly discarded from certain cells to achieve a final data set comprised of equal (n=30) respondents per experimental cell. Monetary payment had positive effects on respondents' willingness to participate in research, as has been reported previously (Edwards et al. 2002), regardless of the level of risk. Higher monetary payments did not appear to blind respondents to the risks of a study. Payment did not appear to have a significant effect on respondents' propensity to neglect to tell researchers about negative effects of the study. However, the findings did raise other concerns-notably the potential for payments to diminish the integrity of a study's findings and

the ethical issues related to paying subjects to participate in research. The HRA (National Research Ethics Advisors' Panel 2014) have since recommended:

> "*Where it is considered ethically acceptable for individuals to take part in a study for no payment it would also be acceptable to pay individuals for participation in that study proportionate to the level of burdens involved and/or (justified) risk. Financial or other incentives, of themselves, are not considered coercive nor present an undue inducement to a potential participant where the risks and burdens involved are those that a competent, adult participant might reasonably accept for no payment*."

Whilst this hypothetical study had several limitations, it suggested additional research with respect to the payment of research studies was indicated. The results of this study were based on the responses of pharmacy students and therefore not generalisable to all groups who participate in RCTs. Students also do not represent all healthy individuals who volunteer for research. This study concluded that further work was necessary to assess if: the effect of monetary payment on willingness to participate in research was different for members of different socioeconomic groups and whether members of different socioeconomic groups evaluated risk differently at different levels of payment. There was no consideration given to the role of an adult within a family and whether this would also have an impact on the effect of monetary payment on willingness to participate in research. It could, however, be theorised that it might, and further research in this area would also be beneficial.

Overall, these studies indicate that families' economic and cultural backgrounds may impact on parental willingness for their child to participate in a clinical trial. Parents do not always perceive the different arms of a trial to be in equipoise and it is unclear whether this mistrust is greater in ethnic minorities or families from lower socio-economic backgrounds.

With regard to ethnicity, South Asian participation in research has been highlighted as low particularly. Studies exploring health professionals' perspectives on ethnic minorities' participation in clinical trials are predominantly US-based. Quay et al. (2017) conducted a scoping review to examine the barriers and facilitators to recruitment of South Asians throughout the world to health research studies and to describe strategies for improving recruitment. Study selection was limited to English

language articles or articles that could be translated using Google Translate and translations were verified by research staff familiar with the language of publication where possible. All types of studies, including primary randomised and non-randomised quantitative studies, qualitative studies and systematic reviews, were included. Commentaries and narrative reviews were excluded to avoid identifying themes from single or few perspectives. The researchers included studies involving South Asian individuals (i.e. Sri Lankan, Bangladeshi, Pakistani, Nepalese, Bhutanese, Maldivian and Indian) in any setting, as well as studies involving multiple ethnic groups where South Asians were a specified subgroup or comprised the majority of participants. Studies assessing or reporting on barriers and facilitators to recruitment and recruitment strategies were included. This included studies assessing the impact, comparative impact or effectiveness, of barriers, facilitators and recruitment strategies. From the 1846 articles identified, 15 met the inclusion criteria and were included in the thematic synthesis. Study populations ranged in size from n=2 to n=1319. The majority of included studies were conducted in specific clinical populations, and most were conducted in the UK (n=12) and dealt with recruitment of clinical populations to clinical trials (n=10). Multiple facilitators and barriers to enrolment of South Asians in health research studies were identified. Factors that facilitated South Asian participation in research included wanting to improve one's health and engage in disease prevention, to contribute to scientific knowledge and greater societal advances and a sense of obligation to healthcare providers. Many of the barriers to participation related to cultural insensitivity, lack of awareness of research or lack of efforts by the researchers to make contact, and tangible issues like time and cost of participating, and language barriers. Several actionable strategies were discussed, the most common being engagement of South Asian communities, provision of incentives and benefits, language sensitivity through the use of translators and translated materials and the development of trust and personal relationships. A strength of this review was that a range of perspectives and ideas regarding recruitment of South Asians were summarised and grouped thematically. However, participants were only from the UK, the USA, India and Australia, meaning transferability to other countries may be challenging. Although the review did include studies involving children as well as adults, it is unclear if the role of being a parent as well as from an ethnic minority may influence willingness to participate in clinical trials. The focus of this review was mainly on clinical trials and

therefore the recruitment recommendations may not be generalisable to other types of research studies. None of the research studies included oral or dental research and therefore the findings from this review may not be generalisable especially when considering parents of children participating in a dental research study.
Limkakeng et al. (2013) carried out a systematic review of literature between 1985-2009 to understand Chinese patients' motivations and concerns to participate in clinical trials. They identified five articles (number of participants per study ranging from 34 to 401) which met their inclusion criteria. Three independent reviewers carried out the systematic review. One reviewer had no previous experience conducting a systematic review but was fluent in Chinese language and enabled articles in Chinese language to be included. Only studies using qualitative methods, as defined by the study team, (interviews, focus groups, ethnographic, or surveys) to collect data were included in the literature search. Subjects who were born in China were considered subjects of Chinese heritage and trials conducted within and outside of China were included. Three of the five studies were conducted in the USA whilst the remaining were conducted in China and Singapore. One study compared Chinese-American immigrants to non-Chinese participants, the rest focused exclusively on Chinese heritage subjects. All studies were conducted with adults (age range 18- 73 years old) with two studies evaluating the elderly. Six themes favouring research participation were identified: personal benefit to participants, financial incentives, participants' sense of altruism, family or physician recommendations, advertisements, and convenience to the participants. Five factors were seen as a barrier to participation in clinical trials: mistrust of researchers, language barrier, lack of financial and other support, cultural and social barriers, lack of knowledge about clinical trials. These themes have mainly appeared in prior studies of research participation, demonstrating shared values between cultures with regard to research. This review was solely on studies related to patients of Chinese heritage and therefore the findings may not be generalisable to all ethnic minorities or parents whose children are from ethnic minorities.

Interventions to stimulate participation in research are typically multi-faceted, and result from efforts to make the approaches to target groups socially and culturally appropriate (Dietrich et al. 2006, Tu et al. 2006). It has been reported that socio-culturally-specific interventions have the potential to increase recruitment when

recruiting a particular racial or ethnic group (Watson and Torgerson 2006). Critical factors that shape health-seeking behaviour for Hispanics in the USA, that could be equally relatable to all ethnic groups in the UK, has been investigated, with poor access to care, lack of transportation, need for child care, costs related to the patient's lost time at work, competing family responsibilities, and the lack of culturally appropriate or language-matched care (Lewis et al. 1998, Naranjo and Dirksen 1998) being reported. Published research from the USA on reaching Hispanic populations generally prescribe strategies that take into account cultural barriers (such as anxiety about raising negative health topics) and the strong emphasis in Hispanic culture on family and trusting relationships. Consequently, cultural adaptations to recruitment methods including face-to-face communication by supportive community health advisors, practical assistance for keeping appointments (such as transportation and child care) and family-oriented decision-making have been suggested. Therefore, with a paucity of dental research studies involving children, it would be sensible for any necessary cultural adaptations to be considered when designing a research study involving parents as this may influence their enrollment, along with their child.

2.3.2. *Health status of child*

Peay (2018) investigated the factors associated with parental interest in enrolling children with paediatric neuromuscular disorders into clinical trials. The study was an online survey of parents of trial-naïve children with muscular dystrophy, 4 to 12 years of age, and spinal muscular atrophy (SMA), up to 12 years old). Parents were included in this study if they had not previously consented or attempted to enrol their child in a clinical trial. The questionnaire asked about perceived barriers to (24 items) and facilitators of (13 items), clinical trial participation for their child. Barriers (‘My child has not been enrolled in a clinical trial because…’) and facilitators (‘I would be more interested in putting my child in a clinical trial if…’) were each rated on a scale of one (very untrue) to seven (very true). The majority of the 203 respondents to this survey were based in the US, with the remainder in Canada; 47.8% of the children had a diagnosis of one of the muscular dystrophies (mean age 7.7 years old) and 48.4% had SMA (mean age 3.4 years old).The top three perceived barriers to trial participation were ‘my child could receive placebo (mean rating = 4.52)’, ‘I don’t have enough information about the potential risks of clinical trials (mean rating = 4.21) and ‘I don’t have enough information about the day-to-day requirements of clinical trials

(mean rating = 4.18). The top three facilitators were ‘I was confident that the trial would improve researchers’ understanding of the disease’ (mean rating = 6.19), ‘My child was guaranteed to get the treatment (if it worked) after the trial (mean rating = 6.10) and ‘My child’s doctor suggested that a clinical trial might be a good fit’ (mean rating = 5.94). Logistic regression was used to examine predictors of interest in trial participation and showed that the child’s age and disease severity were not significantly associated with parental interest in trial participation. This is particularly noteworthy as it argues against the notion, that with more serious child symptoms, parents experience an increasing urge to participate in research (Vanhelst et al. 2013, Shilling and Young 2009). However, it should be noted that this survey was about perceived barriers to, and facilitators of, trial participation in the abstract; expressed views might not have translated into actual decisions when offered participation in an actual trial. A major limitation of this study is that the number of parents sent the questionnaire is not reported, and therefore it is not possible to calculate a response rate or to ascertain the likely extent of non-response bias. Respondents were recruited primarily through patient advocacy groups and, as recognised by the authors, were therefore not necessarily representative of all parents whose child might be approached for a clinical trial. The possibility of social desirability biases are also acknowledged by the authors. This study highlights that further exploration of the role of disease progression and severity in predicting clinical trial participation may be found in other healthcare fields and should be considered.

Caldwell et al. (2003) investigated parents’ attitudes to children’s participation in RCTs and sought to identify factors influencing the decision to participation and perceived risks and benefits. They compared responses across a range of parents of children with health problems of varying severity (from none to life-threatening) at the Oncology Unit, Renal Treatment Centre, various research groups involved in RCTs and hospital wards in Westmead, Australia. Paediatricians and researchers from the hospital were requested to identify parents who could provide a range of views to participate in focus groups. Parents with healthy children from a local primary school were invited to participate in focus groups by advertisement in the school newsletter. There were four focus groups and five individual interviews involving a total of 33 participants. The study parents (n=33) varied in age (21-60 years old), sex (n=4 fathers, n=29 mothers), ethnicity (n=26 Australian/New Zealand, n=4 Asian, n=1

Eastern European, n=1 Pacific Islands), level of education (junior high – tertiary education), distance (0 to 100 km) from hospital and research experience (n=9 previous participation in a RCT, n=24 no previous experience in RCT). The percentage of parents who agreed to participate in the attitudinal study varied with source; RCT participants (n=9 verbally agreed to participate out of 12 parents approached), oncology unit (n=12 out of 15), renal treatment centre (n=10 out of 19), hospital inpatients focus group (n=17 out of 46), hospital inpatients individual interview (n=6 out of 10), school newsletter (n=1 out of 760) and school personal invitation (n=8 out of 17) and participation rates in the focus groups and individual interviews also varied across these sources. As found in other studies, parents faced a dilemma when making decisions about trial participation; having to weigh the risks against the benefits of participation. Perceived benefits of trial participation included provision of free medication, the chance to access new and effective treatments not routinely available and the ability to help other people's children. Parents from the oncology unit and RCT participant parents believed there were benefits for all participants including better care and monitoring of their child. RCT parents reported the highest number of personal gains from trial participation. The risk of their child being randomised to a less effective treatment worried many parents who reported feeling guilty if their child deteriorated. Many parents found the responsibility of consent by proxy difficult; they would be willing to participate in an RCT themselves but were more hesitant about their child's participation. Parents identified many inconveniencies for trial participation, including additional hospital visits, time demands, travel, inadequately equipped waiting rooms and their child's distress. Some parents thought the constant reminder of their child's illness may be stressful for parents. With the exception of oncology and RCT parents, who understood RCTs and the consent process, most other parents had little knowledge about RCTs. Many parents were unaware of RCTs only being conducted when there is uncertainty about the best treatment and many parents were fearful of their child being a "guinea pig". Oncology parents felt an obligation to participate in trials for altruistic reasons and RCT parents believed trial participation was personally beneficial for their child, despite negative responses from family and friends. Parents thought that those who had a child with a life-threatening condition would be more prepared to participate in trials. Parents also felt that children's preferences about trial participation needed to be considered but they preferred making the final decision in treatment trials for life-

threatening situations on behalf of their child. Many parents did not understand randomisation, assumed treatment allocation decisions were made by doctors or researchers and were hesitant about random allocation and wanted their doctor to choose the “best” treatment. Blinding to treatment particularly concerned parents of chronically ill children because it worsened the feeling of loss of a sense of control. Parents claimed they would seek their doctor’s advice on trial participation because they trusted their opinion and medical knowledge and felt that being informed about relevant trials was part of the doctor’s role. A major limitation of this study is that the reasons for parents declining participation was not fully reported, and therefore it was not possible to ascertain the likely extent of non-response bias.

Fortnum et al. (2014) conducted a feasibility study exploring the views of parents of children with Down syndrome and professionals with a responsibility for the health and education of these children, on participation in, and value of, future research into interventions for otitis media with effusion (glue ear). Data were collected from parents of children aged 1-11 years old with Down syndrome via self-completed questionnaires (n=122), face-to-face interviews (n=21) and focus groups (n=11 participants). Data were collected from professionals including: audiologists; ear, nose and throat surgeons; audiological physicians; speech and language therapists; and teachers of the deaf, via self-completed questionnaires (n=99) and by participating in a Delphi survey (n=42). The response rate for the parent questionnaires was just over 30% with responses rates across the six participating centres varying from 0% to 36.8%, raising the risk of non-response bias. All parents completed the questionnaire in English. The response rate for the professional questionnaires was unclear. This study was particularly noteworthy in relation to the discussion section regarding barriers and facilitators to research participation specific to children with Down syndrome, which comes with multiple symptoms, socio-developmental issues as well as practical difficulties. It was reinforced by the study team that this feasibility study was designed to assess if parents and professionals were willing to take part in a trial for glue ear in children with Down syndrome and to determine if further information through research would be practical, beneficial and cost effective. It was readily acknowledged that the quantitative study failed to obtain its anticipated response rate from both parents and professionals and neither groups within the qualitative study were truly representative of the population that they were

selected to represent. Despite these limitations, the issues raised are still relevant to this thesis. Parents' reported that their willingness to participate in a research study would vary over time. For example, they would be more likely to be willing to participate in a study when symptoms were not well controlled, when treatment is not working or when the treatment options were new, than when the condition was stable and well controlled. Likewise age could be associated with a complex relationship: research involving younger children may be perceived to have the greatest impact but it is also likely to be perceived as most risky and potentially traumatic to both child and parents, particularly for parents of very young children who are adjusting to parenting a disabled child. This was a high quality feasibility study, with a clearly specified methodology. Whilst this study was predominantly focusing on research relating to children with Down syndrome, the findings may very well be applicable to other research studies with children with additional health needs requiring medical care.

In summary, the medical health status of a child may influence parents' willingness to allow their child to participate in research. It is unclear if the nature of the condition impacts on the feasibility and acceptability of collecting data from parents. Due to an absence of published research, it is unclear if similar results may be found for dental health status.

2.3.3. *Educational attainment of parents*

A potential parental barrier to recruitment and retention of their child in research is the quality of the information provided to them. Conventionally, research study information is provided in printed form. These documents need be understandable to potential trial participants to support them in making an informed decision and it has been reported several times that these information leaflets, based on regulatory standards, can be inconsistent with what potential participants want to know (Martin-Kerry et al. 2015). When evaluating parents' perceptions of research with newborns, educational level of the parents was found to be associated with some significant differences between groups with parents with a college education more inclined than parents without a college education to express attitudes that were favourable towards research (including research with professionals other than doctors) along with a greater awareness of the ethics review process (Singhal et al. 2002).

Clinicians often make use of patient information materials to inform patients/caregivers about their child's health condition and to supplement verbal advice provided. To help maximise their effectiveness, the readability of these materials should suit the skill level and other characteristics of the patient/caregiver. Readability analyses of adult consent documents have indicated a large gap between the required reading level to understand the information and the actual reading ability of research participants (Grootens-Wiegers et al. 2015).

In summary, the educational status of a parent may influence their willingness to allow their child to participate in research. It is unclear if the readability of parent information leaflets impacts on the feasibility of recruiting parents to RCTs involving their children.

2.3.4. *Other barriers and facilitators that potentially influence parents*

A systematic review, restricted to English language publications, by Ross et al. (1999) to identify problems with recruitment and retention of clinicians or patients to clinical trials identified 78 relevant quantitative or qualitative research studies from 1986-1996. The studies identified had been conducted in high-income countries (e.g. USA, UK, and the Netherlands) and were predominantly adult cancer studies (n=39) and those based in a hospital setting (n=51). Papers relating to Phase I or Phase II trials were excluded as were papers commenting on barriers without supporting evidence. The review confirmed that the additional demands of a research study may cause concern for some patients, influence their decision to participate, and lead to later attrition. Participating in a trial was associated with specific barriers to recruitment of clinicans and patients to RCTs. Patient barriers included: additional procedures and appointments, patient preferences, worry caused by uncertainty over the choice of treatments or random allocation, and concerns about the amount and format of providing information and obtaining consent. Many of the studies identified within the systematic review were designed to identify problems with recruitment to trials but the impact of specific barriers could not be quantified. It was concluded that the recruitment aspects of a RCT should be carefully planned and piloted but further work was needed to quantify the extent of problems associated with patient participation, and to understand more clearly why clinicians and patients do or do not take part in RCTs. Over half of the studies included in the review were conducted in

the USA (n=41) and the rest were mainly from Canada or the UK. Although this systematic review did not focus primarily on parents of children participating in clinical trials, many of these concerns may still be worthy of consideration. The main weakness associated with this systematic review is that the search strategy was not specified.

A subsequent systematic review (Fayter et al. 2007), limited to English language publications, considered the review by Ross (1999) and deemed it an appropriate synthesis of the early literature so began their search from 1996-2004. This review focused on adults and children with cancer or health care professionals recruiting cancer patients to trials and excluded general populations' views about trial participation. Of the 58 published studies, 56 were selected for inclusion and all of these were from westernised countries with the majority of the included studies from the USA (n=27) or the UK (n=14). The review included a range of methodologies including 27 surveys, 11 chart reviews, eight qualitative studies and four mixed-methods. A number of studies were identified as vulnerable to selection bias; in most cases this was thought to be linked to poor reporting of the methods of recruitment of participants but it was acknowledged that four studies showed clear potential for selection bias. The reliability and validity of survey instruments was often unclear due to inadequate reporting of survey design and methods of piloting. Whilst the majority of studies related to factors influencing participation in specific clinical trials, in seven of the studies the decision to participate in a clinical trial was hypothetical in that patients were being surveyed about their attitudes to trials rather than being asked to participate in an actual trial. Similarly to Ross et al. (1999), this review reported similar factors to participation in clinical trials such as time constraints, resource issues, the importance of the research question, patient preference for a particular treatment (or no treatment), worry about the uncertainty (such as uncertain side effects, uncertain outcome and the possibility of unnecessary tests) of trials, as well as concerns about information and consent. In addition to its observed poor or limited reporting of methods of data collection and analysis, the main weakness with this systematic review was its lack of generalisability to research involving parents of children recruited to a research study. Only one of the included studies within this systematic review related specifically to trials involving children (Wiley et al. 1999). This study assessed parents' perceptions of randomisation. It was a case control

study which included children with varying cancer diagnoses and cases were parents of any patients who refused randomisation with controls being parents from the same institution. Parents were asked to complete a questionnaire which included free choice and open-ended questions in addition to responses on a Likert scale. Responses to the open-ended item “is there anything you would like to tell us about why you did or did not agree to randomisation for your child” highlighted that parents who accepted randomisation felt that the RCT afforded them hope that there was a cure for their child and noted their reluctance to make the “wrong” decision. Those who refused to participate in the RCT tended to express fear about randomisation and commented on the desire to have decisional control. This systematic review suggested a checklist that could be adapted for use by parents with questions including:

- ‘What key information needs to be given to enable patients to feel more comfortable with the uncertainties involved in the trial and the concept of clinical equipoise?’
- ‘How might the timing of the request to participate in the trial be sensitively addressed?’
- ‘How might practical barriers such as cost to patients, transport and time commitments be addressed?’
- ‘How might the benefits of the trial be explained to patients?’

Whilst this review focused on the benefits, modifiers and barriers to participation in cancer trials, it also highlighted the limitation of research literature in identifying, in a clear, reliable and consistent way, the barriers involved in trial participation more generally. It was clear that, in many cases, the recruitment barriers might reflect particular characteristics of the selected sample, specific contexts, cultural influences, or features of the trial or trials in question. Given the threats to internal validity that emerged in many studies, it was not possible to ascertain which factors were universal, which were generalisable to certain subgroups or settings, or which might have been merely a reflection of barriers the respondents were asked about (Fayter et al. 2007).

Kaur et al. (2016) conducted a survey of staff recruiting to a randomised, multi-centre, double-blind, placebo-controlled trial of a drug therapy (MAGNETIC) for

children with severe acute asthma, focusing on their perceived facilitators of, and barriers to, participant recruitment. The target age group for this study was 2-16 years old, and therefore parental consent for participation was required. The MAGNETIC trial recruited 508 children in 27 months (three months longer than originally planned) from across 30 UK sites which were a mix of tertiary children's hospitals with paediatric intensive care unit (PICU) with extensive paediatric research experience (40%); medium (34%) and large (23%) district general hospitals with no PICU and minimal research experience; and large general hospitals with extensive research experience but less paediatric research experience (3%). The perception of clinical teams with regard to facilitators and barriers to recruitment was assessed by asking the respondents (recruiting staff) to score a structured, evidence-based list of potential factors that affected recruitment to clinical trials. Potential factors that affected recruitment to clinical trials were categorised in terms of operating at the level of trial, site, patient, clinical team, information and consent process and central study team. The respondents were asked to grade each factor from –3 to +3 depending on whether the factor was perceived as a strong (–3), intermediate (–2) or weak (–1) barrier, or a weak (+1), intermediate (+2) or strong (+3) facilitator or (0) if the factor was thought to be not applicable. Open questions were asked to gather information on interventions and strategies applied by clinical teams to counter the problems that were identified at the sites. The online survey was emailed to clinical teams involved with recruitment to the trial once there was completion of trial recruitment at all sites. This included PIs, research nurses, medical practitioners, nurse practitioners and nursing staff. Contact details could be obtained for 491 members of the study team out of a list of 656 contacts (75%). This included principal investigators (PIs) and research nurses at all 37 sites and other clinical staff at 30 of the 33 open sites; permission to contact other staff could not be obtained at the remaining three sites. Two hundred and six responses (42% response rate) were received: 169 complete (34%) and 37 partial responses; the 37 incomplete responses were excluded from analysis and overall responses were broken down by staff role, duration and period of involvement in the trial. The facilitators of recruitment related largely to the trial staffing and infrastructure, and to staff skills and attitudes. Communication between the research team and parents was felt to be a facilitator by just over 50% of respondents (n=83). Parental factors were more likely to be perceived as barriers to recruitment, with parental concerns about drug side

effects being mentioned by 65.3% (n=109) of respondents, and parents' attitudes to their child taking experimental drug or placebo cited by 57.2% (n=95). Sub-group analyses showed that perceptions differed between PIs and research nurses; the former sub-set of respondents did not consider parental concerns about side effects or experimental medicinal products to be barriers. The age of the participants was not addressed explicitly in the questionnaire, but overall 57.5% (n=96) of respondents perceived patient inclusion criteria to be a facilitator of recruitment, while only 27.6% considered these criteria to be a barrier. No formal sample size calculation was carried out but the overall response rate to this survey was low, giving rise to concerns regarding non-response bias. Whilst many challenges with recruiting children were reported by the clinical team, there was no indication that there was any age-related participation bias. A major weakness of this study was that it was completed over a two-year study recruitment period where a change of trainee doctors and nurses over this time period resulted in the risk of not all facilitators and carriers being captured. The authors also acknowledged that completion of screening logs was very poor in the MAGNETIC study and therefore they have no idea of how many children had to be screened to yield 508 randomised children; thus it is impossible to ascertain whether those not screened were, on average, older or younger than those who were recruited.

A Cochrane Review (Treweek et al. 2018b) considered the effectiveness of various strategies to improve recruitment to randomised trials. A secondary objective was to assess the evidence for the effect of the research setting (e.g. primary care versus secondary care) on recruitment. This was an update on a previous review completed in 2010 and 24 new eligible trials were identified in this update. From the 68 eligible trials (including antenatal care, cancer, podiatry and surgery with the size of the studies ranging from 15-14,467 participants), 63 studies involved interventions aimed directly at trial participants whilst five evaluated interventions aimed at people recruiting participants. Studies came from 12 countries with the USA (n=25) and UK (n=22) dominating. The overall risk of bias was considered low for 22 studies, unclear for 14 studies and high for 32 studies. Twenty-six studies involved hypothetical trials and 24 of these were considered to be at high risk of bias. However, none of the trials included in this review included paediatric trials although primary, secondary and community care were included. This review (Treweek et al. 2018b) concluded

that having an open trial and using telephone reminders to non-responders to postal interventions both increased recruitment whereas using particular, bespoke participant information leaflets had little or no effect. Since this review did not include any paediatric trials, it is unclear if the same conclusions would be reached for research studies involving children and/or their parents and whether the study setting would make a difference.

In summary, the existing published systematic reviews identifying problems with recruitment and retention of patients to clinical trials have not primarily focused on parents. It is unclear whether parental concerns may be significantly different and whether adjustments to trial methodology may impact on parental willingness for their child to participate and be retained to the end of the research study.

2.3.5. *Understanding the trial processes*

2.3.5.1. Consent

Informed consent is recognised by law in most Western societies. By acknowledging the right of autonomy within the medical context, the informed consent process aims to maintain the right of the autonomous individual to self-determination and free choice (Beauchamp and Childress 2013). A broad definition of personal autonomy is that it; “encompasses self-rule that is free from both controlling interference by others and limitations that prevent meaningful choice, such as inadequate understanding” (Beauchamp and Childress 2013, p.101). Unfortunately, it has been argued that preoccupation with the primary aim of individual autonomy, may jeopardise the quantity and quality of clinical research undertaken in patients. Warner et al. (2008), in a pragmatic RCT involving participants with mild-moderate dementia, stated that an overemphasis on autonomy was likely to have an adverse influence on carers when asked to provide consent for their relatives to participate in research. Similar concerns could apply to other groups lacking capacity to consent for themselves, particularly infants, children, and young people, and result in under-representation of this group within research. A number of alternatives have been proposed, in emergency situations (where deferred consent, presumed consent and waiver of consent (though the latter is rarely allowed in the UK) could be considered (Woolfall et al. 2015)) or, on a more enduring basis (e.g. people with dementia or learning difficulties, and children below the age of 16 years old) (Shepherd 2016). The most

frequently cited suggestions from interview- and focus groups-based research for improving informed consent related to allowing parents more time to make their decision, the amount and type of information provided, organisation of the consent meeting, communication style and providing additional materials (Eder et al. 2007).

Woolfall et al. (2013) conducted a qualitative study to compare what was said during trial recruitment discussions (which routinely take place before practitioners seek parental consent for a trial) with the interpretations that parents took away from these discussions. This study assessed parents' agendas when making a decision about participation in a paediatric clinical trial with some of these agendas, including safety, trial purpose, practicalities of participation and randomisation, overlapping with those prioritised by the researchers. Interestingly parents' agendas were often overlooked by practitioners and parents' agendas were associated with specific misunderstandings, which in turn had the potential to influence parents' decisions about a trial. Even when practitioners' descriptions were clear, parents sometimes incorrectly interpreted the information provided and did not commonly seek clarification from practitioners or express their queries or concerns during the discussions. This study highlights the importance of trial recruitment discussion with parents and that misunderstandings can arise around parental agendas. It is unclear if dental studies are equally prone to misunderstanding and whether different approaches would need to be taken to suit individual parents and children to assist communication and to improve understanding.

2.3.5.2. Randomisation

One of the most difficult aspects of recruiting to RCTs and informing the consent process is explaining randomisation clearly. Woolfall et al. (2013) reported that parents of children participating in research were no different. Randomisation involves allocating participants in a research study to an intervention or control group without taking any similarities or differences between them into account, ensuring that each individual has the same chance of receiving each intervention. It has been shown that participants can be uncertain as to how randomisation is performed (Behrendt et al. 2011, Nabulsi et al. 2011). Snowdon et al. (1997) completed in-depth interviews with parents who had previously agreed for their critically ill baby to

participate in a potentially lifesaving but also potentially risky treatment which might lead to the death of their child. Their findings highlighted that not all patients understood randomisation and that many parents were not comfortable with the concept. Patient concerns regarding randomisation have been reported by other researchers within other healthcare specialities (Featherstone and Donovan 2002, Slevin et al. 1995). The impact of individuals' treatment preferences has traditionally been controlled through the processes of randomisation and, wherever possible, blinding participants to their treatment condition. Reports of parental attempts to manipulate the research process—e.g. by agreeing to randomisation but then withdrawing if their child is not assigned to their preferred trial group also shows how such misunderstandings can cause difficulties (Modi et al. 2013). It is not known whether withdrawing from research studies is widespread or specific to certain types of research and this warrants further investigation.

2.3.6. *Trial commitments and financial implications of participation*

Participants in a RCT need to make a commitment, and usually have to undertake additional research tasks, often without direct financial benefit (Francis et al. 2007). Information about RCTs can be confusing for participants (Robinson et al. 2005) and take time to explain (Featherstone and Donovan 1998). However, an initial barrier is the ease with which participants can join a study. In a qualitative study aimed at exploring the potential barriers and facilitators to recruitment in early cancer detection trials, Das Nair et al. (2014) reported that researchers used focus groups pre-trial to elicit views on how to approach people. Interestingly, the focus groups had very different views about receiving a GP letter as a means of recruiting into a study; In Castlemilk, a deprived area in Glasgow (UK), there were no objections to receiving a GP letter as a means of recruiting into a study, although some participants questioned whether GPs would really be on board, and other participants suggested that GPs were too remote and difficult to engage with. Despite this, the majority of participants in Glasgow seemed satisfied that the GP letter approach would work well, and most indicated that they would respond to such an invitation. In Charleston, a deprived area in Dundee (UK), however, some respondents expressed stronger reservations about whether the GP letter approach would work. People talked about letters being set aside, binned and essentially treated as junk mail. These focus

groups also highlighted that reimbursement of travel expenses could be necessary, the appointments needed to be flexible to work around work commitments, participants should not be overloaded with too many appointments and it should be recognised that participants may drop out if they became unwell during the study (Das Nair et al. 2014). Many large trials now include additional sub-studies that also require extra samples or information to be gathered (Jenkins et al. 2013) and this must be carefully considered to avoid overloading trial participants further. Including families and caregivers in conversations about the trial from the start could impact positively on a research study's success. It is essential to develop and evaluate trial design from the participant's perspective as the logistics of participation can discourage them from remaining in the study until the end. Common logistical barriers include the inability to take time off work, transportation to and from the research site, how often participants are expected to be present, and how far they have to travel. If they have children or rely on caregivers, this can complicate their ability to participate. Consideration of the timing of the study so parents do not have to take time off work, providing an area for child care so that parents can bring the child participating in the research along with any other children, offering home visits, and including other family members in conversations about the trial from the start could all impact on a research study's success. It is unclear if dental studies, particularly in a primary care setting where appointment timing can generally be pretty flexible around patient/parent commitments, are associated with reduced logistical barriers.

2.4. Health professional-related barriers (and facilitators) to trial recruitment and retention and influencing factors

2.4.1. *Introduction*

According to the results of the 2012 National Institute for Health Research (NIHR) survey (Hunn 2017) only 38% of health professionals believed that research was embedded in hospital strategy at board level (Hunn 2017).

With regard to paediatric research, stakeholders, including researchers, regulators and sponsors involved in trials in children, from ten countries from low- to middle-income countries and high-income countries, have acknowledged that changes in the

regulatory environment have encouraged more trials in children to be undertaken, but they contend that inequities and political, regulatory, and resource barriers still exist (Joseph et al. 2016). Participation may also be improved by having trained investigators who understand the complexities of conducting trials in children, appropriate facilities that meet the needs of children and a designated trials co-ordinator to facilitate recruitment and trial conduct (Caldwell et al. 2003). The Royal College of Paediatrics and Child Health (RCPCH) Commission on Child Health Research was established to review child health biomedical and health services research in the UK, and tasked with considering how this might be strengthened and increased.(Modi et al. 2013) This review (Modi et al. 2013), was not limited to clinical trials and evaluated training, infrastructure and capacity, support within the NHS, the extent to which paediatricians were able to support clinical research, activity and funding, parent, public and young people's involvement, whether national clinical guidelines and policies affecting children were adequately informed by research evidence, and the visibility of children's research. It showed that the number of academic paediatricians decreased by 18% between 2000 and 2011; clinical trainees were poorly equipped with core research skills; most newly appointed consultant paediatricians had little or no research experience; less than 5% of contracted consultant time supported research; less than 2·5% of the 2 million children seen in the NHS every year were recruited to studies; and ten of the 20 UK children's hospitals did not have a clinical research facility (Modi et al. 2013). Several recommendations were made to improve early-years research, including the formation of multidisciplinary, cross-institutional groups of clinical and non-clinical child health researchers and their access to facilities suitable for children; an expansion of research posts; support for parents' and young people's advocacy; collaboration between children's research charities; improved research training for paediatric trainees; and closer integration of child health research with core NHS activities (Modi et al. 2013). Five years later, the RCPCH evaluated progress, reflected on their own actions and identified the next step (Hunter et al. 2018). It was recognised that whilst the total number of consultant-level paediatric academics showed signs of increasing, the senior paediatric academic workforce remained small with the number of senior lecturers continuing to decline. The RCPCH made a clear commitment to strengthening the generic research skills of all paediatric trainees through curriculum development, appraisal, examination and expectation.

They also suggested the inclusion of infants, children and young people as the default in research studies unless there was specific justification for their exclusion.

Decision-making is a key skill for clinicians and there are two common theories on how clinicians make decisions; prescriptive and descriptive (McKinlay et al. 1996). The prescriptive theory is where clinicians make decisions on carefully calculated probabilities based on evidence and adjusted to the individual patient. In dentistry, it has been shown, using a two-arm cluster randomized controlled trial, with pre- and post-test assessments, that it takes more than simply having a guideline for dentists to use it (Van der Sanden et al. 2005). Descriptive decision-making, in contrast, being a subjective process, can take account the social and environmental factors, but therefore is also affected by a large number of influences, which can be grouped into three distinct groups: patient characteristics, clinician characteristics and practice characteristics (McKinlay et al. 1996). It is beyond the scope of this review to cover these in depth, but it has been reported that many clinicians are simply unaware of new evidence (Hall 2002). It has been shown that, in controlled conditions at least, clinicians will change their behaviour when the evidence has been presented to them (Robertson and Jochelson 2006). The best mechanism for dissemination of new evidence is uncertain, but one mechanism that has had some success is the introduction of clinical practice guidelines (Knutsson et al. 1989) but these are not the full solution (Cabana et al. 1999). This was demonstrated by Clarkson et al (2008) in a 2x2 factorial design cluster RCT who compared the effectiveness of: (a) paying dentists based in a primary care setting on a fee-for-service basis (i.e. paying them more to apply fissure sealants to newly erupted molars to prevent dental caries), (b) having clinicians attend an educational workshop on evidence-based practice to highlight the importance on placing sealant, (c) both interventions and (d) no intervention. Findings from this study regarding the education intervention suggested that teaching an evidence-based approach to primary care dentists may not produce readily detectable changes in clinical practice. Meanwhile cluster-level analysis showed a significant increase in sealant treatment in the fee-for-service arms.

Therapeutic equipoise is an ethical standard which suggests that, for an RCT to be truly ethical, genuine doubt must exist with regard to any superiority between treatments under comparison (Freedman 1987). Historically, two forms of equipoise

have been conceptualised: one in which an individual clinician or researcher must have uncertainty regarding the optimal treatment and the second in which the professional community of clinicians and/or researchers must be in disagreement or doubt with regard to treatment of choice (Stines and Feeny 2008). If equipoise is not present, the ethical mandate is to make a direct, appropriate treatment recommendation. The 1989 'Convention on the Rights of the Child' (United Nations General Assembly, 1989 recognises:

"The right of the child to the enjoyment of the highest attainable standard of health. The entitlements include access to a range of facilities, goods, services and conditions that provide equality of opportunity for every child to enjoy the highest attainable standard of health."

However, it is recognised that clinicians may find it difficult to distinguish treatment and research goals when they are performed simultaneously (De Vries et al. 2011) and this finding will not be limited to clinicians based in certain medical fields. The moral (ethical) principles of physicians is to place the best interests of patients first. As a solution, for example, most oncologists, even those with substantial trial involvement, focus first of all on the possible benefit to their immediate patient and not on the theoretical benefit of future patients (De Vries et al. 2010). How this translates to dental research and the use of RCTs in unclear.

2.4.2. *Evidence for health professional-related barriers and facilitators to trial recruitment and retention*

Rendell et al. (2007) conducted a systematic review to: assess the evidence for the effect of disincentives and incentives on the extent to which clinicians invite eligible patients to participate in RCTs of healthcare interventions and to assess the evidence in relation to stated willingness to invite participation. From the search, none of the papers identified (n=11) involved RCTs and, instead, 11 observations reporting comparisons between the views of clinicians or clinician/patient characteristics and a measure of recruitment success were included. Five studies explored the influence of patient characteristics on recruitment. Four studies related to medical RCTs carried out in a primary care setting. The studies compared the views of clinicians who had varying success of recruiting their patients into RCTs in a

primary care setting. None of the studies reported sufficient information to allow full assessment of study quality. Clinicians who agreed to participate because they knew the researchers were less likely to participate than motivated clinicians who did not know the researchers. Concern that the doctor-patient relationship would be adversely affected by participation was a barrier to clinicians. Age, gender and ethnicity of patients was considered within the systematic review but it was suggested, given the paucity of data available, that the impact of these demographic factors should not be too heavily weighed upon. As this systematic review did not specifically focus on trials relating to paediatric patients and their patients, it is unclear whether the same barriers and facilitators to clinicians recruiting and retaining participants would exist in paediatric trials.

Tooher et al. (2008) conducted a literature review, limited to English language publications, for studies, of any design including qualitative research, which focused on recruitment to perinatal trials. Studies were included in the review if they obtained data from either participants (women and/or parents), clinicians or others involved in the recruitment of participants for perinatal trials. Studies of nurses' and midwives' attitudes to research in general were included as no studies specific to trials were located. This literature review focussed on barriers and enablers to succesful recruitment and strategies which may be effective in enhancing the recruitment effort. This literature review was then used as reference material in small group discussions during half-day workshops in Australia involving trialists with a range of experience from novice to expert, though it was not clear how these were assessed, or the extent of the range of views seen with the group. Outcomes of the small group discussions were collated by the authors and reported back to all the workshop participants. The literature review identified 53 studies (22 questionnaire design, 11 qualitative design, 4 systematic reviews, 7 'other' reviews and nine which reported recruitment data from a range of different research studies of varying methodologies). Participant factors affecting recruitment were identified in 21 studies and health care professional factors in 24 studies. Strategies to improve recruitment were identified in eleven studies, including four systematic reviews. In making the decision to participate, women and parents weighed up the risk of participation against the possible benefits to their child, with the child typically being prioritised before the mother's own health. A range of practical issues which may impact on

women's participation were also identified, including: work and childcare commitments, holiday plans, transportation issues, privacy and confidentiality concerns in small communities, treatment schedules and medications. Cultural background and language barriers were also reported as participation barriers for women from minority groups. A number of issues potentially impacting on clinicians' participation in research and trials were also identified, including: whether doctors had a strong preference for one treatment arm, whether doctors felt restricted in providing patient care to their patients, how they handled the uncertainty of trial participation and recruitment, the complexity of the trial protocol and the eligibility criteria/relevance of the trials. Younger, healthier and patients perceived as being of high intelligence and/or having a greater understanding were more likely to be invited to participate in a trial. Practical barriers to trial involvement for clinicians were: lack of time available for the different aspects of conducting the research, lack of support from management, lack of financial reward together with expense and financial implications, lack of awareness of ongoing trials and eligibility criteria. The majority of papers included in the literature review were descriptive studies and the study team did not assess their quality. The systematic reviews included many poor quality studies and so were limited in their conclusions. The 7 'other' reviews had limitations including; they did not provide details of search strategy or inclusion criteria; poor methodological reporting; failure to use a control group for comparison making it difficult to establish the effectiveness of the strategies used.

De Vries et al. (2011) discussed a narrative review of (primarily) qualitative studies on the ethical issues associated with parents' and physicians' experiences of the paediatric oncology research practice and compared these experiences with existing theoretical ethical concepts about paediatric research. The focus of the literature review was on RCTs, CCTs and laboratory research using tissue from patients specific to oncology research. Studies focusing on children's experiences were excluded. The search identified 20 qualitative studies, one quantitative study and one combination of quantitative questionnaire and qualitative interviews. Not all studies focussed just on the pediatric oncology research context; some also considered the adult and clinical context. They were included as they were considered to provide important information, particularly relating towards physicians' attitudes towards research and their conflicting professional roles of physician and investigator.

Analysis of the 22 studies revealed four main themes: inter-twinement of research and treatment goals, problems with informed consent, promoting best interests in a research setting and therapeutic misconceptions. It is recognised that clinicians may also find it difficult to distinguish treatment and research goals when treatment and research are performed simultaneously and the review highlighted the tension that can occur in the sense that their role as a researcher can conflict with the traditional definition of their core task to prioritise the best interests of patients. As a solution most oncologists, even those with substantial trial involvement, focused first of all on the possible benefit to their immediate patient and not on the theoretical benefit of future patients (De Vries et al. 2011). The studies included in the narrative review had limitations that were acknowledged: most studies had small sample sizes and were interview- or questionnaire-based studies using a retrospective design (n=19) resulting in uncertainty whether the parents' and physicians' recollections were accurate representations of how they felt and what their thoughts were at the time of diagnosis in a trial. This review (De Vries et al. 2011) identified the need for future research with larger samples and a prospective design to ascertain the relationship between the specifics of the informed consent discussion and parental and physician recollection. This review did not have a clearly specified and comprehensive search strategy and reasons why a wide and comprehensive scoped systematic review were not viable were given but the explanation was unclear. There was a sparseness of data in general, especially in studies involving children (n=16), and the focus was solely on oncology studies, where it was stated that the median age of children diagnosed with cancer is below six years; therefore the findings may not be generalisable to dental research studies where a wider age range of children may be eligible for research participation.

Fletcher et al. (2012) conducted a systematic review to quantify the effects of strategies aimed at improving the recruitment activity of clinicians in RCTs, complemented with a synthesis of qualitative evidence related to clinicians' attitudes towards recruiting to RCTs. This was a systematic review of quantitative and qualitative studies and included English and non-English language articles. Quantitative studies were included (n=8) if they evaluated interventions aimed at improving the recruitment activity of clinicians or compared recruitment by different groups of clinicians. Qualitative studies were included (n=11) if they investigated

clinicians' attitudes to recruiting patients to RCTs. Of the eight quantitative studies, three were RCTs, two were observational time series, two were before and after studies and one was a case study with a comparison group. One quantitative study was rated as strong, one as moderate and the remaining six as weak when assessed for quality using the Effective Public Health Practice Project tool (Effective Public Health Practice Project 2010). One quantitative study involved antibiotic treatment for women in idiopathic preterm labour and therefore placed the adult in the parental role. None of other quantitative studies involved children. Eleven qualitative studies were identified: nine used interviews (semi-structured; in-depth), two used focus groups and one study also analysed trial documents. Although child studies were captured within the the qualitative studies, these studies only incorporated the views of healthcare professionals and/or researchers and none involved the parents. From the included qualitative studies, a total of 174 trialists, from a wide range of professional background, were interviewed or involved in focus groups. A broad range of settings were covered by the included studies, for example, primary and secondary care trials, drug trials and pragmatic surgery trials, trials in mental health and cancer. Eight themes were abstracted from the qualitative data: understanding of research, communication, perceived patient barriers, patient–clinician relationship, effect on patients, effect on clinical practice, individual benefits for clinicians and methods associated with successful recruitment. The most frequently reported subthemes were: difficulty communicating trial methods, poor understanding of research and priority given to patient well-being. Overall, the qualitative studies were found to be of good quality when assessed using the Critical Appraisal Skills Programme checklist (Critical Appraisal Skills Programme 2018). Fletcher et al. (2012) concluded that the use of qualitative methods was the most promising intervention to identify and overcome barriers to clinician recruitment activity. This systematic review was primarily based on studies involving adult subjects and reporting of parental opinions was very restricted due to a paucity of relevant studies.

Health care professionals can be apprehensive and averse to recruiting children for trials due to perceived trial burdens, including the amount of information they have to provide to families. Assisting healthcare professionals to understand families' perceptions of trials and providing 'moral' support may improve recruitment of

children and their families (Young et al. 2011). Unfortunately, there is currently a paucity of research of studies, of any design, which focus on healthcare professional related barriers (and facilitators) to trial recruitment and retention. Understandably, when children or adults lack capacity or have complex communication needs, the process is more demanding for everyone, perhaps involving an augmentative or alternative communication system. Healthcare professionals recognise that more clarity is required for clinicians, researchers and family members research involving children with child-onset disabilities, in the recruitment, consenting, and investigational phases of studies (Rumney et al. 2015).

Further literature relating to healthcare professional-related barriers (and facilitators), comprising quantitative, qualitative and mixed methods research studies will now be discussed. These studies will primarily focus on study conduct.

2.4.3. *Study conduct*

2.4.3.1. Consent/assent considerations

Gibson et al. (2011) investigated how child health researchers approached consent and capacity in Southern Ontario, Canada, where there is no specific legislation governing research consent. The Canadian national reference for human research ethics (Canadian Institutes of Health Research et al. 2010) does not stipulate an “age of consent” and it is therefore the researcher’s responsibility to determine whether the child is independently capable of consenting to research, or if consent should be sought from an authorised third party (usually a parent). Researchers are required to determine the child’s assent and dissent will stop their participation (Gibson et al. 2011). Researchers and research assistants based in Southern Ontario who had conducted research in children under 18 years of age in the previous 18 months were approached using a selective snowball sampling technique, to obtain maximum heterogeneity in terms of discipline, years of research experience, gender, institutional affiliation and substantive field of research. Ten researchers and four research assistants from six institutions were recruited and participated in a semi-structured qualitative interview. The participants’ backgrounds were varied including social work and occupational therapy. They had 3-30 years’ experience in child research in a variety of fields including mental health, palliative care and clinical

intervention. All participants had directly participated in seeking consent in child-health research. The results were categorised: shared family decision making; assessing capacity and effective presentation of information and; perceptions of research ethics boards' requirements. Gibson et al. (2011) study was particularly relevant in the shared family decision-making category and the perceptions of research ethics boards' requirements. Not all participants made a ready distinction between assent and consent processes and instead focussed on ensuring the parent and child were both comfortable with proceeding, providing information and support and maximising the child' understanding. Of particular note, parents were viewed as valuable in helping to explain the study procedures to their child, gauging the child's interest and assessing his/her understanding. Parental participation and support for the study was in many cases viewed as required for emotional and practical reasons. Some researchers nevertheless also raised concerns regarding parental involvement, with two participant's transcripts noteworthy:

> *"How much freedom does the child have because of the pressure of the father being there who has just given his consent?" (P1); "I will often say to parents during the consent process, we find that children disclose more and are more honest when their parents aren't in the room." (P14)*

Participants reported a perceived disconnect of research ethics boards with the "real world" of conducting research and concerns that research ethics boards were overly focussed on liability issues rather than protection of research participants. A major limitation of this study was that it was restricted to Southern Ontario and the Canadian policy, which is markedly different to that of the UK. Secondly, the study involved researchers working with children under 18 years of age but it did not specify which age range they generally had experience of; given the diversity of parental support needed for children between 0-18 years of age this limits the applicability of the findings. There was also a diversity of discipline backgrounds, none of which were dental.

2.4.3.2. Ethical considerations

Cook et al. (2015) investigated, via a qualitative study, the attitudes of Canadian Research Ethics Board (REB) members regarding the benefits owed to research participants and other community members. The term "benefits" was used by the

study team in relation to trial participation potentially benefiting from trial participation, including post-trial access to the pharmaceutical, therapy, or intervention under investigation after the study period. In the case of pharmaceuticals and other intervention-based therapies, this could mean access to a potentially beneficial treatment would end when the trial ended. The researchers identified all Canadian universities with associated medical schools and used public information on the universities' websites to identify REB members where this information was publicly available. These membership lists included academic and lay members who constituted the REB. All were current or recent REB members. Where information was available, the researchers contacted members of REBs who reviewed research involving biomedical, health sciences, and health social sciences. The REB members covered a range of academic disciplines. No lay REB members agreed to participate in the study. In total 23 phone interviews were completed, though it is unclear how many were approached, and members indicated they were familiar with the challenges and issues around providing benefits for participants. Several members specified the role of the ethics committee was to ensure protection from harm but this did not ensure benefits for participants with further comments stating that it was crucially important that researchers clearly communicated this during the consent process. When members were asked what they thought was morally required in terms of benefits to participants some members cited compensating participants for their time and expenses, increasing their knowledge e.g. what the trial accomplished, and providing continued access to an intervention or therapy. The rationale for providing benefits focused on fairness and reciprocity. Several members indicated that research participants should not receive any financial benefits and later explained that participants, community members and citizens should all have access to a beneficial intervention through the healthcare system. Members tended to focus on ethical concerns e.g. obtained informed consent rather than ensuring that study participants directly benefited from successful trials. Ethical principles require that the (potential) benefit: harm ratio in a trial should not be disproportionately on the harm side (Jahn 2011). A common concern was that while benefits (such as post-trial access to the pharmaceutical, therapy, or intervention under investigation after the study period) are not necessary, it was important that this was clearly communicated to participants during the consent process by researchers. When respondents were asked what they thought was morally required in terms of benefits to participants,

regardless of legal requirements or norms, the answers varied around legal requirements. The two most common responses had to do with compensating participants for their time and expenses and for increasing knowledge. Several participants made a clear distinction between “benefits” for participants and “compensation” for time and expenses. Increasing knowledge was the second common theme around morally required benefits for participants. A final recurring theme was continued access to an intervention or therapy as a moral requirement of research. The overall response rate to this study was unclear, giving rise to concerns regarding non-response bias. While a major weakness was that it was it did not contain REB members from all medical schools in Canada meaning that all regions were not represented. This limitation was introduced as REB members names or their contact information was not publicly accessible information and thus the study team were not able to contact them. Predominantly French-speaking regions, for example, were not well represented meaning that not all experiences and issues may have been fully considered. It is impossible to establish whether the same themes would emerge from UK Ethics Board members centred within the NHS, and whether studies involving children and their families would be considered differently, and this is an area to be considered for further research. The Canadian consent process appears to be quite different to the UK consent process and it is unclear the impact this would have on the nature of the data collated.

Patterson et al. (2010) reported healthcare professionals concerns about taking part in UK-based mental health RCTs related to ethics and research approvals, but even when these issues were addressed clinicians remained less than enthusiastic about participation, identifying administrative and clinical duties as barriers. They used interview and observational data from a grounded theory process evaluation of a three arm parallel controlled multicentre trial (MATISSE) designed to test the effectiveness of art therapy in improving global functioning of people with schizophrenia. It was reported that the multicentre trial encompassed inner city, urban and rural areas with ethnically diverse populations. Qualitative data was drawn from individual interviews conducted with two clinical study officers of the Mental Health Research Network established to provide infrastructure to support for the conduct of mental health related RCTs and two research associates (RAs), five MATISSE investigators, five clinicians from two centres and a focus group attended

by all RAs and three (different) CSOs. Observational data were collected throughout the process evaluation. It was clear in this study that reported barriers may often be excuses for why clinicians have not recruited well. Removal of a perceived barrier did not necessarily lead to an improvement in recruitment. This study highlighted that more investigation is required to illuminate what facilitates recruitment in trials that easily meet their recruitment targets.

2.4.3.3. Challenges with conducting research in primary care settings

Goodyear-Smith et al. (2009) investigated the factors that facilitated or hindered recruitment of general practices into a large New Zealand primary care project that aimed to determine general practice characteristics of immunisation coverage. Three GP researchers took primary responsibility for practice recruitment and were initially supplied with details of 75 practices randomly selected using a computerised code. Where a recruiter personally knew the GPs at a particular practice, he/she could elect to invite that practice and the remainder of the randomly selected practices were equally allocated across the recruiters. Data on all attempts to recruit practices were collected to allow quantitative and qualitative analysis of the practice recruitment process. Once the 75 practices had been approached and either accepted or declined, further blocks of practices were randomised until the sample size of 125 practices was achieved. Towards the end of the recruitment phases, a non-medical recruiter was also utilised to aid recruitment due to time constraints for the GP researchers but it was unclear how many practices this non-medical recruiter was intended to recruit. Following recruitment, a member of the research team conducted a semi-structured interview with the three GP recruiters and the project manager regarding the barriers and facilitators they perceived to successful site recruitment. The data from these interviews was triangulated against the quantitative records for further data analysis. From a total of 517 practices, 213 were randomly allocated to recruiters, of which 205 were eligible practices (they provided immunisations to a paediatric population) and 124 (60% of those eligible) were recruited. One practice was enlisted but subsequently dropped out and was removed but it is not clear was the reason behind the drop-out. Recruitment practice bias was excluded in terms of their socio-demographic characteristics, funding, size and location. Recruited practices had a larger proportion of socially deprived patients than the national average but this was in keeping with regional patterns. Larger

organisations with salaried GPs took the longest to recruit and this was put down to the need to negotiate with management staff. The timing of the research study was also a reported barrier with the project coinciding with a mass immunisation strategy which had added time and resource burden on practices, alongside entire practice teams being involved in a lengthy practice accreditation process which created additional burden. The effect of practice variation with different governance structures required a customised process for each practice. The peer-to-peer contact approach, GP to GP, sometimes also had drawbacks with doctors deferring to decline participation immediately as they had difficulty saying no to a colleague. This deferral then required the study team to allocate additional time-consuming follow-up time to discuss the study further with the doctor who eventually declined to participate. A major limitation of this study is that it was an observational study rather than a RCT. It can be theorised that a better designed study would have incorporated an RCT design with randomised practices being approached by a fellow GP or by a non-medical researcher. Nonetheless, the findings, while from Australia and in primary medical care may have implications for site recruitment in other healthcare fields, including dentistry.

Foster et al. (2015) investigated the issues that impeded and facilitated recruitment to a clinical trial in general practice in Australia. All GPs were participating in a cluster RCT, called the MICA study, which tested interventions for improving medication adherence and asthma control in adults. At the end of the MICA study, each of 1662 GPs received a personally addressed invitation fax or letter to participate in the present study, which involved completing a self-reported questionnaire about barriers/facilitators to patient recruitment via fax or email depending on their preference. The invitation letter included a study information sheet and expression of interest fax form. GPs received one follow-up telephone call to confirm receipt of the invitation to allow them to ask questions and 55 enrolled in and trained for the present survey; there were no data available regarding the proportion of GPs who responded but failed to meet the inclusion criteria. GPs who had withdrawn from the MICA study were sent the questionnaire as soon as possible after withdrawal. The 7-item recruitment questionnaire consisted of five 7-point Likert scale questions (scored: 1 = strongly disagree; 7 = strongly agree) about the GP's perceptions of: (1) Intending to approach patients, (2) Not seeing potentially eligible patients, (3) Use of

waiting room advertising, (4) Forgetting to approach patients, and (5) Lack of interest from invited patients; and two free text questions. The first question asked about "Anything further the study team could have done to assist in patient recruitment"; the second asked the GP to estimate the total number of patients they recalled inviting into the study. Comments provided in open text boxes were categorised into themes. There were no statistically significant differences in perceived recruitment barriers between GPs who did or did not enrol patients. Some GPs perceived the study to be too intellectual/confronting for patients or expressed confusion about recruitment information. At the practice level, some GPs within group practices reported lack of empowerment when recruiting within a group practice due to practice policy or culture. Recruitment of patients was impeded by GPs perceiving that they had poor access to eligible patients, and by a delay in the time it took GPs to enrol their first patient. A major limitation of this study is that study material was returned to a research team known to the GPs, potentially biasing the data collected. Recruitment questionnaires were returned by 93% (37/40) of recruiter GPs versus 33% (5/15) of non-recruiter GPs. Whilst that is an excellent response rate for the recruiters, it is less so for the non-recruiters, where there may have been non-response bias. This study, whilst in Australia and in primary medical care, discussed barriers and facilitators to patient recruitment amongst GPs participating in a cluster-RCT and may provide valuable findings which may be found in other healthcare fields, including dentistry, and should be considered.

Spilsbury et al. (2008) investigated the scope and potential contribution of a clinical research nurse to clinical trials of a nursing-specific topic. The clinical research nurses involved in this study had been employed to co-ordinate a large multi-centre RCT comparing the clinical and cost-effectiveness of pressure area care. All clinical research nurses (n=16 from the six participating NHS Trusts in the UK) employed on the trial were approached to participate in a focus group, irrespective of the duration of their appointment as a clinical research nurse (ranging from 10 – 42 months). Nine clinical research nurses from five Trusts agreed to participate; the members of staff from the one unrepresented NHS Trust were no longer working on the trial. Over half of the participants (n=5) were from one NHS Trust but it was not felt to adversely affect the group dynamics. Thematic content analysis was used and coded whether issues were common to the group as a whole or merely a strongly held viewpoint of

one or a few members. Clinical research nurses came from varied clinical medical backgrounds prior to the trial; none relating to dentistry. All participants agreed that the research role was very different from the role of clinical nurse and they required time to transition into the role. Feelings of insecurity were relatively short- lived with most reporting that they gained confidence within months. However, there was one ongoing role tension throughout the trial period: at times, being a registered nurse had to take precedence over their research role and they had to intervene in other patients' care when they observed substandard care was being delivered. Clinical research nurses highlighted that hostility from clinical nursing staff towards the RCT was partly attributed to a lack of involvement of all staff in decisions about participation, perceived burden of trial paperwork creating additional work, poor research awareness (in particular lack of staff understanding of randomisation) and feeling threatened by scrutiny of their practice on a topic specific to nursing – pressure area care. Clinical research nurses emphasised the importance of having someone with whom they could share challenges and difficulties. Where there was more than one clinical research nurse in a given Trust, they gained support from each other and in other centres where clinical research nurses worked in isolation, they developed relationships with colleagues in similar positions to them within their own Trust. All clinical research nurses reported feeling unmotivated at some point during the trial period and this was influenced by isolation, hostility and also by study recruitment problems exacerbated by perceived 'unrealistic' targets set by the research team and feeling that other clinical research nurses were recruiting more patients. Whilst this study only included research nurses from one clinical trial, which is a limitation, it was able to highlight some challenges that the clinical research nurses encountered. It would be expected that similar feelings would be felt by other clinical research nurses particularly in RCTs involving the dental team or children and their parents in a primary care setting.

It is important to remember that when considering their role in research, general medical and general dental practices are small businesses. It has been reported that where research activities, including research costs, have been inadequately budgeted for, practice profits - and therefore partners' incomes - are reduced, resulting in a disincentive to engage and prioritise the work (Snowdon et al. 2006). However, it is unclear, due to a paucity of available literature, if inadequate costing of

research activities is a common problem. It could be theorised that how well a practice is organised/orientated towards research; and how research-naïve the practice may impact on awareness of what resources are required to cover costs. The NIHR Primary Care Research Network and Primary Care Research Recruitment Methods Group have published advice for researchers to aid recruitment in the primary care setting (Ward et al. 2010). Whilst it is recognised that the guidance was helpful, it highlighted the complexity of estimating the time required for recruitment and research related activities involved in a trial when taking into account project-specific variables (White and Hind 2015). This suggests that detailed analysis of primary care research is still required with significant input from health economists to ensure project specific variables are fully considered.

In summary, there is a paucity of evidence on the factors that facilitate or hinder recruitment of participants in general medical and dental practices as perceived by healthcare professionals. None of the studies discussed were conducted in the UK or involved a dental study. The study by Goodyear-Smith et al. (2009) identified that using professionals to recruit their peers into primary care research was not always beneficial and created additional time-consuming follow up without changing the outcome. However, clinical research nurses have also reported challenges with recruitment and interacting with medical teams in hospital settings (Spilsbury et al. 2008). The type of staff selected to recruit participants to studies, and how they present themselves, is therefore particularly noteworthy and warrants further exploration. Detailed estimation of primary care research costs is an important part of research design and planning to minimise the risk of healthcare professionals' being discouraged to engage with research.

2.5. Summary

Existing published systematic reviews identifying problems with recruitment and retention of patients to clinical trials have not primarily focused on parents. There has been a general reluctance about involving children in trials, particularly among parents and healthcare professionals, exacerbating the challenges in recruiting children to research studies. As parents and healthcare professionals are potential gatekeepers who can facilitate or obstruct children participating in research, it is important to consider the impact on both parents and healthcare professionals when

their child has been considered a subject for research. Parent related barriers and facilitators to involvement in research have only been considered in a small number of research studies, of varying qualities and designs, but none within the dental field. It is clear that a number of factors, such as ethnicity, cultural, gender, socio-economic status and the health status of the child are all potential influencers of parents when deciding whether to allow their child to participate in a research study and warrant special consideration.

There is a growing recognition that dental practices in the primary care NHS sector provide an excellent environment to carry out clinical dental research. However, trials in primary dental care, particularly those involving children remain rare, and thus there is as yet insufficient evidence upon which to base a recommendation on enhancing participation in such trials. When a specific paediatric trial within dentistry was funded (the FiCTION RCT), there was a great need to fully understand any recruitment or retention challenges in this setting and to whether parental attitudes changed over the course of the study. It was similarly unclear whether parents' perception of their own dental health acts as a facilitator or a barrier to their child participating in dental research. This thesis is based on the opportunity which arose to set out to address these issues.

2.6. Conceptual framework

Social Learning Theory is cited by some as essential for the promotion of desirable behavioural change (Muro and Jeffrey 2008). This theory is based on the idea that people acquire new behaviours (learn) through observation of others (Muro and Jeffrey 2008). Observational learning may take place at any stage of life (Muro and Jeffrey 2008). Bandura (1986) has expanded and refined this theory, now called Social Cognitive Theory, to include a social element, arguing that people can acquire, maintain and change behaviour as a result of the interplay of personal, behavioural and environmental influences. The concept of self-efficacy (belief in one's ability to accomplish a task) is included in Social Cognitive Theory which also has a greater focus on cognition than the Social Learning Theory. When used to elicit behaviour, Social Cognitive Theory proposes three predictors of clinical behaviour: proximal goals (intention), self-efficacy and outcome expectations (belief of the consequences of the behaviour). In the Social Cognitive Theory there is an assumption that people

will act in ways that they believe will lead to positive and valued outcomes. Self-efficacy not only has a direct influence on behaviour, but also operates through intentions (proximal goals), beliefs regarding the consequences of the behaviour (outcome expectations) and perceived socio-structural determinants (Bandura 1982). Individuals perform activities with which they feel they can cope and avoid activities they feel they cannot manage. Perception of self-efficacy determines initiation and maintenance of, and persistence with, an activity (Bandura 1982). Perceptions of self-efficacy have been found to predict various types of health behaviours well e.g. compliance with diabetes, changing diet, stopping smoking (Syrjala et al. 1999). People develop their self-efficacy perceptions on the basis of their own experience (which is considered the most important factor), models of other people, physiological state in relation to taxing situations and verbal persuasion (Bandura 1982). Attitudes, subjective norms, self-efficacy and perceived control have been found to be significant predictors of intention to attend dental appointments (Luzzi and Spencer 2008).While intentions, self-efficacy and past dental attendance have also been found to be significant predictors of actual dental attendance (Luzzi and Spencer 2008). Therefore it is important to consider any experiences which could influence a patient's self-efficacy resulting in a change in dental attendance.

The characteristics of medicine and public health can be considered in the following stages: (i) cure or treatment of diseases; (ii) health protection/disease prevention; (iii) health education/ health promotion and (iv) improving health perception/ wellbeing/ QoL (Eriksson and Lindström 2008).The biomedical or pathogenic approach where health is generated through the elimination of risks for diseases is the dominating standard at present. A river was used as a metaphor of health development by Antonovsky (Antonovsky 1987). According to Antonovsky, it is not enough to promote health by avoiding stress or by building bridges to keep people from falling into a river (Antonovsky 1987). Instead, people need to learn how to swim (Antonovsky 1987). This principle was subsequently developed via a new analogue: 'Health in the River of Life' (Eriksson and Lindström 2008). This metaphor explains that at birth we are dropped into a river and float with the stream. Some people are born close to the side of the river where they can float at ease, opportunities for life are good and they have many resources at their disposal. Meanwhile, other people are born on the opposite

side of the same river where the struggle for survival is harder and the risk of harm is much greater. A person's outcome in the river is largely based on their ability to identify and use resources to improve their options for health and life. This metaphor describes the salutogenic approach which focusses on resources for health and health-promoting processes to create health (Eriksson and Lindström 2008). Ultimately, a person's ability to enjoy a high QoL is dependent on how well society is able to support the process of health through the course of life (Eriksson and Lindström 2008). By creating and empowering environments where people can see themselves as active participating subjects who are able to identify their internal and external resources, use and reuse them to realise aspirations, to satisfy needs, to perceive meaningfulness and to change or cope with the environment this is likely to lead to an improvement in health (Eriksson and Lindström 2007).

Dental health professionals often experience difficulties when they try to help their patients acquire and maintain actions that preserve their dental health (Freeman 1999). Despite repeated attempts there may be no change in the patient's behaviour and indeed occasionally their dental health worsens (Freeman 1999). The patients' behaviour, however, is only one aspect of patients' life experiences and personal histories are also noted as important (Freeman 1999). For instance, their current actions may be associated with their childhood experiences or with how highly their family rated dental health care amongst other competing lifestyle priorities, or negative dental health care experiences. In the dental literature, psycho-social factors have been given to explain patients' avoidance of dental care and to provide reasons for non-compliance with treatment and preventive regimes (Nuttall 1997). These factors are said to include socio-economic status, age, gender, ethnicity, perception of need, dental anxiety states and feelings of vulnerability (Nuttall 1997). Irrespective of the psycho-social factor, it is the role of the dental health professional to acknowledge that barriers exist and to help their patients access and accept dental health care (Freeman 1999). Despite the efforts required by dental phobics to attend for treatment, it is not unusual for them to flee from the waiting room as their appointment time approaches (Longman and Ireland 2010). Therefore, the ability of a dental health professional to create and empower a dental environment where patients can see themselves as active participating subjects leading to an

improvement in their attitude, subjective norms, self-efficacy and/or perceived control is particularly interesting and warrants further investigation.

We already know that many adults have dental anxiety from negative dental experiences they have encountered, often as a child (Abrahamsson et al. 2002). The interplay between both a mother's and a father's dental fear and that of their child has been examined and both are significant predictors of child dental fear and anxiety (Lara et al. 2012). This suggests that children indirectly learn any anxiety response to dental treatment by observing the behaviour of those around them (Lara et al. 2012). Many adults with dental anxiety may mention their fear in front of their children, creating and maintaining a child's negative impression of dental treatment (Chadwick and Hosey 2003) which may impact on these children for the rest of their lives. Parents with a high level of personal dental anxiety are also often anxious on behalf of their child (Abrahamsson et al. 2002). For very young children a parental presence is important in the dental surgery due to separation anxiety, whereas for older children a parental presence appears not to have such a clear effect on child behaviour, although it may be important to the parent for their own reassurance (Chadwick and Hosey 2003). Many children will discuss with their parents their feelings about receiving dental treatment and parents will witness the dental treatment being provided for their child. It is widely accepted by the dental community that anxious patients can have some of their fears allayed by sequential treatment planning, whereby dental instruments and procedures are introduced gradually(Chadwick and Hosey 2003). It is unclear, but plausible, that a parent indirectly experiencing the gentle introduction of their child to dental instruments and procedures could lead to a change in parental outcomes. It can be postulated that if a parent directly participates in a dental RCT involving a clinical intervention, that this may change their attitude, subjective norms, self-efficacy and/or perceived control. Likewise, if their child directly participates in a dental RCT involving a clinical intervention, this may change a parent's attitude, subjective norms, self-efficacy and/or perceived control.

It has been recognised within medicine that parents lose many of their normal parenting roles when their child is admitted to hospital, resulting in parental anxiety

and uncertainty (Corlett and Twycross 2006). Many parents have limited understanding of illness, treatment and how health services function (Corlett and Twycross 2006). Previous studies report that parents want to be involved in decisions about their child's health care to varying degrees and this desire may change over time (Aarthun and Akerjordet 2014). Their preference towards involvement seems to depend on factors such as parents' demographic characteristics (e.g. age, level of education, income and marital status), emotional condition and professionals' attitudes and competence (Aarthun and Akerjordet 2014). It is unclear whether parents with a high level of personal anxiety are more risk averse on behalf of their child (including regarding novel therapies). The effect, upon parental anxiety, of their child's participation in a RCT is also unclear, but potentially noteworthy as it is possible that their child's involvement could lead a parent to seeing themself as an active participating subject resulting in an improvement in their own health. The published literature has reviewed barriers and facilitators associated with the recruitment and retention of children into research studies and has primarily looked at parent and child socio-economic factors (see Section 2.3). It can be postulated, based on the previous literature, that a parent's willingness to be screened, randomised and retained in a dental RCT until the end of the study may be influenced in some sense by their previous experiences, interest in the research question, trust in the quality of the research and the conduct and attitudes of the dental teams involved (see Section 2.3). However, the published literature in medical or dental trials has not assessed how a child's participation in a RCT could impact on their parent's attitude, subjective norms, self-efficacy and/or perceived control. From a clinical perspective, little is known about parental attitudes to dental care and how they might be impacted by bringing their children to dental appointments and participating in an RCT with their child.

Over recent years, researchers and oral health professionals have increasingly used patient-oriented or patient-reported outcomes (PROs) alongside disease-oriented outcomes (e.g. number of teeth) to better capture the impact of diseases and interventions on the patient (Mittal et al. 2019). The importance of assessing both patients' perceptions of health and presence or absence of disease lies in the need to have accurate data to promote health, and optimise stakeholder acceptance of, and

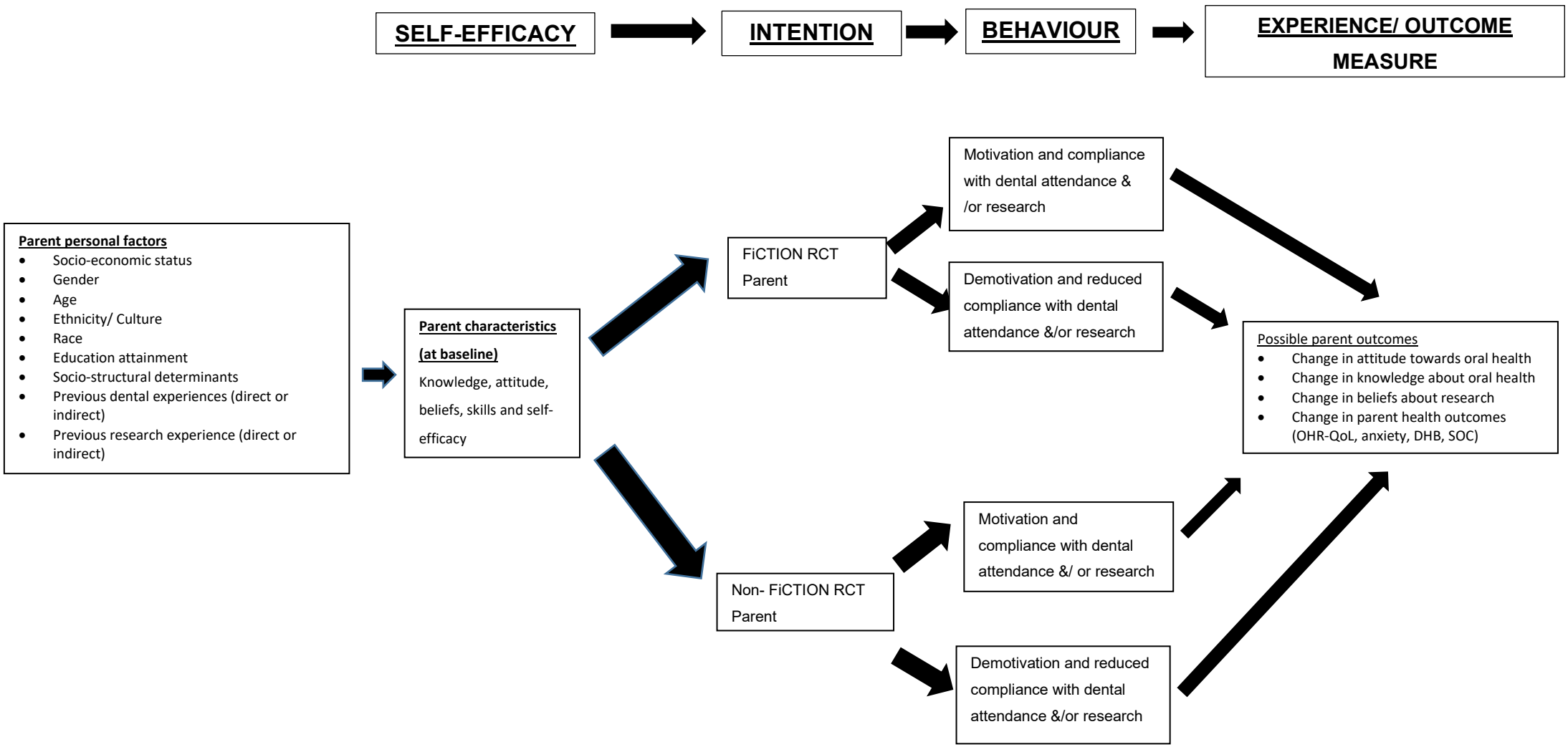
effectiveness of, disease prevention programmes. This assessment is also key in the allocation of health resources. Oral health-related quality of life (OH-RQoL) is one such outcome measure, which aims to evaluate the impact of oral health on daily life. Patients' assessment of their health related quality of life is often markedly different to the assessment of the same patient by their health care professional (Slevin et al. 1988) and thus patient assessment of disease impacts and health care interventions is an important component of the overall data capture and analysis. Directly experiencing a dental intervention can lead to a change in OH-RQoL, as has been found with patients after orthodontic treatment (Javidi et al. 2017) and implant supported overdentures (Mishra and Chowdhary 2019).

In a paediatric dentistry context, the patient/dental team need to include the parent. In the UK, parents have a legal right to participate in decision-making about their child's health care to ensure that health care is provided in accordance with the children's and the families' needs and preferences (Entwistle and Watt 2006). From a health promotion perspective, this provides parents the opportunity to improve their personal control over their child's health care and their own life circumstances (Eriksson and Lindström 2008). The moral (ethical) principles of physicians require them to place the best interests of patients first. Dental teams have the potential to greatly influence a patient's self-efficacy and subsequent behaviour with respect to dental care. All stakeholders expect that the care provided is based on robust evidence, and clinical research trials are fundamental to providing this evidence. Its key for the clinician (and team) to be in clinical equipoise – that they feel that no one way to treat is better than another based on the current evidence before the trial begins (De Vries et al. 2010).

Bringing together these concepts and ideas allowed a map of possible relationships between variables to be described (Figure 2). This map, also known as a conceptual framework and the supporting text can be used to explain the natural progression of the research question being studied (Villeneuve et al. 2010, Imenda 2014). I accept that the conceptual framework may only apply to the specific research study for which it was created. Applications to other research problems may be limited. However, by synthesising the existing literature described in Chapter 2, it may serve

as a springboard for other research in this area. Cumulatively and over a period of time, this may lead to the articulation of a theory from which a theoretical framework may evolve.

Figure 2: Conceptual Framework



Chapter 3: Aims and Objectives of the study

This study investigated parents' perceptions of their own dental health and their thoughts about their child being involved in a primary care based dental trial in the UK.

3.1. Aims

1. To quantify if their child's participation in a RCT impacts on a parent's dental anxiety, oral health-related quality of life and attitude to their own dental care and that of their children (IMPACT quantitative study – see Chapter 5).

2. To investigate parents' views, knowledge and experience around their child participating in dental research (IMPACT qualitative study – see Chapter 6).

3.2. Research hypothesis

There is a difference in change from baseline to 18 months, with respect to parental oral health-related quality of life (OHIP-14), dental health beliefs (DHB) and sense of coherence (SOC-13) regarding their own dental care and that of their children, between parents of children with active caries and participating in an RCT in primary dental care (FiCTION) and parents of children without active caries and not participating in an RCT.

3.3. Objectives

1. To quantify the difference at baseline, with respect to parental dental anxiety (MDAS), oral health-related quality of life (OHIP-14), dental health beliefs (DHB) and sense of coherence (SOC-13) regarding their own dental care and that of their children, between parents of children with active caries and participating in an RCT in primary dental care (FiCTION) and parents of children without active caries and not participating in an RCT (IMPACT quantitative study – see Chapter 5).
2. To quantify the difference in change from baseline to 18 months between these two groups of parents in parental dental anxiety (MDAS), oral health-related quality of life (OHIP-14), dental health beliefs (DHB) and sense of coherence (SOC-13) regarding their own dental care and that of their children (IMPACT quantitative study – see Chapter 5).

3. To investigate parents' views, knowledge and experience regarding their own dental health and their families' dental care and any differences therein between those parents whose children were participating in the FiCTION RCT and those parents whose children were not participating in that RCT (IMPACT qualitative study – see Chapter 6).
4. To investigate parents' views, knowledge and experience about participation in research and any differences between parents whose children were participating in the FiCTION RCT and those whose children were not participating in that RCT (IMPACT qualitative study – see Chapter 6).

Chapter 4: Methodology

4.1. Introduction

This chapter describes the overall research methodology for the IMPACT study, including justification for the mixed-methods research design used. The methods employed in the delivery of the research itself are described fully in Chapter 5 (Quantitative Study), Chapter 6 (Qualitative Study) and Chapter 7 (Triangulation of findings).

4.2. The mixed methods approach to research

“Mixed methods (also known as multi-method) research involves integrating quantitative and qualitative approaches to generating new knowledge and can involve either concurrent or sequential use of these two classes of methods to follow a line of inquiry” (Stange et al. 2006, p. 292). Mixing quantitative and qualitative research methods in the design and execution of research and the approaches needed to do so is complex. In addition, the definition of a mixed-methods design in research has caused confusion for researchers, with significant variations in terms of what was being mixed, the stage at which mixing occurred, the amount and purpose of mixing and the rationale behind the research (Johnson et al. 2007).

Howe (1988) suggested that combining different data types as well as different analysis methods would improve the power of the data collected. He felt that quantitative and qualitative researchers differed chiefly in terms of the assumptions they were willing to make at the design, analysis and interpretation of results stages of the research. Barbour (1999) suggested that quantitative methods were most appropriate for addressing questions of prevalence, causality, the relationship between variables, prediction, comparison and measuring outcomes, whereas qualitative methods were more appropriate for addressing questions of process (e.g. organisational change, decision-making, perceptions, understandings, and experience). However, Barbour (1999) suggested that by combining methods, assumptions made by researchers can be re-examined to both enhance and challenge accepted models of research, while Denzin (Flick 2018) suggested that use of mixed methods overcomes personal biases associated with single methodologies. There has been a surge of international interest in mixed methods research with one fifth of health service research studies funded by the Department of Health in England between 1994 and 2004 being mixed method studies (O'Cathain

et al. 2007); the suggested justification being that the benefits associated with mixed method approaches outweigh the challenges.

4.3. IMPACT Study design

A convergent, parallel, mixed methods approach (Ivankova et al. 2006) was used to address the aims of the IMPACT study (see Section 3.1). In a convergent design, the qualitative and quantitative data are collected and analysed during a similar timeframe. With a parallel design, qualitative and quantitative data collection occurs in parallel and analysis for integration begins well after the data collection process has proceeded or has been completed. Frequently, the two forms of data are analysed separately and then merged. The IMPACT study comprised two strands, one from each of two theoretical paradigms: (i) quantitative data derived from a questionnaire based study; (ii) qualitative data derived from in-depth semi-structured qualitative interviews of a sub-sample of parents who had returned the baseline questionnaire for the quantitative element. In order to generate greater understanding of the research area, particularly around parents' knowledge and understanding of their own dental health and that of their children, findings were then compared to generate detailed and in-depth appraisal of where findings from each strand were in agreement (converged), offered complementary information on the same issue (complemented) or appeared to contradict each other (were discrepant or dissonant) (O'Cathain et al. 2010).

4.4. Prioritisation of data

In mixed methods research, the weight or attention assigned by the researcher to each component or strand of the research throughout the data collection and analysis process is called 'prioritisation'. Cresswell and Miller (2000) suggested that the decision of whether and how to prioritise one methodological approach over another should be based on the specific interests of the researcher, the target audience for the findings and the focus of the research itself. For this study, I felt that the participants' previous dental experiences were equally as important as their understanding of research and it was impossible to ascertain, with any degree of certainty, whether one would be more important than the other with regard to parent's willingness to take part in IMPACT. In view of this, both topics were given equal

status and both methodological approaches were used in parallel, without one being prioritised over the other.

4.5. Strengths of a mixed-methods approach

With quantitative data, it has been reported that researchers “eliminate their biases, remain emotionally detached and uninvolved with the study participants and justify their stated hypotheses” (Johnson and Onwuegbuzie 2004, p. 14). It has been argued that when only a quantitative approach is taken, data not displaying statistical significance is often neglected or alternatively attention is focused on ‘deviant cases’ and this distorts the evaluation of data (Lacey 2015).

Since qualitative research does not generally seek to enumerate, it is viewed as the antithesis of the quantitative method. The goal of qualitative research is the development of concepts which help us to understand social phenomena in natural settings, giving emphasis to the meanings, experiences, and views of all the participants. However, with qualitative data some researchers can become overwhelmed by the amount of data collected, resulting in research being poorly focused and ineffective (Carr 1994) and a focus on deviant cases also being a significant risk.

In quantitative research, the importance of internal validity and external validity (generalisability) has been long accepted and well documented in the literature. In qualitative research, discussions of validity have been more contentious and different typologies and terms have been produced. It has been suggested that:

> *“whereas quantitative methods aim for reliability through the use of tools such as standardised questionnaires, qualitative methods score higher on validity, by investigating how people’s natural behaviour impacts results and what individuals actually mean when they describe their experiences, attitudes and behaviours”.*(Pope and Mays 1995)

However, it must be acknowledged this is a complicated issue with researchers considering validity in many different ways: statistical conclusion validity, internal validity, construct validity and external validity (Onwuegbuzie and Johnson 2006). It is recognised that qualitative approaches are limited in their ability to assess links

and/or associations between cases and can result in the creation of subjective and potentially idiosyncratic topics that may have little or nothing in common with the wider population.

4.6. Recognised weaknesses of using a mixed methods approach

Although there are potential benefits to a mixed methods approach – namely: to strengthen the weaknesses that are associated with only quantitative or only qualitative research, to provide a more complete and comprehensive understanding of a research problem, to enable further development of better and more specific instruments, and to help explain how causal processes work – it is nonetheless recognised that there may be some limitations of this approach. One problem is failure to integrate the data and findings from the quantitative and qualitative components to create synergy (Barbour 1999) and thus failing to strengthen the weaknesses associated with either or both research methods. This lack of synergy is evident in some earlier mixed methods research with the knowledge gained only being equivalent to (and not greater than) independent qualitative and quantitative studies (Tariq and Woodman 2013). This inevitably brings the worthwhileness of a mixed-methods approach into question and highlights the need to ensure full integration of the two composite components. Another problem is that many researchers do not have the specialised skills to manage both quantitative and qualitative methods, both of which are needed for a mixed methods approach (Bowers et al. 2013). A mixed methods approach is also generally more costly than using a single method with regard to the time needed for data collection and analysis (O'Cathain et al. 2009). In the case of IMPACT, this challenge could not be overlooked as the study was both time- and cost-sensitive.

4.7. Justification of a mixed-methods approach with the IMPACT Study

The study team recognised that IMPACT was investigating a relatively unexplored area within healthcare and collectively felt that we were still “feeling our way” with primary dental care research. It was therefore agreed that a qualitative approach might complement and enhance a quantitative study by furnishing explanations for unexpected or anomalous findings. Likewise a quantitative approach may enhance qualitative work in terms of analysis of data; sampling strategies and amalgamation of findings from separate studies (Barbour 1999). By using mixed methods, IMPACT

hoped to address the acknowledged weaknesses associated with single method research designs and to explore the results, triangulating for any differences that could otherwise be blamed as a methodological artefact (Johnson and Onwuegbuzie 2004).

4.8. Triangulation

In keeping with the mixed method design, inferences drawn from the separate quantitative and qualitative analyses were considered using the triangulation protocol (O'Cathain et al. 2010). Triangulation, has been defined as "a validity procedure where researchers search for convergence among multiple and different sources of information to form themes or categories in a study" (Creswell and Miller 2000, p. 126) The purpose of triangulation can be to generate detailed and in-depth appraisal of where findings from each study agree (converged), offer complementary information on the same issue (complemented) or appear to contradict each other (discrepant or dissonant) (O'Cathain et al. 2010). Triangulation is now often recommended by many methodologists to enhance the quality of research.

Because much research is founded on the use of a single research method and, as such, may suffer from limitations associated with that method, or from its specific application, triangulation offers the prospect of enhanced confidence. Triangulation can be achieved by using multiple methods, data, investigators and theories, as discussed by Denzin (Flick 2018) who drew a distinction between four different types of triangulation; data triangulation, investigator triangulation, theoretical triangulation and methodological triangulation. Data triangulation, which refers to the use of the same method, such as at different points in time, to check for consistency. Methodological triangulation, which refers to the use of more than one method for gathering data, was used in this thesis to increase the credibility and validity of the results. Denzin (Flick 2018) also distinguished between within-method and between-method triangulation. Between-method triangulation was chosen for the IMPACT study as it involves using contrasting research methods, such as a questionnaire-based and observation-based data collection (or as was the case here, in depth interviews), whereas within-method triangulation involves the use of varieties of the same method to investigate a research issue e.g. using two contrasting scales within the same self-completion questionnaire. Within-method triangulation allows cross-

checking for internal consistency whereas between-method triangulation tests the degree of external validity. In between-method triangulation, by analysing the two data types separately and then undertaking additional analysis whereby the data and findings from both approaches are compared, contrasted and combined, the quantitative and qualitative data are initially kept separate and analysed using techniques associated with and appropriate to that type of data. This enables the integrity of each data type to be preserved whilst also potentially providing further information; i.e. the synergistic component (Tariq and Woodman 2013).

It has been reported that many mixed method studies fail to integrate adequately quantitative and qualitative studies and the associated data, leading to results being presented as "separate, disconnected data sets rather than achieving a whole greater than the sum of the parts" (O'Cathain et al. 2010). For the IMPACT project, data from both strands was initially kept separate from each other and separate analysis of the quantitative and qualitative strands was completed using methods appropriate to the individual datasets (see Chapters 5 and 6) before bringing together the findings from each strand to compare for convergence and divergence. The IMPACT data was considered in terms of groups (e.g. FiCTION status, gender, age, geographical area) and these findings were then integrated with existing knowledge, or indeed lack of knowledge, within the literature, in order to form meta-themes or conclusions (Teddlie and Tashakkori 2009) which form the basis of Chapter 7.

4.9. Quantitative study; Relevance of variables

In order to investigate parents' willingness to participate in primary dental care research studies, involving their children, it is important to explore why parents make certain decisions. The study team felt, based on an appraisal of existing published literature and collective judgment, that parents' personal dental health, functional well-being, emotional well-being, expectations and satisfaction with dental care and sense of coherence of that care may all have important implications on their beliefs, values and attitudes towards (their child's) participation in a primary dental care research study.

It is important to recognise that beliefs, values and attitudes are not quite the same and neither are synonymous with behaviour or behaviour change (Fishbein and

Ajzen 1975). A belief is an internal feeling that something is true, even though that belief may be unproven or irrational (Darling and Cassidy 2014). An example of a belief is: “When winter comes it gets colder and when summer comes it gets warmer.” There is no real proof of this but general daily life teaches this to be true. Beliefs come from real experiences but we sometimes forget that the original experience may not be the same as what is happening in life now. We tend to think that our beliefs are based on reality, but it is our beliefs that govern our experiences. Beliefs may be religious, cultural or moral. Beliefs are precious because they reflect who we are and how we live our lives. A value is a measure of the worth or importance a person attaches to something; our values are often reflected in the way we live our lives (Darling and Cassidy 2014). Values can influence many of the judgments we make, as well as having an impact on the support we give to others. Common values are those that are widely shared amongst a group, community or culture. They are passed on through sources such as the media, institutions, religious organisations or family. A common family value is that “family comes first”. An attitude is the way a person expresses or applies their beliefs and values, and is expressed through words and behaviour (Darling and Cassidy 2014). An attitude usually describes what we think is the ‘proper’ way of doing something. Our own attitudes can make us blind to other people’s values, opinions and needs. The study team concluded, after an appraisal of existing published literature relating to dental health and research participation, that no distinction had been made between the use of these terms, resulting in some ambiguity and confusion.

4.10. Quantitative study; ensuring validity and reliability

Quantitative research is often confirmatory in nature and driven by theory and the current state of knowledge about the phenomenon under study (Sieber 1973). It is also usually focused on numerical data, collected using methods such as questionnaires; the research requires statistical analysis to investigate and summarise what is being observed (Creswell and Miller 2000). When using existing questions/questionnaires to measure the constructs that one is interested in, it is important to ensure that the selected instruments have adequate validity (i.e. that they are indeed measuring the construct of interest) and reliability (i.e. that they are doing so in a reproducible and consistent manner).

Certain recommended quality control indicators must be considered when conducting a critical appraisal of available questionnaires (Brazier et al. 1992). The first is its internal consistency reliability, which is the extent to which items within the scale correlate with each other. Cronbach's alpha, a widely used method to assess internal consistency, is based on the average correlation of items within a scale (Cronbach 1951); Cronbach's alpha of 0.7 and above is generally taken as indicative of adequate internal consistency reliability. The second recommended quality indicator is test-retest reliability which can be assessed in a number of ways using within-subject standard deviation, Pearson or Spearman correlation coefficients and intra-class correlation coefficients.

In addition, questionnaires should be checked in terms of validity which ensures that a questionnaire accurately measures what it aims to do regardless of the responder (Bolarinwa 2015).

By utilising a questionnaire with high test-retest reliability, internal consistency and validity, the likelihood of better quality data being collected is maximised, which is clearly important. These indicators were considered when selecting appropriate scales for the quantitative study.

In appraising health-related quality of life measures, it has been recommended that six other key areas (conceptual and measurement model, responsiveness, interpretability, burden, alternative modes of administration, cultural and language adaptations or translations), in addition to reliability and validity, should also be considered (Aaronson et al. 2002). Whilst these recommendations were originally made in respect of health-related quality of life measures, there was no reason to think that these criteria should not be also applicable in the appraisal of instruments measuring dental anxiety (DA) or attitudes.

4.11. Selection of outcome measures based on a critical appraisal of those available

The study team felt, based on an appraisal of existing published literature and collective judgment, that parents' DA, oral health-related quality of life (OH-RQoL)

and how they value their life may all be important predictors for parental beliefs, values and attitudes towards (their child's) participation in a primary dental care research study. A range of potential outcome measures to assess these variables were critically appraised, as described below.

4.11.1. *Dental anxiety and its measurement*

DA is a common worldwide problem, and hence a public health concern, that impinges on a patients' decision to visit the dentist (Cohen et al. 2000). DA has been reported to contribute to irregular dental attendance, delay in seeking dental care and even avoidance of dental care (Chadwick 2002). It ultimately leads to deterioration of dental health, which may have a significant influence on the individual's dental health status and OH-RQoL (McGrath and Bedi 2004). Misdiagnosis of a dental condition may even result from a dentist-patient relationship that is dominated by significant DA (Eli 1993). In addition, dentists perceive anxious patients as a major job-related stressor (Cooper et al. 1987, Moore and Brodsgaard 2001). Identifying anxious patients can enable the dentist to better anticipate their patient's behaviour, resulting in the dentist being better equipped to help alleviate the patient's anxiety (Appukuttan et al. 2015), and may also help reduce the anxiety felt by the dental team. DA has been recognised as a complex phenomenon involving threat to self-respect, loss of control and social anxiety (Abrahamsson et al. 2002). In lay terms, being anxious when at the dentist might refer to a range of feelings, from relatively mild apprehension to extreme dental phobia. The term "dental anxiety" has therefore been used to cover a range of conditions from a general feeling of fear and apprehension, to extreme or disproportionate anxiety and dental phobia (Stouthard et al. 1993). The most frequently used DA measures have been subject to criticism as they do not capture the complex phenomenon of DA even though their reliability and validity is satisfactory from a psychometric perspective (Stouthard et al. 1993). Furthermore, although dental fear and anxiety have been thoroughly investigated during the last decades, mainly with quantitative instruments, there is a lack of studies and instruments describing dental fear with the patients' own words and from their perspective (Abrahamsson et al. 2002).

The distinction between use of the terms "fear" and "anxiety" has been poorly differentiated within published dental literature and therefore both terms were

included when conducting a critical appraisal of the literature. Quantitative measures to assess DA can be subdivided into specific measures of dental care anxiety in adults (Schuurs and Hoogstraten 1993), in children (Al-Namankany et al. 2012) and general measures of anxiety that have been used across age ranges (Crofts-Barnes et al. 2010). Only DA questionnaires that have been used with adults are discussed in this thesis. A review was carried out of relevant DA questionnaires and these were critically appraised as indicated in the following sections. The most commonly adopted scales are discussed and take into account the order in which they were initially developed and their subsequent refinement. Unfortunately, none of these fully capture the complex phenomenon of DA.

4.11.1.1. Dental Anxiety Scale (DAS)

The Dental Anxiety Scale (DAS), is a 4 item measure created in 1969 by Corah (1969). Respondents are asked about four dentally-related situations and are asked to indicate which of four responses (of increasing severity) is closest to their likely response to that situation. When the scale was first described in 1969, it was reported to have a test-retest correlation coefficient of 0.82 over 3 months. When published, the scale also reported a validity correlation between dentist's ratings regarding the patient's behaviour and the patient's reported anxiety of 0.41 and 0.42. In 1978, Corah et al. (1978) concluded that a DAS score of 15 or higher was associated with a highly anxious patient. However, the methods used to determine this cut-off are unclear. The reliability of DAS was further investigated by Schuurs and Hoogstraten (1993) who subsequently reported, from an appraisal of multiple studies, a reasonably high internal consistency (from 0.62 to 0.81 using Cronbach's α) and a test-retest reliability of approximately 0.8. However, the context validity of the DAS is not as certain; DAS has been used extensively but does not have any reference to local anaesthesia (LA) injections, a major focus of anxiety for many adults. A number of other criticisms have been levelled against DAS; (1) it can only provide meaningful measures for extremely high or extremely low DA (Humphris et al. 1995); (2) it was not designed to be a measure of DA for a given dental visit (i.e. not designed to measure state anxiety); (3) DAS attempts to record the typical affective response of individuals to dental procedures and tries to measure the specific trait anxiety construct associated with dental visits and treatment but does

not correlate strongly with general trait anxiety using traditional measures (Moore et al. 1991a, Weisenberg et al. 1974).

4.11.1.2. Modified Dental Anxiety Scale (MDAS)

The DAS became the Modified Dental Anxiety Scale (MDAS) when a fifth item was added regarding LA, and the response format was modified to give a consistent answering scheme for each item, ranging from 'not anxious' to 'extremely anxious' (Humphris et al. 1995). MDAS, like the DAS, does not assess the anxiety reaction to a specific dental treatment session, but rather a predisposition to be anxious at the dentist. Humphris et al. (1991) reported that a parent's MDAS did not correlate strongly (r=0.126, n=43) with their trait measure of general anxiety. Humphris et al. (1995) recommended that a cut-off score of 19 and above be used to indicate a strong likelihood of the respondent being dental phobic. At this time the reliability (internal consistency = 0.89, test- retest= 0.82) of the MDAS was also calculated. The internal consistency reliability of the DAS versus the MDAS scale has since been assessed using Cronbach's alpha. Humphris et al. (1995) reported reliability of DAS to range from 0.75 in 4th year dental students to 0.92 in psychology students, while Ilguy et al. (2005) reported a reliability coefficient of 0.85 in anxious patients referred for dental treatment. For MDAS, the range was from 0.84 to 0.90 in the study by Humphris et al. (1995), with Ilguy et al. (2005) reporting a value of 0.88. Generally, reliability was higher for MDAS than for DAS.

Conversion tables were created in 2007 to allow existing DAS scores to be converted to the MDAS score to allow comparison with findings from older studies (Freeman et al. 2007). The MDAS remains a popular scale and continues to be modified into many languages including Chinese, German and Turkish (Giri et al. 2017).

In addition to the MDAS, there is also the MDAS/4 version which was developed by Haugejorden and Klock (2000), although the differences between MDAS and MDAS/4 are not clear. The authors reported the internal consistency of DAS, MDAS and MDAS/4 to be 0.91, 0.89 and 0.92 respectively. Inter-item correlations of DAS, MDAS and MDAS/4 gave Pearson's rho(r) between 0.59 and 0.92, except for item 5 of MDAS which was lower at 0.35-0.51. It is unclear why MDAS/4 has not used widely.

4.11.1.3. Dental Fear Survey (DFS)

The Dental Fear Survey (DFS) was published by Kleinknecht (1973) with 27 items to identify specific fear stimuli and measure patients' reactions. The questionnaire assessed items concerning the avoidance of dentistry and physiological arousal during dental appointments, in response to various items of dental stimuli such as seeing the needle and experiencing the smell of the dental office. In addition, one item asked for an overall rating of general fear of dentistry and four items elicited information concerning reactions to dentistry among family and friends (Kleinknecht et al. 1973). Later, the authors reduced the DFS to 20 items as a result of a Factor Analysis (Kleinknecht et al. 1984). Three dimensions of the questionnaire were found to be stable and reliable constructs: avoidance of dental treatment, somatic symptoms of anxiety, and anxiety caused by dental stimuli. Other amended versions of the DFS have also been created, but are rarely used. Schuurs et al. (1993) calculated a test-retest reliability of 0.74 for items across participants and 0.73 for participants across all items but it is unclear over what time period. The 20 item version was subsequently introduced for speed and Cronbach's alpha was very high at 0.93. Concerns, however, have also been raised regarding the content validity of the DFS due to the absence of dental procedures which may be feared most. From the literature search I conducted, very few papers assessed reliability or validity through studies conducted in adults or children.

4.11.1.4. Justification for choice of scale to measure dental anxiety

Criticism of the DAS and the DFS, the most commonly used anxiety questionnaires, centres on the construct definition and the robustness of the scales' development. With regard to the MDAS, no theoretical definition of the construct is given and only the first three items are summed to give a score to assess scale reliability. Nonetheless, it has been reported that, unlike DAS, MDAS shows signs of good construct validity (Humphris et al. 2000). The DFS is unbalanced with regard to its content: cognitive and affective reaction modes are missing, as are items about interpersonal aspects of DA. Schuurs and Hoogstraten (1993) came to similar conclusions about the DAS and the DFS. In their appraisal of dental fear and anxiety questionnaires, they concluded that the DAS may yield ambiguous answers and provides only limited information. The DFS provides an incomplete assessment of DA. Therefore, given the choice between DAS, MDAS and DFS, I selected MDAS

due to the fact it had reasonable reliability and validity and was much shorter to complete. Reducing research burden to participants was considered essential, considering some parents would also be involved in the FiCTION RCT and would also be required to complete several other questionnaires as part of the IMPACT studies.

The remaining DA scales used in adults are used infrequently and erratically (Gale 1972, Gatchel 1989, Geer 1965, Marks and Mathews 1979, Neverlien 1990, Stouthard and Hoogstraten 1990, De Jongh and Ter Horst 1993). When they have been used, it is generally to show their comparison with DAS, MDAS or DFS. Evidence for the validity and reliability of all of these other, infrequently used, measures was weak.

4.11.2. *Oral Health-Related Quality of Life (OH-RQoL)*

Recent years have seen a shift in the focus of dentistry from valuing only clinical assessments to measuring subjective experiences of patients (Cohen 1997). This change in approach has led to the development of an important construct of 'Oral Health-Related Quality of Life (OH-RQoL) (Sischo and Broder 2011). The term OH-RQoL has multiple definitions, varying from very simple to complex (Locker 1988, Kressin et al. 1996, Gift and Atchison 1995, U.S. Department of Health and Human Services 2000). The meaning of OH-RQoL has evolved with better understanding of the concept (Sischo and Broder 2011) as early attempts to define OH-RQoL were vague and restricted the term to the oral cavity in general. For example, Locker (1988) defined OH-RQoL as 'the functioning of the oral cavity and the person as a whole and with subjectively perceived symptoms such as pain and discomfort'. A more simple but comprehensive definition described OH-RQoL as 'the extent to which oral disorders affect functioning and psychosocial well-being' (Locker et al. 2000). OH-RQoL has also been described as "the impact of oral conditions on individuals' functioning and well being" (Kressin 1997, p.119). The United States Surgeon General's report (U.S. Department of Health and Human Services 2000, p.135) on dental health defined OH-RQoL as "a multidimensional construct that reflects (among other things) people's comfort when eating, sleeping, and engaging in social interaction as well as their self-esteem and their satisfaction with respect to their oral health". This thesis uses a widely accepted definition of OH-RQoL

throughout; OH-RQoL is " the impact of oral disease and disorders on aspects of everyday life that a patient or person values, that are of sufficient magnitude, in terms of frequency, severity or duration to affect their experience and perception of their life overall" (Locker and Allen 2007, p.409). Measurement of OH-RQoL is becoming increasingly important, particularly in the planning, development and evaluation of evidence-based health policy, resource allocation and service delivery (Guyatt et al. 1993). Clinically, it may assist in screening and monitoring for psychosocial problems (Fitzpatrick et al. 1992) and outcomes of care (Fayers and Machin 2007).

OH-RQoL questionnaires have been designed, and are used extensively, in dental research to provide a comprehensive measure of self-reported dysfunction, discomfort and disability arising from oral conditions (Gilchrist et al. 2014).

To examine change over time, an instrument that is responsive to small changes is necessary. Wiebe et al. (2003) reported that, in RCTs, disease-specific instruments were more responsive than general instruments. Given the nature of this present research and specific aims and objectives of this study, it was felt that an oral-specific instrument was more appropriate than a generic measure of health-related quality of life. The well-established oral specific OH-RQoL instruments include;

- the Oral Health Impact Profile (OHIP) (Locker and Slade 1993);
- the General Oral Health Assessment Index (GOHAI) (Atchison 1997)
- the Dental Impact on Daily Living (DIDL) (Leao and Sheiham 1995);
- the Oral Impact on Daily Performance (OIDP) (Adulyanon and Sheiham 1997), and;
- the Oral Health Related Quality of Life-UK (OHQoL-UK) (McGrath and Bedi 2001).

Reflecting on Aaronson's criterion of 'conceptual and measurement model', Sheiham and Tsakos (2007) recommend that OHRQoL measures should be supported by a relevant theoretical model. Of measures used in adults, only the OIDP and the OHIP and their derivatives relate to an underlying conceptual / theoretical model (in both cases the Locker (1989) model of oral health) and therefore for the purposes of the present study only these two instruments were considered for inclusion.

4.11.2.1. The Oral Health Impact Profile (OHIP)

The OHIP questionnaire was originally designed by the World Health Organisation and adapted by Locker (1988) to evaluate dental health. This model was subsequently adapted by Slade and Spencer (1994) to create 49 questions within 7 dimensions. The 7 dimensions comprise: functional limitation, physical pain, psychological disability, social disability and handicap. The standard response format of the OHIP is a five-point ordinal rating scale –'never (score = 0), 'hardly ever' (score = 1), 'occasionally' (score = 2), 'often' (score = 3) or 'very often' (score = 4). The scores can be added to provide an overall score, or perhaps more usefully, the score within each dimension can be calculated by summing the score for the items within that dimension (Inglehart and Bagramian 2002). The OHIP-49 has adequate cross-cultural consistency (Allison et al. 1999) and internal reliability ranging from 0.70 – 0.83 (Broder et al. 2000). A shortened version, OHIP-14, was developed based on two questions from each of the original seven dimensions in the OHIP-49 (Slade 1997) and has a high internal consistency (Cronbach's alpha = 0.88) and is also sensitive to detecting clinically meaningful change over time (Locker et al. 2004). Internal consistency of OHIP-14 scores has been investigated in patients with DA (Cronbach's alpha: 0.92) and general population subjects (Cronbach's alpha:0.94) (Mehrstedt et al. 2007). OHIP-14 has shown good test-retest reliability (Slade 1997, Vermaire et al. 2008). Various methods have been used to show good construct variability; i.e. the extent to which OHIP-14 scores are related to specified variables in accordance with an established theory or 'hypothetical construct' (Fernandes et al. 2006).

4.11.2.2. Oral Impact on Daily Performances (OIDP)

The OIDP scale was developed by Adulyanon et al. (1997) and focuses on measuring the impact of oral conditions on a person's ability to perform daily activities. Cronbach's alpha for the scale was reported as 0.65 (Adulyanon and Sheiham 1997) which is clearly lower than the usual "acceptable" value of 0.7. This scale was designed as a 10 item scale but some abbreviated versions do exist that have been used with adolescents (Åstrøm and Okullo 2003) and the scale has been amended for use in several different languages. Unfortunately, this scale has been mainly used with elderly patients, making it difficult to determine its validity and reliability in young to middle aged adults (Ilha et al. 2016). Where the questionnaire

has been used with young to middle aged adults, it has frequently been translated into another language (Åstrøm and Okullo 2003); unfortunately the cross-cultural validation process has not always been very robust, leading to difficulty comparing cohorts.

4.11.2.3. Justification for choice of scale for measuring Oral Health Related Quality of Life

In terms of respondent burden, both the OIDP and OHIP-14 inventories are relatively short and thus suitable for use in population surveys, but there have been few reports comparing OHIP-14 and OIDP. In a cross-sectional study involving adolescents in Myanmar, both OIDP and OHIP-14 showed reasonably satisfactory reliability (Soe et al. 2004). However, OHIP-14 emerged as the superior measure with respect to construct validity in that it discriminated better than the OIDP in groups who reported being affected by an oral impact during the preceding months before completing the survey than in those not affected (Soe et al. 2004). Robinson et al. (2003) found similar results comparing OIDP and OHIP-14 among dental attendees in the UK, while Baker et al. (2006) compared OHIP-14 and OIDP in UK dental patients with xerostomia and found that the OHIP-14 inventory performed better overall.

4.11.3. *Measuring how people view their life*

Researchers have often found weak and indirect relationships between clinical status and subjective assessments of oral disease (OH-RQoL) (Baker 2007, Baker et al. 2010, Daly et al. 2010). A possible explanation for this finding is that other factors intervene in the relationship between clinical status and OH-RQoL. Recently, dental health research has identified several individual and environmental factors to be associated with OH-RQoL, for example, sense of coherence, self-esteem and socio-economic status (Savolainen et al. 2005, Baker 2007, Baker et al. 2010, Piovesan et al. 2010, Nammontri et al. 2013). These factors have been found to mediate relationships between clinical status and OH-RQoL (Baker et al. 2010).

According to the literature, a sense of coherence (SOC) is one of the most important factors determining life satisfaction and ability to cope with difficult situations (Zielińska-Więczkowska et al. 2012) and SOC is strongly related to perceived health, especially mental health (Eriksson and Lindström 2007). The idea that being able to

change a person's attitude to dental care, which could result in a change in behaviour, leading to improved life satisfaction is therefore important.

4.11.3.1. Dental Health Beliefs

The concept that changing a person's dental health beliefs will result in a change in behaviour (and thus a different dental health outcome) was discussed by Broadbent et al. (2006). They measured six self-reported oral-health-related behaviours via questionnaires when individuals were aged 15, 18 and 26 years old. Unfavourable dental health beliefs were related to poorer dental health; however, it was demonstrated that dental beliefs can change over time. Exploration of dental health beliefs in a sample of Chinese people in north-east England, via focus groups, highlighted inter-generational differences in dental health beliefs, with older groups believing more in traditional remedies and having less faith in preventative dental health measures (Kwan and Holmes 1999).

4.11.3.2. Sense of Coherence (SOC)

The concept of sense of coherence (SOC) was proposed by Antonovsky (1993) to explain why some people become ill under stress and others stay healthy. Antonovsky (1993) believed that, in general, a person with a strong SOC is less likely to feel stress and tension, and to believe that they can meet demands. It has been reported that the stronger the SOC the better the perceived health in general, regardless of age, gender, ethnicity, nationality, and study design (Eriksson and Lindström 2007). An individual's SOC has been shown to have an impact on their QoL; the stronger the SOC, the better the QoL (Eriksson and Lindström 2007). SOC, measured using a SOC questionnaire, has three components – comprehensibility, manageability, and meaningfulness (Antonovsky 1993). Comprehensibility is the extent to which events are perceived as making logical sense, that they are ordered, consistent, and structured. Manageability is the extent to which a person feels they can cope. Meaningfulness is how much one feels that life makes sense, and challenges are worthy of commitment.

From a psychologist's point of view, SOC could be considered as a psychological and social factor facilitating dental health, while DA could be seen as a barrier making it more difficult to maintain or improve dental health, as well as contributing to

problems with managing dental health-related behaviours such as regular dental attendance and completing dental treatment. A person's SOC is an important contributor to the development and maintenance of their health but does not alone explain overall health. In reference to attitude, SOC measures how people view life and, in stressful situations, how they identify and use their General Resistance Resources (GRRs) (Eriksson and Lindström 2007) to maintain and develop their health. People with higher GRRs (e.g. money, intelligence, self-esteem, preventative health orientation, social support and cultural capital) are believed to be more enabled to manage the challenges of life. The use of the SOC scale can help people to identify resources and use them in order to improve their choices for health and a productive life (Langeland et al. 2013, Nilsen et al. 2015).

Some studies show that a weak SOC may be associated with high DA (Lindmark et al. 2011, Wennstrom et al. 2013, Jaakkola et al. 2013). While it has been proposed that a strong SOC may be protective against DA (Carlsson et al. 2015). However, recent findings suggest SOC may not be influenced by age or gender, conflicting with earlier findings (Drageset et al. 2008). It has also been suggested that an individual's SOC could be used as a screening tool in addition to an oral assessment during treatment planning (Lindmark et al. 2011) although, this was discounted by Erickson (2007) as currently there are no guidelines for the interpretation of an individual's SOC level.

Antonovsky's originally created 29 item questionnaire to measure SOC comprises 11 comprehensibility, 8 manageability and 10 meaningfulness items (Antonovsky 1987). A short form of items was subsequently created that is made up of 5 comprehensibility, 4 manageability and 4 meaningfulness items. While the reliability for the 29-item version (SOC-29), as represented by Cronbach's alpha, ranges from 0.85 to 0.95, for the 13 item (SOC-13) version it ranges from 0.74 to 0.91 (Antonovsky 1987, Larsson and Kallenberg 1999). Eriksson and Lindstrom (2005) systematically reviewed and analysed the reliability and validity of the SOC scale from research published between 1992 and 2003 and in 124 studies the range of internal consistency reliability scores of the SOC-29 was 0.70 to 0.95 whereas for SOC-13, in 127 studies it was 0.70 to 0.92. Furthermore, in 60 studies using modified SOC scales of 3, 6, 10 and 16 items, the range was from 0.35 to 0.91.

The 13 item subset of the original 29 item version of the SOC scale, SOC-13, has good internal consistency and has been proposed for use when time or space limitations operate (Pallant and Lae 2002). It also has a high validity and stability, which becomes more stable amongst subjects over 30 years old (stability coefficient 0.81) compared with younger adults (0.70) (Feldt et al. 2006). Within dentistry, Nammontri et al. (2013) using the SOC-13, reported that when a higher SOC was generated, usually through an intervention, the OH-RQoL also improved. Savolainen et al. (2005) reported that adult subjects with a strong or moderate SOC had significantly fewer problems related to oral conditions, as measured by the OHIP-14, than those with a low SOC. This is consistent with the findings of Baker et al. (2010) in their work involving adolescents. A strong SOC has also been associated with regular attendance at the dentist (Savolainen et al. 2004).

4.11.3.3. Dental Beliefs Survey

The Dental Beliefs Survey (DBS) was created to examine the interpersonal process or relations between patient and provider. The purpose of the DBS is to identify the extent to which the patient sees the relationship with dental personnel and their behaviour as part of dental fear. Whilst dental beliefs and dental fear certainly have something in common, studies have shown that the correlation between the Dental Beliefs Survey-Revised (DBS-R) (an amended version of the DBS) and DAS only goes so far and there are differences between these two concepts (Moore et al. 1991b, Johansson and Berggren 1992, Abrahamsson et al. 2006). Unfortunately, various DBS questionnaires exist making comparison difficult; these range in the number of scale items (from 15 to 28), the number and type of dimensions and the Likert scale format. Reliability, measured using Cronbach's alpha, has ranged from 0.85 (Acharya 2008) to 0.96 (Abrahamsson et al. 2006). Construct validity has been reported at 0.6 when compared against MDAS (Buchanan et al. 2016).

Other identified methods used to assess beliefs, values and attitudes to dental treatments used in adults are used infrequently and erratically.

4.11.3.4. Justification for choice of scale for measurement of dental health beliefs

It is important to focus on the origins of dental health, keeping healthy and an individual's ability to cope with dental treatment, as well as the origins of dental disease. A patient's beliefs, values and attitudes to life and the dental health maintenance associated with it should therefore be captured. From the measures available, dental health beliefs (DHB) (Broadbent et al. 2006) and SOC-13 (Larsson and Kallenberg 1999) were the most appropriate in terms of reliability, validity and decreased respondent burden.

4.11.4. *Summary of scales selected for use in the quantitative study*

In summary, the MDAS (Humphris et al. 1995), OHIP-14 (Locker et al. 2004), DHB (Broadbent et al. 2006) and SOC-13 (Larsson and Kallenberg 1999) measures were the chosen validated instruments, addressing respectively DA, OH-RQoL, dental beliefs, and sense of coherence, because of their reliability, validity and low respondent burden. However, it was recognised that socio-cultural factors can also play a major role in shaping attitudes and beliefs. For this reason, additional questions were added to the quantitative study questionnaire to enquire about respondents' anthropometric, demographic and dental treatment status. These questions were derived from the Adult Dental Health Survey (Nuttall et al. 2011).

4.12. Qualitative study: theoretical assumptions

Qualitative research seeks to understand human behaviour and to investigate the meaning that people attach to their experiences. The ultimate goal with the qualitative element of this study was to develop concepts that would improve our understanding of social phenomena in a primary (dental) care setting rather than an experimental setting (such as a laboratory) or a secondary care setting. In qualitative research the study design is underpinned by the researcher's ontological belief (belief in what constitutes reality) and epistemological belief (belief in knowledge and how obtain to it). As I am a dentist as well as a PhD student, it was felt that my work experience may impact on the data collection and analysis stages, both consciously and subconsciously.

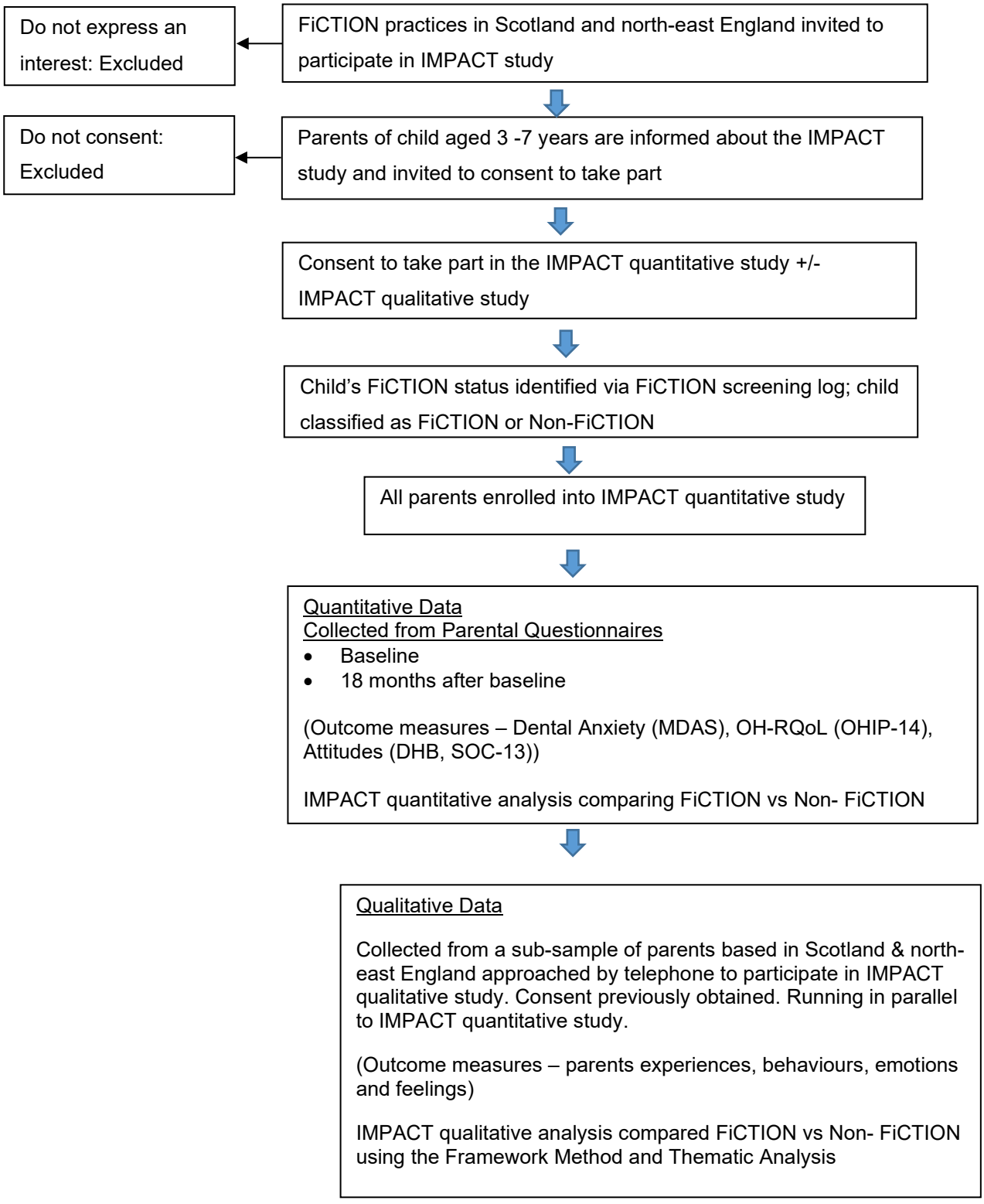
There are two main epistemological stances used within social sciences research; positivism and interpretivism (Green and Thorogood 2013). Positivists believe that an objective reality can be understood and measured and that it remains unaffected by social science research. Interpretivism meanwhile takes the standpoint that people are different and are likely to experience the world in different ways and that there are multiple ways of knowing the world. As a dentist, I acknowledged that my clinical background may influence her interpretation of the data being collected and therefore knowingly adopted an interpretivism stance for this qualitative study.

Ontological viewpoints can be considered in terms of idealism and realism (Mays and Pope 2000). Idealism is a theory that states that our reality is shaped by our thoughts and ideas and that social reality is only knowable through the human mind. Therefore it may be concluded that idealistic interpretations are subjective and therefore unlikely to be uniform. Realism meanwhile deals with the fact that reality has an absolute existence independent from our thoughts, ideas and even consciousness. Unsurprisingly, these viewpoints can be seen as oversimplification and, as a result, a number of variants exist. Subtle realism, which was the ontological approach used in this study, acknowledges that a researcher will impact the research with their subjective perceptions and understandings used in their interpretation of the data collected.

It is recognised that what people say is often very different from what they do or how they behave (Flick 2018). Semi-structured interviews, which were used in this qualitative study, use a set of predetermined, open-ended questions. Other questions are asked that relate to the responses given during the interview. This type of interview was selected to ensure the data collected met the research objectives. I accepted that the potential for in-depth exploration of the topic was not as strong as with an unstructured interview.

In summary, Chapter 4 has provided an overview of why a mixed-methods approach was used for this thesis. Figure 3 shows an overview of the different elements of the research and how these relate to the FiCTION RCT. Chapters 5 & 6 will now give a detailed account of the research approaches utilised, data collection and analysis for the quantitative and qualitative studies respectively.

Figure 3: Overview of the different elements of the IMPACT study and how these relate to the FICTION RCT



Chapter 5: Quantitative Study - Parental Questionnaire Survey

5.1. Introduction

Parental knowledge and comprehension towards clinical dental research, and regarding RCTs in particular is unclear. It is not known whether taking part in a RCT impacts parents' dental anxiety (DA), oral health-related quality of life (OH-RQoL) or attitudes to their own dental care and that of their children. By including a sample of parents whose children were participating in the FICTION RCT as well as a sample of non-participating parents (whose children were assessed for FiCTION but were either ineligible or did not participate at their parents' request), DA, OH-RQoL, attitude and past dental experiences were compared through a questionnaire survey.

5.2. Aim

The aim of the quantitative study was:

To quantify if their child's participation in a RCT impacts on a parent's DA, OH-RQoL and attitude to their own dental care and that of their children.

5.3. Objectives

The objectives of the quantitative survey were:

1. To quantify the difference at baseline, with respect to parental dental anxiety (MDAS), oral health-related quality of life (OHIP-14), dental health beliefs dental health beliefs (DHB) and sense of coherence (SOC-13) regarding their own dental care and that of their children, between parents of children with active caries and participating in an RCT in primary dental care (FiCTION) and parents of children without active caries and not participating in an RCT.
2. To quantify the difference in change from baseline to 18 months between these two groups of parents in parental dental anxiety (MDAS), oral health-related quality of life (OHIP-14), dental health beliefs (DHB) and sense of coherence (SOC-13) regarding their own dental care and that of their children.

5.4. Methods

5.4.1. *Parental questionnaire*

5.4.1.1. Design

A questionnaire survey with 18 months follow up (to co-ordinate with the mid-point in the 3 year FiCTION RCT). The questionnaire comprised validated scales for DA, OH-RQoL, dental health beliefs and sense of coherence as well as some non-validated individual questions relating to dental treatment and demographic data (Sections 5.4.1.6 and 5.4.1.7).

5.4.1.2. Dental Anxiety: Modified Dental Anxiety Scale (MDAS)

The Modified Dental Anxiety Scale (MDAS) (Humphris et al. 1995) was selected to assess DA (see Section 4.11.1.2). The MDAS scale comprises five questions with each response scoring from “not anxious” (1) to “very anxious” (5) to produce a total score ranging from 5 to 25, with higher scores denoting greater anxiety. The derived primary outcome measure was the total MDAS score. In addition, due to a cut off value of 19 or higher being considered a sign of high DA (Humphris et al. 1995), this threshold was also recorded as a derived binary outcome variable (High Dental Anxiety: Yes/No)

5.4.1.3. OH-RQoL: Oral Health Impact Profile - 14 (OHIP-14)

The Oral Health Impact Profile 14 (OHIP-14) (Slade 1997) (see Section 4.11.2.1) was selected as the measure of parental OH-RQoL. The OHIP-14 profile comprises 14 questions with each question scoring from “never” (0) to “very often” (4) to produce a total score ranging from 0 to 56. The higher the score, the more dissatisfied parents are with their own dental health. The overall OHIP-14 score was treated as a continuous variable.

5.4.1.4. Attitude: Dental Health Beliefs (DHB)

Parental attitudes pertaining to their own dental health and that of their children were measured using the DHB Questionnaire (Broadbent et al. 2006) (see Section 4.11.3.2). The DHB questionnaire comprises six questions with each response recorded in the range from “extremely important” (1) to “not at all important” (4) to produce a total score ranging from 6 to 24, with lower scores denoting more favourable oral-health-related beliefs. Whilst use of this questionnaire is still in its

infancy, it has been used to investigate whether individuals who hold favourable oral-health-related beliefs over time have better adult dental health in adulthood than those who do not hold favourable oral-health-related beliefs. Since there is a lack of suitable measures available for exploring the relationship between dental health beliefs and dental health, the DHB model was adopted in the present study.

5.4.1.5. Attitude: Sense of Coherence - 13 (SOC – 13)

The SOC-13 (Eriksson and Lindström 2005) (see Section 4.11.3.1) instrument comprises thirteen questions with three sub-dimensions: comprehensibility (5 items), manageability (4 items) and meaningfulness (4 items). Each item is scored from 1 to 7 to produce an overall total score ranging from 13 to 91. Each sub-dimension has its own domain score: comprehensibility (ranging from 5 to 35), manageability (ranging from 4 to 28) and meaningfulness (ranging from 4 to 28). The overall SOC-13 score was derived and domain scores were also calculated separately for the three sub-dimensions. The higher the SOC scores, the better people are able to deal with the stressors of everyday life and to use the resources at their disposal to counter these stressors.

5.4.1.6. Adult Dental Health Survey

The questions regarding general and dental health and dental experiences of FiCTION and Non-FiCTION parents at baseline had previously been used in the 2009 Adult Dental Health Survey (ADHS) (Nuttall et al. 2011).

5.4.1.7. Demographic data

Demographic questions regarding a parent's age, ethnicity, education and relationship status to child were based on those previously used in the 2009 ADHS (Nuttall et al. 2011).

5.4.1.8. Piloting the questionnaire

Two non-clinical colleagues with young children (a senior researcher and an administrator) within the School of Dental Sciences at Newcastle University, who were not eligible to participate in the IMPACT study, were issued with questionnaires. They were provided with minimal verbal instructions and asked to complete and

return the questionnaire, by following the instructions listed on the front page, and writing any comments about clarity of the questions and ease of completion on the questionnaire itself. After both questionnaires had been returned, their content (including any feedback) was reviewed, and the parents were contacted to ascertain whether any further amendments were required. Both colleagues reported that they felt no changes were required and that they been able to complete the questionnaire without difficulty or complication. The data from these pilot questionnaires were subsequently destroyed.

The questionnaire (see Appendix A) for use with parents at baseline and 18 months was then piloted with three parents in Scotland and north-east England to test content and face validity and to obtain information regarding any difficulties associated with completion of the questionnaire. These parents, identified via social connections, were asked to complete the questionnaire and provide comments regarding content and format which were then used to refine further the design of the questionnaire. Their collective comments related to the questionnaire format; the validated scales were not altered. They recommended the questionnaire be presented in booklet format and that the non-validated questions relating to dental treatment and demographic data be placed at the beginning and end of the questionnaire respectively. The completed pilot questionnaires were subsequently destroyed and the data were not analysed.

5.4.2. *Study setting*

The NIHR-HTA FiCTION Trial - Filling Children's Teeth: Indicated or Not? (Innes et al. 2013) was a multi-centred 3 arm, parallel group, patient-randomised trial to compare three treatment strategies used to manage decay in children with dental caries in primary teeth (see Section 1.6.4). The IMPACT study was nested within the FiCTION RCT and conducted within two (Scotland and north-east England) of the five geographical centres being used in FiCTION. All 42 practices in these two centres, who had enrolled at least one child in FiCTION at that time, were approached to participate in the IMPACT Study. These study settings included urban and rural locations.

5.4.3. *Ethical Committee opinion and Research and Development (R&D) approval*

A favourable ethical opinion was obtained from National Research Ethics Service (NRES) Committee North East – Newcastle and North Tyneside 1 (REC Reference: 13/NE/0180, Date: 26/11/2013). The project was conducted in accordance with the ethical principles set out in the Declaration of Helsinki (2013) (World Medical Association 2013).

Research and Development (R&D) management approval was obtained, in north-east England from North of England Commissioning Support (NECS) and in Scotland from the NHS Research Scotland (NRS) Permissions Coordinating Centre. Site-Specific Information (SSI) forms were generated for NHS Ayrshire & Arran, NHS Borders, NHS Grampian, NHS Greater Glasgow & Clyde, NHS Lanarkshire, NHS Lothian and NHS Tayside.

5.4.4. *Participant inclusion criteria*

The inclusion criteria for participants were:

- Parents of children screened for, and participating in, the FiCTION RCT within Scotland and north-east England;
- Parents of children screened for, but not participating in, the FiCTION RCT (due to ineligibility for/ unwillingness to take part in FiCTION) within Scotland and north-east England.

No other restrictions were placed (e.g. based on age, gender, ethnicity, country of birth) on parental recruitment.

5.4.5. *Target sample size*

The role of the sample size calculation was to determine how many parents were required for the planned analysis of the primary outcome to be informative. As no similar data was available and there were no publications on what comprised a minimal clinically important difference (Cook et al. 2018) for the included measures, it was difficult to determine what might comprise an appropriate target difference between the two groups in change over time. In September 2012, each outcome measure was considered in turn and the choice of the primary outcome, upon which

the power calculation was made, was based upon consideration of the relevant published literature and views of the study team (see Section 2.6). It was not possible to locate a study involving young to middle-aged adults which had reported changes in score from before and after dental treatment for any of the outcome measures. The choice of outcome measure for the sample size calculation was therefore based on an existing observational study in elderly adults with measurements undertaken before and one month after completion of dental treatment (Locker et al. 2004). This paper was selected as it had used the OHIP-14 questionnaire, which the study team identified as a suitable and appropriate validated scale, and a time period had lapsed after invasive dental treatment had been completed. This paper reported mean pre- and post-treatment OHIP-14 scores for 116 participants of 15.8 (SD=13.7) and 11.5 (SD 11.1). This change in mean OHIP-14 score of 4 from baseline to 18 months was agreed to be clinically meaningful by the study team and therefore, the initial sample size calculation was based on this change in mean score. Since the standard deviation of the change from baseline was not provided in the paper, the sample size calculation was based on a *t*-test of the mean difference between groups in OHIP-14 scores at 18 months. This calculation showed that to detect, as statistically significant, a mean difference between groups of four points in OHIP-14 scores at 18 months, a sample size of 255 participants per group would be required (assumed standard deviation 12, 90% power, 5% significance level, two-sided test), allowing for a loss to follow-up at 18 months of 25% (Innes et al. 2013). Minitab 16 (2010) computer software was used to complete this calculation.

Participant recruitment for FiCTION was originally expected to take place over a 12-month period. Across the 42 FiCTION practices in Scotland and north-east England, it was expected that 5000 children would be screened by dental practitioners over this period. It was assumed that 85% of these would be excluded from the FiCTION trial because they did not meet eligibility criteria, with a further 20% meeting eligibility criteria but declining participation in FiCTION, a total pool of 4,400 ‘Non-FiCTION’ children. Likewise, it was assumed that 12% of screened children, 600 in total, would be enrolled in FiCTION.

Therefore, a sample size of 255 per IMPACT group (FiCTION and Non-FiCTION) was determined to be feasible based on approximately half (n=21) of the FiCTION

dental practices in Scotland and the north-east of England also being involved in the IMPACT Study. It was recognised, however, that this would require a higher participation rate (255/300, 85%) from the FiCTION pool than from the Non-FiCTION pool (255/2200, 11.6%) and therefore that the target sample size of 255 participants would be achieved earlier for the Non-FiCTION parents. Nonetheless, the results of the FiCTION Pilot and Rehearsal study previously undertaken in 2010-11 suggested that this would not be a barrier for two reasons:

1. All practices and dentists who began recruitment of patients were retained throughout the Pilot Rehearsal Trial and the majority expressed an interest in continuing with the Main Trial. This suggested that the dentists were motivated and keen to participate in research.
2. Of those eligible, 80% of parents agreed to participate in the FiCTION Pilot study. The study team felt that this suggested parents were keen to participate in primary care research and as the burden associated with the IMPACT study was low this was unlikely to be a significant reason for them to decline.

Furthermore, the initially proposed method of recruitment for IMPACT was for general dental practitioners (GDPs) to recruit parents in person, suggesting the target sample size for FiCTION parents was feasible.

In fact, a slightly higher number of FiCTION practices in Scotland and north-east England than originally anticipated, 27 rather than 21, agreed to take part in IMPACT (Sections 5.4.6 and 5.5.1.1). Recruitment of the dental practices in England began in August 2013 and the first completed questionnaire was returned in December 2013. Recruitment of the dental practices in Scotland began in November 2013 and the first completed questionnaire was returned in May 2014.

Unfortunately, recruitment and retention of the dental practices and recruitment of parents proved challenging for both the FiCTION RCT (FiCTION Trial 2017) and IMPACT (as discussed further in Section 5.6.2.1). A contract variation request to the HTA was submitted by the FiCTION RCT team in August 2014 explaining that, based on the recruitment trajectory at the time, with recruitment anticipated to continue until December 31st 2014 and follow-up until 30th June 2016, the study would only recruit 1113 children resulting in a lower (61%) power to detect the target differences between the arms of the trial's primary outcome (FiCTION Trial 2017). It was

subsequently agreed with the HTA (in November 2014) that, to increase the chances of achieving acceptable power (82%), recruitment could continue until 30th June 2015 and that new sites could be added to facilitate this recruitment. Thus, allowing for 25% loss to follow-up, the effective sample size would be three groups of 278 children followed up for on average 35.5 months (FiCTION Trial 2017).

The study team for IMPACT had calculated their sample size in full knowledge that it was based on a different population, time scale and situation but felt that a small to medium (0.3) standardised effect size (Cohen 1992) of 4/12 (mean difference/pooled standard deviation) was acceptable (Rothwell et al. 2018). Given the challenges with recruitment and retention of parents for both studies, and uncertainty regarding whether the HTA would agree to an extension to the FiCTION RCT, the IMPACT study team decided to re-assess their sample size calculation with their attention on data from newly published relevant studies. At this time (October 2014), they identified a recently published study of OH-RQoL in children and adults (Santa-Rosa et al. 2014) (mean age of all participants was 15.9 years (SD 4.8); range 9-27 years), in which OHIP-14 was measured before and 24 months after completion of aesthetic restorative dental treatment. The study team felt the patient group in that study was slightly more representative of the participants in the IMPACT study and made the decision to revise the sample size calculation based on the summary statistics reported in this publication, but using the same rationale as in the original sample size calculation. The paper reported mean pre- and post-treatment OHIP-14 scores of 9.8 (SD=6.7) and 5.9 (SD 5.5). While the observed mean change over time was similar in magnitude to that observed by Locker et al. (2004) (3.9 vs. 4.3), the variability of OH-RQoL scores was considerably smaller. Using a revised estimate of standard deviation of 6, it was estimated that to detect, as statistically significant, a mean difference between groups of 4 points in OHIP-14 scores at 18 months, a sample size of 66 participants per group would be required (90% power, 5% significance level, two-sided test), continuing to allow for a loss to follow-up at 18 months of 25% (Innes et al. 2013). The revision to the IMPACT sample size was implemented in November 2014. Recognising that enough parents had already been recruited into the Non-FiCTION group for IMPACT, FiCTION parents were specifically targeted at this stage.

5.4.6. *Recruitment and retention procedures*

5.4.6.1. Recruitment and retention of dental practices

Dental practices, participating in the FICTION RCT, within Scotland (N=25) and north-east England (N=17) were invited to participate in IMPACT. Initial letters were sent to the practice principals in all 42 FiCTION practices, introducing them to the IMPACT study (see Appendix B). I followed this up with a telephone call two weeks later. Face to face practice visits were also arranged with 31 interested practices to answer any questions/queries. At the request of the dental practices, the total target size required per group for IMPACT recruitment was discussed with them. Based on the original calculations of a target size of 255 per group recruited from 21 dental practices, each FiCTION practice willing to take part in IMPACT was assigned a target of thirteen parents whose children were participating in the FiCTION RCT and thirteen parents whose children had been screened for FiCTION but were not participating therein, because of ineligibility or unwillingness to participate. Given the expected return rate of the questionnaires, the dental practice teams could then be expediently informed when the target sample size had been reached, meaning that excessive recruitment within one group was unlikely.

5.4.6.2. Recruitment and retention of parents

The practices agreeing to participate in IMPACT distributed a covering letter, participant information leaflet and consent form (see Appendix C) to all parents identified by the practice database search used for screening for the FiCTION RCT. IMPACT paperwork was distributed bv the practice, either by post with help from me, or given in person to the parent when attending the practice for their child's dental appointment. This dental appointment could be the one at which the child was screened for the FiCTION RCT. Some of the practices which chose to contact parents by post decided to send the FiCTION and the IMPACT invitation materials in the same package. In instances where a parent had more than one child who was eligible for screening for FiCTION, the IMPACT paperwork was sent in reference to their eldest child. This reduced the research burden on parents with more than one child and ensured a consistent approach was always being taken. Parental consent forms for IMPACT were returned in a pre-paid self-addressed envelope to me at Newcastle University. IMPACT patient identification numbers were the same as the screening number used by the FiCTION RCT (Section 5.4.9) to facilitate cross-

checking of FiCTION status. If there was no response to the original invitation letter within two weeks, the dental practice was contacted and another invitation pack posted out to the parent. The recruitment outcome was recorded for each parent invited to participate in the IMPACT Study (Tables 5.6 and 5.7 – Numbers eligible and recruitment response rate to IMPACT by practice in Scotland and England).

5.4.7. *Parental consent*

Those parents agreeing to participate in the IMPACT questionnaire survey were asked to enter their own personal contact details on the consent form and return it to me in the stamped addressed envelope provided. At this time, they were also asked if they were willing to be contacted regarding participation in a future in-depth qualitative interview (see Chapter 6).

Upon receipt of a completed consent form, the IMPACT baseline parental questionnaire was sent with a covering letter (see Appendix D) along with a self-addressed return envelope.

5.4.8. *Distribution of the questionnaires*

5.4.8.1. At Baseline

Each parental baseline questionnaire was issued after the child had been screened for the FiCTION RCT. Where possible their FiCTION status was ascertained using the dental practice FiCTION screening log (held either by the practice or by Newcastle Clinical Trials Unit (responsible for trial management of the FiCTION RCT) as;

FiCTION eligible and joined;
FiCTION eligible and declined;
FiCTION ineligible, or;
FiCTION status unknown (but then confirmed at a later date).

For purposes of analysis the FiCTION eligible and declined group and FiCTION ineligible group were combined to produce a single Non-FiCTION group.

Written instructions for parents were issued along with the questionnaires including a note of when I was available via telephone or email for any queries. A reply-paid envelope was provided to return the completed questionnaire directly to me.

5.4.8.2. At 18 month follow-up

Follow-up questionnaires were posted to study participants 18 months from receipt of baseline questionnaire, again with a reply-paid return envelope. Those who had not completed a baseline questionnaire were not contacted at 18 months.

5.4.8.3. Reminders

If either the baseline or 18 month questionnaire was not returned within four weeks of initial posting, a reminder letter, including a duplicate questionnaire, was posted to the parent and a follow-up telephone call was made by me to parents who had provided a contact telephone number. If there was still no response four weeks after the reminder was issued, no further contact attempts were made and the parent was considered to be a non-respondent at that time point. Dental practices were contacted when a questionnaire was 'returned to sender' to confirm whether a different address was held by the practice; where applicable questionnaires were re-issued. The outcome was recorded for every parent recruited (Tables 5.6 and 5.7 – Numbers eligible and recruitment response rate to IMPACT by practice in Scotland and England).

5.4.9. *Data management*

5.4.9.1. Data entry

Once written consent had been obtained, consent forms were kept in a secure room, to which only I had access and held separate to the questionnaire responses. To maintain confidentiality, names and/or addresses did not appear on any questionnaires. All further paperwork was anonymised through the use of a patient identification code which could be linked back by me to the consent form and contact database.

Any queries regarding entries in the questionnaires were systematically re-visited by the study team and resolved through discussion on a case-by-case basis. A data entry coding sheet for the questionnaire survey responses was developed and used by me to enter the data from the questionnaires into the Statistical Package for Social

Sciences-SPSS 22 (IBM Corporation 2013). Any missing data were given the code "99".

Data errors can creep in at every stage of the process from initial data acquisition to archival storage. By having only one person entering the data, it was felt this would increase the likelihood of the data being entered in a consistent manner and thus minimise the chance of any data integrity errors being introduced. The use of integrity constraints (e.g. restricting the values that could be entered in respect of responses to the OHIP-14 items to the values 0-4, or 99 to denote a missing response) within SPSS, meant that it was impossible to enter data that violated the constraint and also reduced the likelihood of data entry errors being introduced. For each item in the questionnaire, the possible responses were entered as numeric data (e.g. 1, 2, 3) and each numeric data value was assigned a value label (e.g. 1="not anxious", 2="slightly anxious").

The questionnaire data were then re-entered by me into a separate file and the two files compared. Any inconsistences between entries were corrected by referring back to the completed questionnaire. This stage was completed to minimise keystroke errors.

As the completed questionnaires were returned, the 18 month follow-up data were entered into the relevant row and column of the SPSS datasheet. After completion of baseline and 18 month follow up data collection and entry, the entire data set was manually cross-checked for data entry errors by comparing the computerised records against the original questionnaires for every returned questionnaire.

The data contained within individual practice FiCTION screening logs were subsequently compiled electronically by Newcastle Clinical Trials Unit into one central database on an Excel spreadsheet. As part of quality assurance for the IMPACT study, I then compared the FiCTION status of the child as recorded in the screening log for each dental practice against the FiCTION central database randomisation log retained by the Newcastle Clinical Trials Unit. The dental practice FiCTION screening logs were frequently incomplete but by using screening and the central database logs the child's FiCTION screening number, the child's FiCTION

status could be firmly established. The FiCTION status within the IMPACT data set was then updated where necessary.

5.4.9.2. Data cleaning

Using SPSS, frequency tables were generated for each variable, missing data were identified and the extent to which any data were missing was determined. A check for outliers was also made at an individual item level and on derived variables (i.e. the domain and sub-dimension scores for the MDAS, OHIP-14, SOC-13 and DHB at each time point, and change over time in these scores). There are three explanations for finding outliers in data; measurement errors, data entry errors and genuinely unusual values. The quality controls described above had minimised the chances of data entry errors for individual variables; if there was suspicion that they had nonetheless occurred, the data set was cross-checked against the completed questionnaire and the error rectified. Unusual value outliers were identified using boxplots when comparing data at each point in time as well as “change over time” data that were in some sense “far” from what was expected based on the rest of the data. In discussion with the study team, the decision was made to include the outliers and compare the results of analyses performed both with and without the outliers included.

5.4.9.3. Defining the final data set

5.4.9.3.1. Missing data

Missing data can occur in research because an element in the target population is not included on the survey’s sampling frame and/or because a sampled element does not participate in the survey (subject non-response). Item non-response may occur because a respondent overlooks one or more items (e.g. turns two pages of the questionnaire at once), or because they refuse to answer the item on the grounds that it is too sensitive, or they do not know the answer to the item.

In this study, item non-response was considered when defining the final data set. When constituent items of a scale have high inter-correlation, it is possible to impute values for missing items based on the non-missing data. However, it is not clear exactly how much data can be missing before imputation becomes inappropriate. It has been suggested that, in studies where the item non-response rate exceeds 3%,

or the percentage of respondents with missing responses exceeds 50%, or the percentage of respondents for whom more than half of the responses in a subscale are missing exceed 10%, the data collection procedures and/or the use of a self-assessment tool should be critically examined (Fairclough and Cella 1996). In this study, when deciding how much missing data to accept, differentiation was made between the four outcome measures (MDAS, OHIP-14, DHB and SOC-13) and a decision was based on the length of the scale.

Table 5.1: Strategy used to determine final data set when non-response items were present

Type of scale	Outcome measure	Number of questions within scale	Number of allowable missing items	Based on
Short	MDAS	5	0,1,2 missing items	<50% (Fairclough and Cella 1996)
	DHB	6	0,1,2 missing items	<50% (Fairclough and Cella 1996)
Long	OHIP-14	14	0 or 1 missing item	<1/7 (Slade 1997)
	SOC-13	13	0 or 1 missing item	<1/7 (Slade 1997)
	SOC-13 comprehensibility sub-scale	5	0,1, 2 missing items	<1/7 (Slade 1997)
	SOC-13 manageability sub-scale	4	0 or 1 missing items	<1/7 (Slade 1997)
	SOC-13 meaningfulness sub-scale	4	0 or 1 missing items	<1/7 (Slade 1997)

Individual participant mean imputation was used as a simple form of imputation in these scenarios. The imputed value was the calculated mean of a given participant's valid responses to other questions within the same total scale (this is referred to as the ‘participant mean’). Where the number of missing items exceeded the criterion values shown in Table 5.1, no imputation took place and the scale score was set to ‘missing’. The number of missing items per scale at baseline and 18 months can be found in Appendix E.

5.4.9.3.2. Loss to follow up

As the focus of the analysis was on change over time scores, no imputation of 18-month data based on baseline values (e.g. using last observation carried forward) was made where a questionnaire was not returned at 18 months and the parent was “lost to follow-up”. However, as it was important to consider the reasons underlying

loss to follow up and the extent to which there may have been attrition biases, respondents at 18 months were compared descriptively with non-respondents, based on their baseline characteristics and the baseline mean total scores for each outcome variable. These data are presented in Tables 5.12 – 5.17 in Section 5.5.2.1.

5.4.9.3.3. Excluded data

As part of the data checking process, the parent's date of birth and relationship to the child was cross-matched across paired baseline and 18 month questionnaires. Where different data on one or both of these variables were given in the baseline and 18 month questionnaires, this suggested that the two questionnaires may have been completed by different parents, and therefore were not suitable for inclusion of analysis of change over time. Such instances of mis-matched parents were discussed by the study team and a decision reached on a case-by-case basis on whether to exclude the participant at follow-up or to allow them to remain in the dataset. The most common source of mis-match was where the parent reported their own date of birth on one questionnaire but their child's on the other. There were no cases where the date of birth was the same but the gender changed between the two questionnaires. Where there was any doubt, the participant was removed from the dataset and considered "excluded". All excluded parents, and parents lost to follow up, were removed from the summaries reporting change from baseline to 18 months.

5.4.10. *Statistical analysis plan*

Demographic and clinical characteristics were tabulated by IMPACT status (FiCTION versus Non-FiCTION) and overall. For purposes of analysis, the FiCTION eligible and declined group (n=6) and FiCTION ineligible group (n=200) were combined to produce a single Non-FiCTION group.

This was an observational study and the statistical analysis plan for reporting the findings of this study was based on the "Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)" recommendations (Vandenbroucke et al. 2007). Therefore, data at baseline were summarised descriptively using appropriate summary statistics for continuous data and frequencies and percentages for categorical data for the two groups (FICTION and

Non-FiCTION) and overall. Statistical tests were not used to compare the groups at baseline and therefore p-values were not reported.

5.4.11. *Data analysis*

Data were analysed using SPSS-22 (IBM Corporation 2013). The statistical analysis approach was agreed with the study team, two of whom are statistically trained, one a biostatistician, to characterise the different aspects of questionnaire data. Initially, descriptive analysis was conducted to generate summary statistics including mean, median, standard deviation and range. Informal comparisons between groups based on FiCTION and Non-FiCTION status were made, in particular looking at participants lost to follow-up/ excluded and those remaining in the study to the end (and who were therefore included in the final analysis of change over time).

5.4.11.1. Analysis of covariance (ANCOVA)

Where a change score for a variable is calculated (i.e.18 month score minus baseline score), a one-way ANOVA may be appropriate to test a null hypothesis of there being no difference between groups in mean change score. However, analysing change scores in this way does not control for baseline imbalance or possible regression to the mean. Observational, non-randomised studies, such as IMPACT, are at particular risk of baseline imbalance (Vickers and Altman 2001). In this instance, a better approach is to use analysis of covariance (ANCOVA), a regression method, which when calculating a mean change score can control for a baseline imbalance and other potentially confounding variables, called covariates.

When choosing to analyse data using ANCOVA, a critical part of the process involves checking the assumptions of the statistical model. If the data had not met these assumptions, the ANCOVA would have been the incorrect statistical model to use. (Lund and Lund 2015) The following assumptions were therefore assessed:

- a linear relationship between baseline and 18 month scores for each validated scale; this was assessed by visual inspection of scatterplots.
- homogeneity of variance across the range of the outcome measure; this was assessed informally by plotting the standardised residuals from the ANCOVA model against the predicted values from the model.

- the expectation of a horizontal band of points with 95% of standardised residuals within ±2 standard deviations; this was assessed by visual inspection of scatterplots.
- approximate normality of the standardised residuals; this was assessed by visual inspection of histograms and normal Q-Q Plots.

Following confirmation that the assumptions had been met, to quantify if there were any statistically significant differences in mean change from baseline to 18 months in MDAS, OHIP-14, DHB and SOC-13 scores, between FICTION and Non-FiCTION, parents, ANCOVA, controlling for baseline score, was used. The analysis was then expanded to include a number of additional covariates, including age and gender (Table 5.2) shown in previous research to be related to scores on the scales used in this study.

Table 5.2: Covariates considered with further ANCOVA analysis

Validated Scale	**Covariate**	**Reference**
MDAS	Age	(Humphris et al. 2009)
	Gender	
	Education	
OHIP-14	Dentate or edentulous	(Locker and Quinonez 2009) (Nuttall et al. 2011)
	Age	(Nuttall et al. 2011)
	Gender	
	Self- reported general and dental health	
DHB	Age	(Broadbent et al. 2006)
	Self-rated dental health	
	Gender	
SOC-13	Age	(Eriksson and Lindström 2005)
	MDAS	(Jaakkola et al. 2013)
	OHIP-14	(Eriksson and Lindstrom 2007)

Each covariate is briefly discussed below and the reasoning behind its inclusion in further ANCOVA analysis is given:

- DA has been reported frequently in previous studies to vary with sex, age and education (Humphris et al. 2009).
- The ADHS 2009 (Nuttall et al. 2011) stated that, by comparison with older adults, higher proportions of younger dentate adults self-reported good or very

good general and dental health. Women were more likely than men to say that they had good or very good dental health; however, there were no differences in the proportions of women and men saying they had good or very good general health.

- A strong association has previously been demonstrated between gender and dental health beliefs with fewer males than females endorsing favourable dental beliefs. Findings also suggest people's that DHBs are not necessarily fixed, with a noticeable change in beliefs having been noted between adolescence and young adulthood (Broadbent et al. 2006).
- SOC tends to increase with age over the whole life span. Using SOC-29 items (based on the mean age of respondents in cross sectional studies) previous research has shown that the oldest people (both male and female) show the highest mean scores for SOC (Eriksson and Lindström 2005). Adults with high dental fear (reported using MDAS) had a lower SOC than those with no to moderate dental fear, adjusting for gender and education in a cohort of 18 year olds (Jaakkola et al. 2013). The majority of studies comparing QoL have been carried out on various disease-specific groups, instead of the general population, and have shown that SOC enhances QoL directly (Eriksson and Lindström 2005). The relationship of high dental fear (using a single-item DA scale) and SOC-3 (another SOC scale) has been adjusted for age (adults 19-96 years old); whilst increasing age was found to be strongly associated with low DA, age was only considered as a predictor of DA with regard to its most extreme outcomes i.e. no DA and extreme DA (Carlsson et al. 2015). In this instance, SOC was not considered a significant predictor of DA but age was; nonetheless there must be caution as different DA and sense of coherence scales have been used vis-a-vis IMPACT (Carlsson et al. 2015).

5.5. Results

5.5.1. *Response rate*

5.5.1.1. Practices

Recruitment of the initially calculated target sample of 255 parents per group (FiCTION and Non-FiCTION) was determined to be feasible, based on approximately half (n=21) of the FiCTION dental practices with Scotland and north-east England

also being involved in the IMPACT Study. However, it was recognised from the outset that some dental practices in all areas were more successful than others at identifying and recruiting patients to the FiCTION RCT. The study team felt, therefore, that recruiting from more than the required 21 dental practices within Scotland and north-east England would lighten the burden on individual practices by reducing: their recruitment target; the duration of the study; and administrative workload related to the IMPACT study. The study team was keen to minimise any barriers to recruitment to the study and decided to over-sample and invite all the dental practices actively involved in the FiCTION RCT in the two clinical centres of Scotland and north-east England at that time to participate. Of the 42 dental practices contacted, 13/26 (50%) FiCTION practices in Scotland and 14/16 (88%) FiCTION practices in north-east England agreed to take part in IMPACT. With a target size of 255 per group being recruited from 27 dental practices, this reduced the burden to a target per practice to 10 parents whose children were participating in the FiCTION RCT and 10 parents whose children had been screened for FiCTION but were not participating therein. With the subsequent revision of the target size of 66 per group, this further reduced the recruitment burden to between 2 and 3 parents per group per practice. Based on the assumptions set out in Section 5.4.5 regarding numbers screened and rates of eligibility and consent, a total of 3214 children were expected to be screened for FiCTION across these 27 practices, with 2732 being ineligible for FiCTION, 96 being FiCTION eligible but declining participation in the trial, and 386 being FiCTION eligible and enrolled. Thus expected IMPACT consent rates for the revised sample size of 66 per group were 17.1% (66/386) and 2.3 (66/2828) for FiCTION and Non-FiCTION parents respectively.

5.5.1.2. Parents

In total, across all 27 dental practices, 2980 parents, slightly fewer than expected, were identified as being potentially eligible for participation in the IMPACT study and subsequently sent invitation packs and asked to return a completed consent form, either opting in or opting out of participation in the IMPACT study. Rates of return of the consent form varied at a practice level but this variation was similar in both regions, Scotland (0.0% to 20.6%) and north-east England (5.0% to 16.7%).

The slower than predicted pace of recruitment for the FiCTION RCT impacted on the length of time a practice was involved in the FiCTION RCT; moreover, the FiCTION practice screening logs were not always completed accurately. I therefore could not readily assess how many of the 2980 children whose parents were contacted for IMPACT were 'FiCTION eligible and participating', without double-checking with every practice the FiCTION status for each participant listed on the FiCTION screening log. Recognising that an increasing number of practices were experiencing study fatigue and were requiring repetition and/or supplementary FiCTION practice training in view of staff turnover, the decision was made to not confirm the FiCTION status for all 2980 potentially eligible parents. Instead, FiCTION status was confirmed only for parents who returned the IMPACT consent form, either opting in or opting out of participation in the IMPACT study.

As mentioned in Section 5.4.5, the revision to the IMPACT sample size was implemented in November 2014. A further 11 Non-FiCTION parents, who had already opted into participation in the IMPACT study, returned a completed questionnaire between November 2014 and January 2015, and subsequently were included within the study. In total, 332 parents (11.1%) of those sent the IMPACT invitation pack returned the consent form. Of these parents, the child's FiCTION status was ascertained as; FiCTION eligible and joined (n=66), FiCTION eligible and declined (n=6) and FiCTION ineligible (n=258) as described in Section 5.4.4. As planned (Sections 5.4.4 and 5.4.8.1), the six parents whose children were eligible for participation in FiCTION but who had declined to take part were combined with the FiCTION-non-eligible parents to produce a single Non-FiCTION group (n=264). Two children (n=2) were not brought to their FiCTION RCT screening dental appointment and therefore were not eligible to participate in the IMPACT study; their parents both declined to take part in the IMPACT study on the returned consent form.

For the 332 parents who returned an IMPACT study consent form, those who consented to participate tended to take longer to return the completed consent form than those declining especially if they were enrolled in the FiCTION RCT (Table 5.3).

Table 5.3: Mean (SD) number of days between the date of issue of the IMPACT invitation packs and the date of return of the completed consent form, either consenting or declining to participate in the IMPACT study.

Number of days between issue of invitation packs and date of return of consent form	**Participants consenting to participate in the IMPACT study (n=312)**		**Participants declining to participate in the IMPACT study (n=20)**		
	FiCTION	**Non-FiCTION**	**FiCTION**	**Non-FiCTION**	**Not screened for FiCTION**
Mean (SD)	42.2 (33.4)	23.7 (18.0)	16.0 (11.3)	26.6 (13.0)	14.5 (2.1)
Total responses	64	248	2	16	2

Table 5.4: Response of parents, by FiCTION status, to the IMPACT study.

	Parent IMPACT consent forms returned, n=332					**Parents consenting to participate in IMPACT study, n=312**		**Parents declining to participate in IMPACT study, n=20**		
	FiCTION		**Non-FiCTION**		**Not screened for FiCTION**	**FiCTION**	**Non-FiCTION**	**FiCTION**	**Non-FiCTION**	**Not screened for FiCTION**
	n	**(% of consent forms returned)**	**n**	**(% of consent forms returned)**	**n (% of consent forms returned)**	**n (% of returned consent forms)**	**n (% of returned consent forms)**	**n (% of returned consent forms)**	**n (% of returned consent forms)**	**n (% of returned consent forms)**
Total responses	66	(19.9%)	264	(79.5%)	2 (0.6%)	64 (20.5%)	248 (79.5%)	2 (10.0%)	16 (80.0%)	2 (10.0%)

Almost all of the 332 parents (n=312, 94.0% of those returning a consent form, 10.5% of those contacted) who returned the consent form agreed to participate in the IMPACT study. (Table 5.4). Rates of consent were slightly higher (64/66, 97%) for FiCTION than for Non-FiCTION (248/264, 94%).

All consenting parents met the IMPACT criteria and were then sent a baseline questionnaire. In total, and following issue of reminder questionnaires to those who did not respond to the initial mailing, 261 parents (84% of those consenting to IMPACT) returned a completed baseline questionnaire and were included in the study. Tables 5.6 and 5.7 show the number of parents sent invitation packs and their subsequent response by site.)

The simplifying assumption was made that if a completed questionnaire, whether original or marked duplicate, was returned more than 7 days after the reminder was dispatched it had been triggered by that reminder. Most parents returned the initial questionnaire without a reminder (n=188, 72%), but for some parents (n=73, 28%) the reminder may have helped trigger the return of the questionnaire.

Of the 312 parents who consented to participate in IMPACT, 261 parents returned a baseline questionnaire, and of these the child's FiCTION status was ascertained as; FiCTION eligible and joined (n=55), FiCTION eligible and declined (n=6) and FiCTION ineligible (n=200) as described in Section 5.4.5. Amongst those consenting to participate in IMPACT, baseline response rates were therefore 86% (55/64) for FiCTION, 100% (6/6) for FiCTION eligible but declined, and 83% (200/242) for FiCTION ineligible, 83% (206/248) for Non-FiCTION overall. The original sample size target was 255 people per group and the original strategy was to invite all parents who returned a consent form to participate. When the sample size was revised to 66 parents per group, the Non-FiCTION parents target sample had already been reached and the imbalance of numbers of FiCTION versus Non-FiCTION parents could not be rectified.

21% (55/261) and 22.5% (45/200) of the returned baseline and 18 month questionnaires respectively were from FiCTION parents. Response rates for the 18-month follow-up questionnaires were 82% (45/55) for FiCTION and 75% (155/206) for Non-FiCTION participants respectively. Whilst it is evident that FiCTION parents had a slightly lower attrition rate from baseline to 18 months, the expected 25% attrition rate (which had been incorporated into the sample size calculation) was fairly accurate for both groups combined (Table 5.5).

Table 5.5: Number of IMPACT questionnaires returned by FiCTION and Non-FiCTION parents at baseline and 18 months in Scotland and England.

	FiCTION		**Non-FiCTION**		**Total**	
	Baseline	**18 months from baseline**	**Baseline**	**18 months from baseline**	**Baseline**	**18 months from baseline**
	n	**n**	**n**	**n**	**n**	**n**
Scotland	19	16	72	58	91	74
England	36	29	134	97	170	126
Total	55	45	206	155	261	200

Table 5.6: Number of eligible parents and recruitment response rate to IMPACT by practice in Scotland

Numbers eligible and recruitment response rate to IMPACT by practice (Scotland)								
	IMPACT invitation packs sent	**Consent forms returned**		**Parents consenting to participate in IMPACT and sent a baseline questionnaire**		**Number of baseline questionnaires returned**		**Number of 18 month questionnaires returned**	
	n	**n**	**(% of those sent)**	**n**	**(% of sample)**	**n**	**(% of those who consented)**	**n**	**(% of returned baseline questionnaires)**
Scottish Practice 1	53	5	(7.5%)	4	(7.5%)	3	(75.0%)	2	(66.7%)
Scottish Practice 2	100	19	(19.0%)	18	(18.0%)	16	(88.9%)	13	(81.3%)
Scottish Practice 3	11	2	(18.2%)	2	(18.2%)	2	(100.0%)	1	(50.0%)
Scottish Practice 4	65	11	(16.9%)	11	(16.9%)	10	(90.9%)	8	(80.0%)
Scottish Practice 5	99	3	(3.0%)	3	(3.0%)	2	(66.7%)	2	(100.0%)
Scottish Practice 6	56	3	(5.4%)	3	(5.4%)	3	(100.0%)	3	(100.0%)
Scottish Practice 7	13	2	(15.4%)	2	(15.4%)	2	(100.0%)	1	(50.0%)
Scottish Practice 8	46	3	(6.5%)	3	(6.5%)	3	(100.0%)	3	(100.0%)
Scottish Practice 9	21	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Scottish Practice 10	212	32	(15.1%)	31	(14.6%)	28	(90.4%)	21	(75.0%)
Scottish Practice 11	52	3	(5.8%)	3	(5.8%)	3	(100.0%)	2	(66.7%)
Scottish Practice 12	34	7	(20.6%)	7	(20.6%)	7	(100.0%)	6	(85.7%)
Scottish Practice 13	179	13	(7.3%)	12	(6.7%)	12	(100.0%)	12	(100.0%)
Scottish Practices TOTAL	941	103	(10.8%)	100	(10.6%)	91	(91.9%)	74	(81.3%)

Table 5.7: Number of eligible parents and recruitment response rate to IMPACT by practice in England

Numbers eligible and recruitment response rate to IMPACT by practice (England)									
	IMPACT invitation packs sent	**Consent forms returned**		**Parents consenting to participate in IMPACT and sent a baseline questionnaire**		**Number of baseline questionnaires returned**		**Number of 18 month questionnaires returned**	
	n	**n**	**(% of those sent)**	**n**	**(% of sample)**	**n**	**(% of those who consented)**	**n**	**(% of returned baseline questionnaires)**
English Practice 1	131	15	(11.5%)	15	(11.5%)	10	(66.7%)	8	(80.0%)
English Practice 2	80	4	(5.0%)	3	(3.8%)	2	(66.7%)	2	(100.0%)
English Practice 3	50	3	(6.0%)	3	(6.0%)	3	(100.0%)	3	(100.0%)
English Practice 4	262	27	(10.3%)	24	(9.2%)	22	(91.7%)	18	(81.8%)
English Practice 5	305	37	(12.1%)	32	(10.5%)	26	(81.3%)	20	(76.9%)
English Practice 6	100	13	(13.0%)	12	(12.0%)	12	(100.0%)	8	(66.7%)
English Practice 7	400	47	(11.8%)	43	10.8%)	36	(83.7%)	25	(69.4%)
English Practice 8	173	27	(15.6%)	26	(15.0%)	18	(69.2%)	12	(66.7%)
English Practice 9	107	9	(8.4%)	9	(8.4%)	7	(77.8%)	5	(71.4%)
English Practice 10	38	5	(13.2%)	5	(13.2%)	3	(60.0%)	1	(33.3%)
English Practice 11	139	15	(13.2%)	13	(9.4%)	13	(100.0%)	11	(84.6%)
English Practice 12	130	12	(9.2%)	12	(9.2%)	7	(58.3%)	4	(57.1%)
English Practice 13	64	4	(6.3%)	4	(6.3%)	3	(75.0%)	3	(100.0%)
English Practice 14	60	11	(18.3%)	11	(18.3%)	8	(72.7%)	6	(75.0%)
English Practices TOTAL	2039	229	(11.2%)	212	(10.5%)	170	(80.2%)	126	(74.1%)

5.5.2. *Socio-demographic and dental health data*

The basic baseline socio-demographic characteristics and dental history according to FiCTION status of parents are given in Tables 5.8 and 5.9.

The baseline study sample was 261 parents residing in the UK; 55 FiCTION parents and 206 Non-FiCTION parents. These parents had children who attended one of the 27 dental practices recruited for IMPACT which were also involved in the FiCTION RCT. The mean age of parents was 38.1 years (SD 5.8 years). There was little baseline difference between parents in the FiCTION and Non-FiCTION groups in terms of their age, relationship to the child or ethnicity (Table 5.8). The majority of questionnaires, irrespective of FiCTION status, were completed by mothers and by parents who identified themselves as white. This is interesting to note since the UK has become more ethnically diverse with rising numbers of people identifying with an ethnic minority ethnic group than ever before in England and Wales (Office for National Statistics 2012b) and Scotland (National Records of Scotland and Scottish Government 2014b). At the last census in 2011, the white ethnic group accounted for 86% of the usual resident population in England (Office for National Statistics 2012b) and 96% of the usual resident population in Scotland (National Records of Scotland and Scottish Government 2014b). Across north-east England over 95% identified as white (Office for National Statistics 2012b). Previous research has suggested that ethnic minorities are under-represented in research (Smart and Harrison 2017), but analysis of this data set would suggest the IMPACT study was representative of the ethnic mix of Scotland and north-east England.

There were large differences in the highest education level completed between the two IMPACT groups, with higher levels of educational attainment amongst the Non-FiCTION group (29.5% Non-FiCTION completed postgraduate education versus 16% FiCTION), suggesting either a different demographic mix of parents, a differing understanding of terminology used to describe education attainment or simply chance variation. Overall 54% (141/250) of participants, for whom information on highest level of education was available, had completed undergraduate or postgraduate university education; 44% in FiCTION and 59.5% Non-FiCTION. This is a higher percentage than that for the UK population as a whole (Office for National Statistics 2012a, National Records of Scotland and Scottish Government 2014a). In 2011, 26% of the population in Scotland and 27% in England and Wales aged 16 and over had achieved Census Level 4 or above qualifications, such as a university degree (Office for National Statistics 2012a, National Records of Scotland and Scottish Government 2014a). In 2011, 27% of the population in Scotland and 23% in

England and Wales reported they held no qualifications but it is important to note that the group who reported no qualifications may have included those aged 16 and over who were still studying towards the completion of their formal education (National Records of Scotland and Scottish Government 2014a, Office for National Statistics 2012a). The lowest percentage of Level 4 or above attainment in England and Wales was in the North East at 22% (Office for National Statistics 2012a). This highlights that the IMPACT study parents may not have been representative of the educational attainment level of the populations of Scotland and north-east England as a whole.

Table 5.8: Demographic characteristics of FiCTION and Non-FiCTION parents at baseline

Baseline characteristics						
	FiCTION (n= 55)		**Non-FiCTION (n=206)**		**Total (n=261)**	
	n		**n**		**n**	
Age (years)						
Mean		38.1		38.1		38.1
Standard Deviation		6.7		5.5		5.8
Total responses	47		197		244	
Relationship to child						
Mother	46	(86.8%)	182	(88.3%)	228	(88.7%)
Father	7	(13.2%)	16	(7.8%)	23	(8.9%)
Other	0	(0.0%)	6	(2.9%)	6	(2.3%)
Total responses	53		204		257	
Ethnicity						
White	53	(96.4%)	197	(96.1%)	250	(96.2%)
Indian, Pakistani or Bangladeshi	0	(0.0%)	5	(2.4%)	5	(1.9%)
Mixed race	0	(0.0%)	3	(1.5%)	3	(1.2%)
Other	2	(3.6%)	0	(0.0%)	2	(0.8%)
Total responses	55		205		260	
Highest level education completed						
Primary school	4	(8.0%)	5	(2.5%)	9	(3.4%)
Secondary school	12	(24.0%)	13	(6.5%)	25	(9.6%)
Some additional training	12	(24.0%)	63	(31.5%)	75	(28.7%)
Undergraduate university	14	(28.0%)	60	(30.0%)	74	(28.4%)
Postgraduate university	8	(16.0%)	59	(29.5%)	67	(25.7%)
Total responses	50		200		250	
Country of Residence						
England	36	(65.5%)	134	(65.0%)	170	(65.1%)
Scotland	19	(34.5%)	72	(35.0%)	91	(34.9%)
Total responses	55		206		261	

It can be seen, by comparing the country of residence, that more parents were recruited from England than Scotland, irrespective of FiCTION status (overall 65.1% England, 34.9% Scotland); this is not particularly surprising given than this is proportional to the number of invitation packs sent in England and Scotland. There was the same ratio of participants from England and Scotland in both the FiCTION and Non-FiCTION status groups.

Table 5.9: General health and dental health of FiCTION and Non-FiCTION parents at baseline

Baseline health						
	FiCTION (n=55)		**Non-FiCTION (n=206)**		**Total (n=261)**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
How is your health in general; would you say it was…						
Very good	25	(45.5%)	101	(49.8%)	126	(48.8%)
Good	24	(43.6%)	89	(43.8%)	113	(43.8%)
Fair	6	(10.9%)	9	(4.4%)	15	(5.8%)
Bad	0	(0.0%)	2	(1.0%)	2	(0.8%)
Very bad	0	(0.0%)	2	(1.0%)	2	(0.8%)
Total responses	55		203		258	
Would you say your dental health (mouth, teeth and/or dentures)…						
Very good	11	(20.0%)	50	(24.6%)	61	(23.6%)
Good	26	(47.3%)	104	(51.2%)	130	(50.4%)
Fair	18	(32.7%)	41	(20.2%)	59	(22.9%)
Bad	0	(0.0%)	6	(3.0%)	6	(2.3%)
Very bad	0	(0.0%)	2	(1.0%)	2	(0.8%)
Total responses	55		203		258	
How many natural teeth have you got? Is it…						
None at all	0	(0.0%)	0	(0.0%)	0	(0.0%)
At least 1 but less than 10	1	(1.8%)	0	(0.0%)	1	(0.4%)
Between 10 and 19	4	(7.3%)	2	(1.0%)	6	(2.3%)
20 or more natural teeth	50	(90.9%)	194	(96.5%)	244	(95.3%)
Some natural teeth but don't know how many	0	(0.0%)	5	(2.5%)	5	(2.0%)
Total responses	55		201		256	

As mentioned earlier, the questions regarding general and dental health and dental experiences of FiCTION and Non-FiCTION parents at baseline had previously been used in the 2009 ADHS (Nuttall et al. 2011). In the ADHS, 81% of adults said that their general health was good or very good (Nuttall et al. 2011); in the IMPACT study,

89.1% of FiCTION parents and 93.6% of Non-FiCTION parents reported this. In the ADHS, 71% of adults said that their dental health was good or very good (Nuttall et al. 2011); in the IMPACT study, 67.3% of FiCTION parents and 75.8% of Non-FiCTION parents reported this. Interestingly, it was noted in the ADHS that:

> "*Generally, greater proportions of younger dentate adults rather than older adults said they had good or very good general and dental health. For example, 91 per cent of dentate adults aged 16 to 24 said they had good or very good general health compared with 65 per cent of dentate adults aged 75 to 84. Similarly, 79 per cent of dentate adults aged 16 to 24 reported that they had good or very good dental health compared with 71 per cent of dentate adults aged 75 to 84. Women were more likely than men to say that they had good or very good dental health (73 per cent compared with 68 per cent); however there were no differences in the proportions of women and men saying they had good or very good general health*" (Nuttall et al. 2011).

In the IMPACT study, our parents were at the younger end of the spectrum, though not in the 16-24 year age group. The average age of our parents was 38.1 years, and 54% (140/261) were in the age group 36-45 years. 72% of dentate adults aged 35 to 44 said they had good or very good dental health in the 2009 ADHS; the base was too small to show percentage for participants who were edentulous (Fuller et al. 2011). All parents were dentate in the IMPACT study, and 74% of those aged 35 to 44 years old said their dental health was good or very good, suggesting that IMPACT study parents may have better perceived dental health than the average population in England, Wales and Northern Ireland.

IMPACT adults also reported good or very good general health. All IMPACT adults aged 16 to 24 (n=3/3) reported they had good or very good general health compared with 90% of IMPACT adults aged 25 to 35 (n=71/79), 94% aged 36 to 45 (n=132/140), 94% aged 46 to 55 (n=17/18) and 100% aged 56 to 64 (n=1/1). In the 2009 ADHS survey, 88% of dentate adults aged 35 to 44 years old, the modal age group for IMPACT participants, said they had good or very good general health (Fuller et al. 2011), suggesting that IMPACT study parents may have had better perceived general health than the average population in England, Wales and Northern Ireland.

66% of IMPACT adults aged 16 to 24 (n=2/3) reported they had good or very good dental health compared with 73% aged 25 to 35 (n=58/79), 75% aged 36 to 45 (n=105/140). 72% aged 46 to 55 (n=13/18) and 100% aged 56 to 64 (n=1/1).

Table 5.10: Dental experiences of FiCTION and Non-FiCTION parents at baseline

Baseline dental experience						
	FiCTION (n=55)		**Non-FiCTION (n=206)**		**Total (n=261)**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
Have you ever had fillings?						
Yes	49	(90.7%)	176	(90.7%)	225	(90.7%)
No	5	(9.3%)	18	(9.3%)	23	(9.3%)
Total responses	54		194		248	
Have you ever had any wisdom teeth extracted (taken out)?						
Yes	18	(33.3%)	73	(37.6%)	91	(36.7%)
No	36	(66.7%)	121	(62.4%)	157	(63.3%)
Total responses	54		194		248	
Have you ever had any teeth extracted (taken out)?						
Yes	41	(75.9%)	131	(67.5%)	172	(69.4%)
No	13	(24.1%)	63	(32.5%)	76	(30.6%)
Total responses	54		194		248	
Have you ever had a tooth crowned?						
Yes	12	(22.6%)	66	(34.0%)	78	(31.6%)
No	41	(77.4%)	128	(66.0%)	169	(68.4%)
Total responses	53		194		247	
Have you ever had a dental bridge?						
Yes	5	(9.3%)	17	(8.8%)	22	(8.9%)
No	49	(90.7%)	176	(91.2%)	225	(91.1%)
Total responses	54		193		247	
Have you ever had an implant to replace a missing tooth?						
Yes	1	(1.9%)	8	(4.1%)	9	(3.6%)
No	53	(98.1%)	186	(95.9%)	239	(96.4%)
Total responses	54		194		248	
Have you ever had sedation (that is something that relaxes you but does not put you to sleep) for dental treatment?						
Yes	29	(53.7%)	65	(33.5%)	94	(37.9%)
No	25	(46.3%)	129	(66.5%)	154	(62.1%)
Total responses	54		194		248	

FiCTION and Non-FiCTION parents generally rated their general and dental health similarly to one another with the only noticeable differences being in receiving sedation for dental treatment and provision of a crown where percentages were higher in the FiCTION group. Extractions, to a lesser extent, were also more likely in the FiCTION group. Having 21 or more natural teeth has been regarded as a marker of good function (Nuttall et al. 2011) and 95.3% of IMPACT parents self-reported they had 20 or more natural teeth (90.9% FiCTION and 96.5% Non-FiCTION) while none reported they were edentulous. In the ADHS, adults had their oral condition measured by a clinical examination; 94% of adults were found to be dentate and 6% were edentulous (Fuller et al. 2011). For the 94% dentate adults in the ADHS, 86% had 21 or more natural teeth, 8% had 15-20 teeth and the remaining 6% had 14 or less teeth (Fuller et al. 2011). When comparing the FiCTION and Non-FiCTION self-reported results with the 2009 ADHS, the parents in the IMPACT study, irrespective of FiCTION status, appeared to have better dental health with more sound and untreated teeth. However, it is important to recognise objectivity will be less evident with the self-reported outcome measure used in the IMPACT study (Nuttall et al. 2011).

5.5.2.1. Attrition bias

Of the 312 participants sent a baseline questionnaire, 261 participants completed and returned the baseline questionnaire. All 261 participants who completed a baseline questionnaire were sent an 18 month follow-up questionnaire, and reminder where appropriate, to complete. As mentioned previously (in Section 5.4.9.3.3) as part of the data checking process, the parent's date of birth and relationship to the child in both the baseline and 18 month questionnaires were cross-matched. This identified eight questionnaires that may have been completed by different parents at the two time points, and were therefore not suitable for inclusion of analysis of change over time. Overall, 200 follow-up questionnaires were returned (response rate 76.6%) and 192 of these (73.6% of those providing a baseline questionnaire, 96% of those returning a follow-up questionnaire) were included in the analysis of change over time (Table 5.11)

When comparing the baseline characteristics of all participants (n=261), including those lost to follow-up or excluded and those remaining in the study to end, the

findings were similar irrespective of FiCTION status when considering the parent's age and relationship to the child (Table 5.12). It is interesting to note that 70% (7/10) of ethnic minority participants were lost to follow up and all seven were Non-FiCTION parents. Education did not appear to have a noticeable impact on a parent's likelihood to be excluded or lost to follow up (Table 5.13). When comparing country of residence, FiCTION parents living in Scotland appeared to be more likely to be lost to follow up (Table 5.13) but country of residence was not felt to be of great importance when considering attrition bias in the IMPACT study.

Table 5.11: Number of IMPACT 18 months from baseline questionnaires returned from all participants who returned a baseline questionnaire (n=261), including those lost to follow-up or excluded, and those remaining in the study to the end

	FiCTION (n= 55)		**Non-FiCTION (n= 206)**		**Total (n=261)**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
18 months from baseline	45	(81.8%)	155	(75.2%)	200	(76.6%)
Both baseline and 18 months after baseline questionnaires returned						
Definitely the same respondent[1] (matched)	33	(73.3%)	138	(89.0%)	171	(85.5%)
Interpreted as the same respondent[2] (matched)	8	(17.8%)	13	(8.4%)	21	(10.5%)
Different respondent[3] (unmatched)	4	(8.9%)	4	(2.6%)	8	(2.5%)
Questionnaires included in the analysis of change from baseline	41	(74.5%)	151	(73.3%)	192	(73.6%)

[1]Same parental date of birth (D.O.B) and relationship to child reported in baseline and 18 months follow-up questionnaires.
[2] Child's D.O.B reported in one questionnaire but same maternal or paternal relationship reported and parent's D.O.B reported in the other questionnaire.
[3] Different parental D.O.B or different relationship reported.

Table 5.12: Age, relationship to child and ethnicity at baseline for all participants in IMPACT, including those lost to follow-up or excluded and those remaining in the study to the end, to show the number of participants included in the final analysis of change

	Participants lost to follow up or excluded				**Participants included in the analysis of change from baseline**				**All participants**			
Baseline variable	**FiCTION (n=14)**		**Non-FiCTION (n=55)**		**FiCTION (n=41)**		**Non-FiCTION (n=151)**		**FiCTION (n=55)**		**Non-FiCTION (n=206)**	
	n		**n**		**n**		**n**		**n**		**n**	
Age (years)												
Mean	11	34.2	48	37.1	36	39.3	149	38.4	47	38.1	197	38.1
SD		6.6		6.0		6.3		5.4		6.7		5.5
Relationship to child												
Mother	10	(83.3%)	44	(83.0%)	36	(87.8%)	138	(91.4%)	46	(86.8%)	182	(89.2%)
Father	2	(16.7%)	4	(7.5%)	5	(12.2%)	12	(7.9%)	7	(13.2%)	16	(7.8%)
Other	0	(0.0%)	5	(9.4%)	0	(0.0%)	1	(0.7%)	0	(0.0%)	6	(2.9%)
Total	12		54		41		151		53		204	
Ethnicity												
White	14	(100.0%)	47	(87.0%)	39	(95.1%)	150	(99.3%)	53	(96.4%)	197	(96.1%)
Indian, Pakistani or Bangladeshi	0	(0.0%)	4	(7.4%)	0	(0.0%)	1	(0.7%)	0	(0.0%)	5	(2.4%)
Mixed race	0	(0.0%)	3	(5.6%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	3	(1.5%)
Other	0	(0.0%)	0	(0.0%)	2	(4.9%)	0	(0.0%)	2	(3.6%)	0	(0.0%)
Total	14		54		41		151		55		205	

Table 5.13: Education status and country of residence at baseline for all participants in IMPACT, including those lost to follow-up or excluded and those remaining in the study to the end, to show the number of participants included in the final analysis of change

	Participants lost to follow up or excluded				**Participants included in the analysis of change from baseline**				**All participants**			
Baseline variable	**FiCTION (n=14)**		**Non-FiCTION (n=55)**		**FiCTION (n=41)**		**Non-FiCTION (n=151)**		**FiCTION (n=55)**		**Non-FiCTION (n=206)**	
	n		**n**		**n**		**n**		**n**		**n**	
Education status (completed)												
Primary school	1	(8.3%)	4	(7.5%)	3	(7.9%)	1	(0.7%)	4	(8.0%)	5	(2.5%)
Secondary school	4	(33.3%)	2	(3.8%)	8	(21.1%)	11	(7.5%)	12	(24.0%)	13	(6.3%)
Some additional training	3	(25.0%)	22	(41.5%)	9	(23.7%)	41	(27.9%)	12	(24.0%)	63	(31.5%)
Undergraduate university	4	(33.3%)	13	(24.5%)	10	(26.3%)	47	(32.0%)	14	(28.0%)	60	(30.0%)
Postgraduate university	0	(0.0%)	12	(22.6%)	8	(21.1%)	47	(32.0%)	8	(16.0%)	59	(29.5%)
Total	12		53		38		147		50		200	
Country of Residence												
England	8	(57.1%)	41	(74.5%)	28	(68.3%)	93	(61.6%)	36	(65.5%)	134	(65.0%)
Scotland	6	(42.9%)	14	(25.5%)	13	(31.7%)	58	(38.4%)	19	(34.5%)	72	(35.0%)
Total	14		55		41		151		55		206	

Table 5.14: General health and dental health at baseline for all participants in IMPACT, including those lost to follow-up or excluded and those remaining in the study to the end, to show the number of participants included in the final analysis of change

	Participants lost to follow up or excluded				**Participants included in the analysis of change from baseline**				**All participants**			
	FiCTION (n=14)		**Non-FiCTION (n=55)**		**FiCTION (n=41)**		**Non-FiCTION (n=151)**		**FiCTION (n=55)**		**Non-FiCTION (n=206)**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
How is your health in general; would you say it was…												
Very good	4	(40.0%)	20	(40.0%)	19	(46.3%)	83	(55.0%)	25	(53.1%)	101	(49.8%)
Good	5	(50.0%)	28	(56.0%)	20	(48.8%)	59	(39.1%)	24	(41.1%)	89	(43.8%)
Fair	1	(10.0%)	1	(2.0%)	2	(4.9%)	8	(5.3%)	6	(5.2%)	9	(4.4%)
Bad	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(0.7%)	0	(0.5%)	2	(1.0%)
Very bad	0	(0.0%)	1	(2.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(1.0%)
Total	10		50		41		151		55		203	
Would you say your dental health (mouth, teeth and/or dentures)…												
Very good	2	(20.0%)	7	(14.0%)	9	(22.0%)	50	(33.1%)	11	(20.0%)	50	(24.6%)
Good	3	(30.0%)	29	(58.0%)	22	(53.7%)	73	(48.3%)	26	(47.3%)	104	(51.2%)
Fair	5	(50.0%)	11	(22.0%)	9	(22.0%)	25	(16.6%)	18	(32.7%)	41	(20.2%)
Bad	0	(0.0%)	2	(4.0%)	1	(2.4%)	3	(2.0%)	0	(0.0%)	6	(3.0%)
Very bad	0	(0.0%)	1	(2.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(1.0%)
Total	10		50		41		151		55		203	

Table 5.15: Baseline dental treatment status of all participants in IMPACT, including those lost to follow-up or excluded and those remaining in the study to the end, to show the number of participants included in the final analysis of change

	Participants lost to follow up or excluded				**Participants included in the analysis of change from baseline**				**All participants**			
	FiCTION (n=14)		**Non-FiCTION (n=55)**		**FiCTION (n=41)**		**Non-FiCTION (n=151)**		**FiCTION (n=55)**		**Non-FiCTION (n=206)**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
How many natural teeth have you got? Is it…												
None at all	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
At least 1 but less than 10	1	(10.0%)	0	(0.0%)	1	(2.4%)	0	(0.0%)	1	(1.8%)	0	(0.0%)
Between 10 and 19	2	(20.0%)	0	(0.0%)	6	(14.6%)	6	(4.0%)	4	(7.3%)	2	(1.0%)
20 or more natural teeth	7	(70.0%)	44	(89.8%)	33	(80.5%)	143	(94.7%)	50	(90.9%)	194	(96.5%)
Some natural teeth but don't know how many	0	(0.0%)	5	(10.2%)	1	(2.4%)	2	(1.3%)	0	(0.0%)	5	(2.5%)
Total	10		49		41		151		55		201	
<u>Dental care/treatment</u> **Have you ever had fillings?**												
Yes	9	(90.0%)	43		36	(92.3%)	118	(86.8%)	49	(90.7%)	176	(90.7%)
No	1	(10.0%)	5		3	(7.7%)	18	(13.2%)	5	(9.3%)	18	(9.3%)
Total	10		48		39		136		54		194	
Have you ever had any wisdom teeth extracted (taken out)?												
Yes	3	(30.0%)	12	(25.0%)	14	(35.9%)	54	(39.7%)	18	(33.3%)	73	(37.6%)
No	7	(70.0%)	36	(75.0%)	25	(64.1%)	82	(60.3%)	36	(66.7%)	121	(62.4%)
Total	10		48		39		136		54		194	

Table 5.15 continued

	Participants lost to follow up or excluded				Participants included in the analysis of change from baseline				All participants			
	FiCTION (n=14)		Non-FiCTION (n=55)		FiCTION (n=41)		Non-FiCTION (n=151)		FiCTION (n=55)		Non-FiCTION (n=206)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Have you ever had any teeth extracted (taken out)?												
Yes	7	(70.0%)	33	(68.8%)	33	(84.6%)	86	(63.2%)	41	(75.9%)	131	(67.5%)
No	3	(30.0%)	15	(31.3%)	6	(15.4%)	50	(36.8%)	13	(24.1%)	63	(32.5%)
Total	10		48		39		136		54		194	
Have you ever had a tooth crowned?												
Yes	3	(30.0%)	16	(33.3%)	10	(25.6%)	46	(33.8%)	12	(22.6%)	66	(34.0%)
No	7	(70.0%)	32	(66.7%)	29	(74.4%)	90	(66.2%)	41	(77.4%)	128	(66.0%)
Total	10		48		39		136		53		194	
Have you ever had a dental bridge?												
Yes	1	(10.0%)	3	(6.4%)	4	(10.5%)	9	(6.7%)	5	(9.3%)	17	(8.8%)
No	9	(90.0%)	44	(93.6%)	34	(89.5%)	126	(93.3%)	49	(90.7%)	176	(91.2%)
Total	10		47		38		135		54		193	
Have you ever had an implant to replace a missing tooth?												
Yes	0	(0.0%)	2	(4.2%)	0	(0.0%)	3	(2.2%)	1	(1.9%)	8	(4.1%)
No	10	(100.0%)	46	(95.8%)	39	(100.0%)	133	(97.8%)	53	(98.1%)	186	(95.9%)
Total	10		48		39		136		54		194	

Table 5.15 continued

	Participants lost to follow up or excluded				Participants included in the analysis of change from baseline				All participants			
	FiCTION (n=14)		Non-FiCTION (n=55)		FiCTION (n=41)		Non-FiCTION (n=151)		FiCTION (n=55)		Non-FiCTION (n=206)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Have you ever had sedation (that is something that relaxes you but does not put you to sleep) for dental treatment?												
Yes	5	(50.0%)	17	(35.4%)	18	(46.2%)	50	(37.0%)	29	(53.7%)	65	(33.5%)
No	5	(50.0%)	31	(64.6%)	21	(53.8%)	85	(63.0%)	25	(46.3%)	129	(66.5%)
Total	10		48		39		135		54		194	

When comparing the baseline outcome measures (MDAS, OHIP-14, DHB, SOC-13) for all participants in IMPACT, including those lost to follow-up or excluded and those included in the analysis of change over time (Tables 5.16 and 5.17), summary statistics including mean, median, standard deviation and range were first generated. All scales were reported using mean and standard deviation. Comparison of FiCTION and Non-FiCTION status was made, particularly in respect of participants lost to follow-up and those included in the final analysis of change and the results were very similar. Attrition bias with respect to the baseline outcome measures did not present as a concern.

Table 5.16: Baseline mean (standard deviation) MDAS, OHIP-14 and DHB scores for all participants in IMPACT, those lost to follow-up or excluded, and those remaining in the study to the end

Total score	**Participants lost to follow up or excluded (n=69)**		**Participants included in the analysis of change from baseline (n=192)**		**All participants (n=261)**	
	FiCTION (n=14)	**Non-FiCTION (n=55)**	**FiCTION (n=41)**	**Non-FiCTION (n=151)**	**FiCTION (n=55)**	**Non-FiCTION (n=206)**
MDAS						
Mean (SD)	13.8 (6.2)	12.3 (5.7)	11.1 (6.2)	10.3 (4.3)	11.8 (6.3)	10.9 (4.8)
Total responses	14	52	40	144	54	196
OHIP-14						
Mean (SD)	7.1 (7.7)	8.2 (7.8)	6.5 (5.5)	6.2 (6.0)	6.7 (6.1)	6.7 (6.5)
Total responses	14	52	34	143	48	195
DHB						
Mean (SD)	10.1 (1.8)	9.6 (1.9)	8.9 (1.5)	9.3 (1.9)	9.2 (1.6)	9.4 (1.9)
Total responses	14	55	41	151	55	206

Table 5.17: Baseline mean (standard deviation) SOC-13 scores for all participants in IMPACT, those lost to follow-up or excluded, and those remaining in the study to the end

Total score	**Participants lost to follow up or excluded (n=69)**		**Participants included in the analysis of change from baseline (n=192)**		**All participants (n=261)**	
	FiCTION (n=14)	**Non-FiCTION (n=55)**	**FiCTION (n=41)**	**Non-FiCTION (n=151)**	**FiCTION (n=55)**	**Non-FiCTION (n=206)**
SOC-13 overall score						
Mean (SD)	63.8 (6.5)	62.4 (8.2)	63.7 (8.3)	63.1 (6.5)	63.7 (7.8)	62.9 (7.0)
Total responses	14	53	40	149	54	202
SOC-13 comprehensibility						
Mean (SD)	27.1 (3.4)	25.0 (4.2)	25.7 (4.6)	25.5 (3.8)	26.0 (4.3)	25.4 (3.9)
Total responses	14	53	40	149	54	202
SOC-13 manageability						
Mean (SD)	17.7 (2.3)	17.7 (2.9)	18.4 (3.1)	17.6 (2.5)	18.2 (2.9)	17.6 (2.6)
Total responses	14	53	40	149	54	202
SOC-13 meaningfulness						
Mean (SD)	19.0 (2.7)	19.8 (3.4)	19.7 (2.6)	19.9 (3.0)	19.5 (2.7)	19.9 (3.1)
Total responses	14	53	40	149	54	202

5.5.3. *Participants included in the final analysis of change: summary statistics*

From this point on, this thesis will report only on the 192 parents for whom a questionnaire completed by the same parent was available at both baseline and 18 months follow-up. The number of parents included for some analyses was lower than 192, where parents had not answered sufficient items within various instruments to allow a scale score to be calculated. Section 5.5.3 discusses the summary statistics and 5.5.4 discusses the results from the ANCOVA models.

5.5.3.1. Dental anxiety: Modified Dental Anxiety Scale (MDAS)

In total, 168 participants were evaluated (Table 5.18). The mean baseline total score (SD) was 10.4 (4.7) and the mean 18 month follow-up total score (SD) was 10.7 (4.5). Considering that a cut-off value for MDAS of 19 or above indicates high DA, 8% (14/168) started at or above the cut-off and 71% (10/14) of these parents remained at or above the cut-off 18 months from baseline. No parent moved from low anxiety at baseline to high anxiety 18 months from baseline. For parents who showed high DA at baseline (n=14), the mean baseline total score (SD) was 21.8 (1.7) and the mean 18 month follow-up total score (SD) was lower, but still in excess of the threshold value, at 19.8 (5.5). For parents who reported high DA at both baseline and 18 months from baseline (n=10), the mean baseline total score (SD) was 22.4 (1.5) and the mean 18 month follow-up total score (SD) was similar at 22.6 (2.5). For parents who showed low DA at baseline (n=154), the mean baseline total score (SD) was 9.3 (3.3) and the mean 18 month follow-up score (SD) was slightly higher, but still well below the threshold, at 9.8 (3.4).

5.5.3.2. OH-RQoL: Oral Health Impact Profile-14 (OHIP-14)

In total, 167 participants were evaluated (Table 5.18). The mean baseline total score (SD) was 6.2 (5.7) and the mean 18 month follow-up total score (SD) was similar at 6.3 (5.9).

5.5.3.3. Attitude: Dental Health Beliefs (DHB)

In total, 191 participants were evaluated (Table 5.18). The overall mean baseline score (SD) was 9.3 (1.8) and the overall mean 18 month follow-up score (SD) was slightly lower at 9.1 (1.8).

5.5.3.4. Attitude: Sense of Coherence-13 (SOC-13)

In total, 186 participants were evaluated (Table 5.19). The overall mean baseline total score (SD) was 63.2 (6.9) and the overall mean 18 month follow-up score (SD) was slightly lower at 62.9 (7.3).

The SOC-13 measurement was then further broken down into its three sub-dimensions: comprehensibility, manageability and meaningfulness. For the SOC-13 comprehensibility subdimension, in total, 187 participants were evaluated (Table 5.19). The overall mean baseline domain score (SD) was 25.6 (4.0) and the overall mean 18 month follow-up score (SD) was slightly lower at 24.8 (4.3). For the SOC-13 manageability subdimension, in total, 186 participants were evaluated (Table 5.19). The overall mean baseline domain score (SD) was 17.8 (2.6) and the overall mean 18 month follow-up total score (SD) was slightly lower at 17.7 (2.7). For the SOC-13 meaningfulness subdimension, in total, 186 participants were evaluated (Table 5.19). The overall mean baseline domain score (SD) was 19.8 (2.9) and the overall mean 18 month follow-up total score (SD) was slightly higher at 20.3 (2.8).

Table 5.18: Baseline, 18 months after baseline and change from baseline summary statistics for all 192 participants included in IMPACT for MDAS, OHIP-14 and DHB

Total score	Baseline			18 months after baseline			Change over time (18 months – baseline)		
	FiCTION (n=41)	Non-FiCTION (n=151)	Total (n=192)	FiCTION (n=41)	Non-FiCTION (n=151)	Total (n=192)	FiCTION (n=41)	Non-FiCTION (n=151)	Total (n=192)
MDAS									
Mean	11.2	10.1	10.4	11.3	10.5	10.7	0.1	0.4	0.3
SD	6.3	4.1	4.7	5.7	4.1	4.5	3.5	2.5	2.7
Total responses	38	130	168	38	130	168	38	130	168
OHIP-14									
Mean	6.8	6.1	6.2	6.9	6.1	6.3	0.1	0.0	0.0
SD	5.6	5.8	5.7	6.7	5.8	5.9	4.6	3.6	3.8
Total responses	31	136	167	31	136	167	31	136	167
DHB									
Mean	9.0	9.3	9.3	8.9	9.2	9.1	-0.1	-0.1	-0.1
SD	1.4	1.9	1.8	1.8	1.8	1.8	1.8	1.7	1.7
Total responses	40	151	191	40	151	191	40	151	191

Table 5.19: Baseline, 18 months after baseline and change from baseline summary statistics for all 192 participants included in IMPACT for SOC-13.

Total score	Baseline			18 months after baseline			Change over time (18 months – baseline)		
	FiCTION (n=41)	Non-FiCTION (n=151)	Total (n=192)	FiCTION (n=41)	Non-FiCTION (n=151)	Total (n=192)	FiCTION (n=41)	Non-FiCTION (n=151)	Total (n=192)
SOC-13 overall score									
Mean (SD)	63.9 (8.1)	63.1 (6.6)	63.2 (6.9)	63.1 (9.1)	62.9 (6.8)	62.9 (7.3)	-0.7 (9.3)	-0.2 (7.4)	-0.3 (7.8)
Total responses	38	148	186	38	148	186	38	148	186
SOC-13 comprehensibility									
Mean (SD)	25.6 (4.6)	25.6 (3.8)	25.6 (4.0)	24.8 (4.6)	24.8 (4.2)	24.8 (4.3)	-0.8 (4.6)	-0.7 (4.2)	-0.7 (4.3)
Total responses	39	148	187	39	148	187	39	148	187
SOC-13 manageability									
Mean (SD)	18.6 (2.9)	17.6 (2.5)	17.8 (2.6)	18.0 (3.4)	17.6 (2.5)	17.7 (2.7)	-0.6 (4.0)	-0.0 (3.2)	-0.1 (3.4)
Total responses	38	148	186	38	148	186	38	148	186
SOC-13 meaningfulness									
Mean (SD)	19.6 (2.6)	19.9 (3.0)	19.8 (2.9)	20.0 (3.4)	20.4 (2.6)	20.3 (2.8)	0.4 (3.7)	0.5 (3.0)	0.5 (3.2)
Total responses	38	148	186	38	148	186	38	148	186

5.5.4. *Analysis of change: ANCOVA models*

As described in Section 5.4.11.1, a number of assumptions were assessed and following confirmation that the assumptions had been met, ANCOVA was used to assess the change in each outcome measure, taking into account and adjusting initially solely for each individual baseline score. ANCOVA models were fitted to each dataset including and excluding any outliers within the dataset. In the event that there were outliers, the results of fitting models with and without the outliers were found to be comparable and it was felt more appropriate for analyses including outliers to be reported below. The ANCOVA model resulted in an estimate of the mean difference between the two groups (i.e. between FiCTION and Non-FiCTION) in the change from baseline in the outcome measure, taking into account the baseline values but no other covariates at this stage. ANCOVA model estimates and 95% confidence intervals have been reported.

Table 5.20: Number of IMPACT participants included in the analysis of change after controlling for baseline by outcome measure

	FiCTION (n= 55)		**Non-FiCTION (n= 206)**		**Total (n=261)**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
Participants available in principle* for the analysis of change from baseline	41	(74.5%)	151	(73.3%)	192	(73.6%)
MDAS sub-scale: non-missing data included in the analysis of change from baseline	38	(69.1%)	130	(63.1%)	168	(64.4%)
OHIP-14 sub-scale: non-missing data included in the analysis of change from baseline	31	(56.3%)	136	(66.0%)	167	(64.0%)
DHB sub-scale: non-missing data included in the analysis of change from baseline	40	(72.7%)	151	(73.3%)	191	(73.2%)
SOC-13 sub-scale: non-missing data included in the analysis of change from baseline	38	(69.1%)	148	(71.8%)	186	(71.3%)

*Smaller numbers available for analysis of most sub-scales due to incomplete data.

5.5.4.1. Dental anxiety: Modified Dental Anxiety Scale (MDAS)

An ANCOVA model was fitted to compare FiCTION versus Non-FiCTION participation for change in MDAS after controlling for baseline MDAS. There was a linear relationship between pre- and post-MDAS for each group, as assessed by

visual inspection of a scatterplot. The model was an adequate fit based on an assessment of the standardised residuals.

Higher MDAS scores denote greater DA. After adjustment for baseline MDAS, the estimated mean change from baseline to 18 months was an increase in MDAS of 0.23 for FiCTION parents and of 0.31 for Non-FiCTION parents, with the mean difference in the change being -0.08 (95% CI, -1.02 to 0.87), p>0.9. The adjusted mean change for both groups was small but positive, suggesting that both got slightly more anxious over time on average. However, the mean change in MDAS scores from baseline for both groups would not be considered clinically meaningful (Humphris et al. 2009). The ANCOVA analysis shows that FiCTION status was not statistically associated with a change in MDAS total score and the 95% confidence interval did not include a mean difference in the change in MDAS score between groups that would be considered clinically meaningful (Humphris et al. 2009, Cook et al. 2018) (Table 5.21).

Table 5.21: Mean difference in the change in MDAS between groups (n=168)

MDAS	Adjusted mean change from baseline		Adjusted mean difference in the change (Fiction – Non-Fiction)	
	Fiction, n=38	Non-Fiction, n=130	Estimate	95% CI
Change in MDAS, adjusted for baseline MDAS	0.23	0.31	- 0.08	-1.02 to 0.87

5.5.4.2. OH-RQoL: Oral Health Impact Profile-14 (OHIP-14)

An ANCOVA model was fitted to assess the effect of FiCTION and Non-FiCTION participation on change in OHIP-14 after controlling for baseline OHIP-14. The assumptions underpinning the application of the ANCOVA model (Section 5.4.11.1) were upheld. The model was an adequate fit based on an assessment of the standardised residuals.

The higher the OHIP-14 score, the more dissatisfied parents were with their own dental health. After adjustment for baseline OHIP-14, the mean change from baseline to 18 months was an increase in OHIP-14 of 0.18 for FiCTION parents and a decrease of 0.02 for Non-FiCTION parents, with the mean difference in the change being 0.21 (95% CI, -1.24 to 1.65), p=0.8. The adjusted mean change for FiCTION parents was positive suggesting that their OH-RQoL got slightly worse over time on

average. The adjusted mean change for Non-FiCTION parents was negative suggesting that their OH-RQoL got slightly better over time on average. However, the mean change in OHIP-14 scores for both groups would not be considered clinically meaningful.(Slade 1997) The analysis shows that FiCTION status was not statistically associated with a change in OHIP-14 total score; the 95% confidence interval for the adjusted mean change did not include a difference in change of score between groups that would be considered clinically meaningful (Slade 1997, Cook et al. 2018) (Table 5.22).

Table 5.22: Mean difference in the change in OHIP-14 between groups (n=167)

OHIP-14	Adjusted mean change from baseline		Adjusted mean difference in the change (Fiction – Non-Fiction)	
	FiCTION, n=31	Non-FiCTION, n=136	Estimate	95% CI
Change in OHIP-14, adjusted for baseline OHIP-14	0.18	-0.02	0.21	-1.24 to 1.65

5.5.4.3. Attitude: Dental Health Beliefs (DHB)

An ANCOVA model was fitted to assess the effect of FiCTION and Non-FiCTION participation on change in DHB after controlling for baseline DHB. The assumptions underpinning the application of the ANCOVA model (Section 5.4.11.1) were upheld. The model was an adequate fit based on an assessment of the standardised residuals.

Higher DHB scores denote less favourable oral-health-related beliefs. After adjustment for baseline DHB, the mean change from baseline to 18 months was a decrease in DHB of 0.20 for FiCTION parents and of 0.10 for Non-FiCTION parents, with the mean difference in the change being -0.11 (95% CI, -0.63 to 0.43), p=0.7. The adjusted mean change for both groups was negative, suggesting that both developed slightly more favourable dental beliefs over time on average. However, the mean change in DHB scores for both groups would not be considered clinically meaningful (Broadbent et al. 2006). The analysis shows that FiCTION status was not statistically associated with a change in DHB total score; the 95% confidence interval for the adjusted mean change did not include a difference between groups that would be considered clinically meaningful (Cook et al. 2018, Broadbent et al. 2006) (Table 5.23).

Table 5.23: Mean difference in the change in DHB between groups (n=191)

DHB	Adjusted mean change from baseline		Adjusted mean difference in the change (Fiction – Non-Fiction)	
	FiCTION, n=40	Non-FiCTION, n= 151	Estimate	95% CI
Change in DHB, adjusted for baseline DHB	-0.20	-0.10	-0.11	-0.63 to 0.43

5.5.4.4. Attitude: Sense of Coherence–13 (SOC-13)

An ANCOVA model was fitted to assess the effect of FiCTION and Non-FiCTION participation on change in SOC-13 after controlling for baseline SOC-13. The assumptions underpinning the application of the ANCOVA model (Section 5.4.11.1) were upheld. The model was an adequate fit based on an assessment of the standardised residuals.

The higher the SOC score, the better people are able to deal with the stressors of everyday life and to use the resources at their disposal to counter these stressors. After adjustment for baseline SOC-13, the mean change from baseline to 18 months was a decrease in SOC-13 of 0.39 for FiCTION parents and of 0.32 for Non-FiCTION parents, with the mean difference in the change being -0.06 (95% CI, -2.50 to 2.37), p>0.9. The adjusted mean change for both groups was negative, suggesting that both got less able to deal with the stressors of everyday life over time on average. However, the mean change in SOC-13 scores for both groups would not be considered clinically meaningful (Eriksson and Lindström 2005). The analysis shows that FiCTION status was not statistically associated with a change in SOC-13 total score; the 95% confidence interval for the adjusted mean change did not include a difference between groups that would be considered clinically meaningful (Cook et al. 2018, Eriksson and Lindström 2005) (Table 5.24).

Table 5.24: Mean difference in the change in Total SOC-13 between groups (n=186)

Total SOC-13	Adjusted mean change from baseline		Adjusted mean difference in the change (Fiction – Non-Fiction)	
	FiCTION, n=38	Non-FiCTION, n= 148	Estimate	95% CI
Change in Total SOC-13, adjusted for baseline SOC-13	-0.39	-0.32	-0.06	-2.50 to 2.37

5.5.5. *Multivariable models of change including possible confounding variables*

The ANCOVA models, controlling only for baseline score, reported above, showed that that FiCTION status alone was not statistically significantly associated with change from baseline to 18 months in parental MDAS, OHIP-14, DHB and SOC-13. As documented in the statistical analysis plan, it was proposed that the impact on the FiCTION status effect estimates of including possible confounders (e.g. age, gender, education) would be considered by adding them to the models that included baseline score and FiCTION status only. Multivariable models only included participants with non-missing data for all of the variables included in the model (i.e. list-wise deletion was employed), thereby further decreasing the number of observations. The number of participants included in the multivariable models for each outcome model is shown in Table 5.25.

Table 5.25: Number of IMPACT participants included in the multivariable models of change after controlling for baseline and other possible confounders

	FiCTION (n= 55)		**Non-FiCTION (n= 206)**		**Total (n=261)**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
Participants available for the analysis of change from baseline	41	(74.5%)	151	(73.3%)	192	(73.6%)
MDAS sub-scale: non-missing data included in the multivariable model	33	(60.0%)	127	(61.7%)	160	(61.3%)
OHIP-14 sub-scale: non-missing data included in the multivariable model	28	(50.9%)	132	(64.1%)	160	(61.3%)
DHB sub-scale: non-missing data included in the multivariable model	35	(63.6%)	148	(71.8%)	183	(70.1%)
SOC-13 sub-scale: non-missing data included in the multivariable model	26	(47.3%)	133	(64.6%)	159	(60.9%)

To compare the FiCTION status estimates from the multivariable models with FiCTION status estimates for the ANCOVA models (reported in Section 5.4.4), it was necessary to re-fit the ANCOVA models using the reduced number of participants available with complete data. Hence, in the results which follow, two models are reported for each subscale: Model 1 gives the FiCTION status estimate from the basic ANCOVA model, using data for only the sub-set of participants included in the multivariable model and Model 2 gives the estimates for all variables included in the multivariable model, i.e. including the proposed confounders; both models use data from the same participants to allow a direct assessment of the impact on the FiCTION status estimate of adding the possible confounders to the ANCOVA model. Models in which each possible confounder was added on its own to the ANCOVA model (which included only the baseline score of the outcome variable and FiCTION status) were also fitted. The results of those separate analyses are described in the text, but only the results of fitting all possible confounders simultaneously are presented in the following results tables.

5.5.5.1. Dental anxiety: Modified Dental Anxiety Scale (MDAS)

The possible confounders included in the multivariable modelling of change in MDAS were parental age in years, gender and education level (Section 5.4.11.1). None of the possible confounders were statistically significantly associated with change in MDAS between the two groups (i.e. FiCTION and Non-FiCTION) from baseline to 18 months (either when included one at a time or when added simultaneously to the multivariable models) (Tables 5.26 and 5.27).

After extending the ANCOVA model (Table 5.26) to include the additional possible confounders, age in years, gender and education level (Table 5.27), the estimate of the mean difference in the change from baseline between FiCTION and Non-FiCTION groups was reduced from 0.11 points lower in the FiCTION group to 0.003 points lower (95% CI, -1.0 to 1.0) Based on these data there is no evidence of a statistically significant difference, or a difference that is clinically meaningful (Humphris et al. 2009), in the change in MDAS between groups from baseline to 18 months.

Table 5.26: Model 1: Estimate of the mean difference in the change in MDAS between FiCTION status groups, adjusted for baseline MDAS (n=160)

Variables	Category/increment	Estimate	95% CI	P-Value
FiCTION status (reference category: Non-FiCTION)	FiCTION	-0.11	-1.05 to 0.84	0.8
MDAS at baseline	For an increase of one point on MDAS	-0.18	-0.26 to -0.10	<0.001

Table 5.27: Model 2: Estimate of the mean difference in the change in MDAS between FiCTION status groups, adjusted for baseline MDAS, age in years, gender and education level (n=160)

Variables	Category/increment	Estimate	95% CI	P-Value
FiCTION status (reference category: Non-FiCTION)	FiCTION	-0.003	-1.00 to 1.00	>0.9
MDAS at baseline	For an increase of one point on MDAS	-0.19	-0.27 to -0.10	<0.001
Age in years	For an increase of one year	0.005	-0.07 to 0.08	0.9
Gender (reference category: female)	Male	0.24	-1.20 to 1.68	0.7
*Education level (reference category: postgraduate)	Secondary school	0.72	-0.87 to 2.31	0.4
	Some additional training	0.37	-0.62 to 1.37	0.7
	Undergraduate	0.009	-0.96 to 0.98	>0.9

***** Multivariable models only included participants with non-missing data for all the variables included in the model. The 6 participants who had reported their highest level of education as primary had missing data on at least one other variable and so the primary education category was not included as a level of education in the multivariable model.

5.5.5.2. OH-RQoL: Oral Health Impact Profile-14 (OHIP-14)

The possible confounders included in the multivariable modelling of change in OHIP-14 were parental age in years, gender, general health at baseline and general dental health at baseline (Section 5.4.11.1). No parents self-reported that they were edentulous, so we were unable to include this possible cofounder in the analysis. None of the possible confounders were statistically significantly associated with change in OHIP-14 between groups of parents from baseline to 18 months (either when included one at a time or when added to the multivariable models) (Tables 5.28 and 5.29).

After extending the ANCOVA model (Table 5.28) to include the additional possible confounders of age in years, gender, general health at baseline and general dental health at baseline (Table 5.29), the estimate of the mean difference in the change from baseline between FiCTION and Non-FiCTION groups was reduced from 0.60 points higher in the FiCTION group to 0.59 points higher (95% CI, -0.97 to 2.14) Based on these data there is no evidence of a statistically significant difference, or a

difference that is clinically meaningful (Slade 1997), in the change in OHIP-14 between groups from baseline to 18 months.

Table 5.28: Model 1: Estimate of the mean difference in the change in OHIP-14 between FiCTION status groups adjusted for baseline OHIP-14 (n=160)

Variables	Category/increment	Estimate	95% CI	P-Value
FiCTION status (reference category: Non-FiCTION)	FiCTION	0.60	-0.91 to 2.11	0.4
OHIP-14 at baseline	For an increase of one point on OHIP-14	-0.19	-0.29 to -0.09	<0.001

Table 5.29: Model 2: Estimate of the mean difference in the change in OHIP-14 between FiCTION status groups, adjusted for baseline OHIP-14, age in years, gender, baseline general health and baseline general dental health (n=160)

Variables	Category/increment	Estimate	95% CI	P-Value
FiCTION status (reference category: Non-FiCTION)	FiCTION	0.59	-0.97 to 2.14	0.5
OHIP-14 at baseline	For an increase of one point on OHIP-14	-0.20	-0.31 to –0.10	<0.001
Age in years	For an increase of one year	-0.03	-0.14 to 0.07	0.5
Gender (reference category: female)	Male	0.26	-1.89 to 2.41	0.8
General Health at baseline (reference category: Very good)	Good	1.14	-0.17 to 2.45	0.09
	Fair	-0.07	-2.54 to 2.39	>0.9
General Dental Health at baseline (reference category: Very good)	Good	-0.26	-1.72 to 1.19	0.7
	Fair	-0.50	-1.34 to 2.35	0.6

5.5.5.3. Attitude: Dental Health Beliefs (DHB)

The possible confounders included in the multivariable modelling of change in DHB were parental age in years, gender and baseline general dental health (Section 5.4.11.1). None of the possible confounders were statistically significantly associated with change in DHB between groups of parents from baseline to 18 months (either when included one at a time or when added to the multivariable models. (Tables 5.30 and 5.31). The analysis was expanded to include gender as it was felt by one of the statisticians to be standard practice to report this (Section 5.4.11.1).

After extending the ANCOVA model (Table 5.30) to include the additional possible confounders age in years, gender and general dental health at baseline (Table 5.31), the estimate of the mean difference in the change from baseline between FiCTION and Non-FiCTION groups was reduced from 0.20 points lower in the FiCTION group

to 0.11 points lower (95% CI, -0.68 to -0.46) Based on these data there is no evidence of a statistically significant difference, or a difference that is clinically meaningful (Broadbent et al. 2006), in the change in DHB between groups from baseline to 18 months.

Table 5.30: Model 1: Estimate of the mean difference in the change in DHB between FiCTION status groups adjusted for baseline DHB (n= 183)

Variables	Category/increment	Estimate	95% CI	P-Value
FiCTION status (reference category: Non-FiCTION, n=0)	FiCTION	-0.20	-0.76 to 0.36	0.48
DHB at baseline	For an increase of one point on DHB	-0.43	-0.56 to -0.31	<0.001

Table 5.31: Model 2: Estimate of the mean difference in the change in DHB between FiCTION status groups adjusted for baseline DHB, age, gender and dental health status (n=183)

Variables	Category/increment	Estimate	95% CI	P-Value
FiCTION status (reference category: Non-FiCTION)	FiCTION	-0.11	-0.68 to -0.46	0.7
DHB at baseline	For an increase of one point on DHB	-0.44	-0.57 to -0.31	<0.001
Age in years	For an increase of one year	-0.02	-0.06 to 0.02	0.3
Gender (reference category: female)	Male	-0.39	-1.31 to 0.52	0.4
General Dental Health at baseline (reference category: Very good)	Good	-0.14	-0.67 to 0.39	0.6
	Fair	-0.37	-1.00 to 0.27	0.3

5.5.5.4. Attitude: Sense of Coherence–13 (SOC-13)

The possible confounders included in the multivariable modelling of change in SOC-13 were parental age in years, gender, MDAS at baseline and OHIP-14 at baseline (Section 5.4.11.1). None of the possible confounders were statistically significantly associated with change in SOC-13 between groups of parents from baseline to 18 months (either when included one at a time or simultaneously in multivariable models) (Tables 5.32 and 5.33).

After extending the ANCOVA model (Table 5.32) to include the additional possible confounders age in years, gender, MDAS at baseline and OHIP-14 at baseline (Table 5.33), the estimate of the mean difference in the change from baseline between FiCTION and Non-FiCTION groups was increased from 1.19 points higher in the

FiCTION group to 1.54 points higher (95% CI, -1.12 to 4.20) Based on these data there is no evidence of a statistically significant difference, or a difference that is clinically meaningful (Eriksson and Lindström 2005), in the change in SOC-13 between groups from baseline to 18 months.

As mentioned previously (in Section 4.11.3.1), an individual's SOC has been shown to have an impact on their QoL; the stronger the SOC, the better the QoL (Eriksson and Lindstrom 2007). Whilst none of the possible confounders were statistically significantly associated with change in SOC-13 between groups of parents from baseline to 18 months when added to the multivariable model, the relationship between the OHIP-14 confounder and the change score in SOC-13 was close to significance (p=0.07). For an increase in one point in OHIP-14, the change in SOC-13 from baseline to 18 months decreased on average by 0.16 points but, even if it had been significant, the change would not be considered clinically meaningful (Eriksson and Lindström 2005).

Table 5.32: Model 1: Estimate of the mean difference in the change in SOC-13 between FiCTION status groups adjusted for baseline SOC-13 (n=159)

Variables	Category/increment	Estimate	95% CI	P-Value
FiCTION status (reference category: Non-FiCTION)	FiCTION	1.19	-1.45 to 3.84	0.4
SOC-13 at baseline	For an increase of one point on SOC-13	0.56	-0.71 to -0.41	<0.001

Table 5.33: Model 2: Estimate of the mean difference in the change in SOC-13 between FiCTION status groups, adjusted for baseline SOC-13, age, gender, baseline MDAS and baseline OHIP-14 (n=159)

Variables	Category/increment	Estimate	95% CI	P-Value
FiCTION status (reference category: Non-FiCTION)	FiCTION	1.54	-1.12 to 4.20	0.3
SOC-13 at baseline	For an increase of one point on SOC-13	-0.57	-0.73 to -0.42	<0.001
Age in years	For an increase of one year	-0.04	-0.22 to 0.14	0.7
Gender (reference category: female)	Male	1.67	-2.13 to 5.46	0.4
MDAS at baseline	For an increase of one point	-0.10	-0.33 to 0.13	0.4
OHIP-14 at baseline	For an increase of one point	-0.16	-0.35 to 0.02	0.07

5.6. Discussion

In this section I first present a summary of the principal findings of the quantitative study. Then the strengths and weakness of the design of the quantitative study are discussed with comparison to other relevant publications. The findings of this study are then considered in terms of potential impact on clinicians and/or policymakers. Finally, areas where further research may be needed are discussed.

5.6.1. *Statement of key results with reference to study objectives*

261 parents completed a baseline questionnaire; of these, 55 were parents of FiCTION RCT participants. Quantitative analysis showed no difference at baseline in MDAS, OHIP-14, DHB or SOC-13, between FiCTION participant parents (Mean (SD) score 11.8 (6.3), 6.7 (6.1), 9.2 (1.6), and 63.7 (7.8) respectively) and FiCTION non-participant parents (10.9 (4.8), 6.7 (6.5), 9.4 (1.9), and 62.9 (7.0) respectively). For all participants in IMPACT, including those lost to follow-up or excluded and those included in the analysis of change over time, the baseline analysis sets were very similar with respect to the primary outcome measures (MDAS, OHIP-14, DHB and SOC-13). Moreover, as discussed further in Section 5.5.2, there was little baseline difference between parents in the FiCTION and Non-FiCTION groups in terms of their age, relationship to the child or ethnicity, there were, however, marked differences in the highest education level completed between the two IMPACT groups, with higher levels of educational attainment amongst the Non-FiCTION parents. In keeping with the STROBE recommendations (Vandenbroucke et al. 2007), statistical tests were not used to compare the groups at baseline and therefore p-values were not reported.

5.6.2. *Statement of key results with reference to study hypothesis*

From this quantitative study, the data are not consistent with the research hypothesis and therefore we failed to reject the null hypothesis of no difference.

There was no difference in mean change from baseline to 18 months, with respect to parental oral health-related quality of life (OHIP-14), dental health beliefs (DHB) and sense of coherence (SOC-13) regarding their own dental care and that of their children, between parents of children with active caries and participating in an RCT in

primary dental care (FiCTION) and parents of children without active caries and not participating in an RCT.

Follow-up questionnaires were returned by 200 parents (response rate 76.6%) and 192 of these (73.6% of those providing a baseline questionnaire, 96% of those returning a follow-up questionnaire) were included in the analysis of change over time. The basic ANCOVA models, controlling only for baseline score, showed the mean difference in the change (95% CI) for FiCTION and Non-FiCTION parents from baseline to 18 months was -0.08 (95% CI, -1.02 to 0.87), p>0.9' 0.21 (95% CI, -1.24 to 1.65), p=0.8; -0.11 (95% CI, -0.63 to 0.43), p=0.7; and 0.06 (95% CI, -2.50 to 2.37), p>0.9 for MDAS, OHIP-14, DHB and SOC-13 respectively. The basic ANCOVA models, controlling only for baseline score, showed that FiCTION status alone was not statistically significantly associated with change from baseline to 18 months in parental MDAS, OHIP-14, DHB and SOC-13. After extending the ANCOVA model to include a number of additional possible confounders, the estimates of the mean difference in the change from baseline between FiCTION and Non-FiCTION groups were: reduction from 0.11 points lower in the FiCTION group to 0.003 points lower (95% CI, -1.0 to 1.0); reduction from 0.60 points higher in the FiCTION group to 0.59 points higher (95% CI, -0.97 to 2.14); reduction from 0.20 points lower in the FiCTION group to 0.11 points lower (95% CI, -0.68 to -0.46); and an increase from 1.19 points higher in the FiCTION group to 1.54 points higher (95% CI, -1.12 to 4.20) for MDAS, OHIP-14, DHB and SOC-13 respectively. None of the possible confounders (e.g. age, gender and ethnicity), either when included one at a time or when added simultaneously to the multivariable models, were statistically significantly associated with change from baseline to 18 months and their inclusion had only a very minor effect of the estimated between-group differences.

5.6.3. *Strengths and limitations of this quantitative study*

In this section of the chapter some of the strengths and weaknesses of this quantitative study will be addressed, followed by discussions about the representativeness of the data. These arguments allow an understanding of the robustness of the data, and emerging issues can be tentatively shown that may require further investigation. In commencing this discussion of the strengths and weaknesses of the quantitative study, it must be remembered that this study was

based on the opportunity which arose when a specific paediatric trial (the FiCTION RCT) was funded. The protocol of the quantitative study had to interface with the existing FiCTION RCT. This led to some methodological restrictions in the quantitative study. These are discussed along with any resultant issues.

5.6.3.1. Access to the FiCTION RCT Team

By embedding the IMPACT quantitative study within the FiCTION RCT, this provided me with access to a local network of skilled researchers who were able to provide valuable expertise on governance aspects of undertaking clinical research in primary dental care and provide advice on the feasibility of my dental practice and parent recruitment strategies at various points. They were also able to provide advice on which practices were not randomising any participants and were likely to withdraw from the FiCTION RCT. Access to this support was particularly useful given that it was my first experience of undertaking quantitative research.

5.6.3.2. Recruitment and retention of dental practices

It was my aim to have a representative sample of FiCTION practices from Scotland and north-east England enrolled in the IMPACT study. Of the 42 dental practices contacted, 13 in Scotland (50% of all Scottish FiCTION practices) and 14 from north-east England (88%) respectively agreed to take part in IMPACT. It is probably reasonable to conclude that the IMPACT practices were representative of the dental practices enrolled in the FICTION RCT in these regions. Significant efforts were made by the FiCTION RCT team to recruit a random and representative sample of practices while taking in to consideration data on practice characteristics including: size (number of registered patients), practice-level index of multiple deprivation and practice-level tap-water fluoridation status (ppmF^-).

All members of primary care staff involved in the FiCTION RCT received clinical and trial process training (which included Good Clinical Practice and informed consent training). This meant that I was able to ask staff in dental practices to issue IMPACT invitations to parents at the time of their attending the practice for their child's dental appointment. However, some practice teams reported that that they found it difficult to administer the IMPACT quantitative study whilst also trying to run the FiCTION RCT and deliver routine clinical practice. These types of problems have been reported in other studies in primary care dental research (Martin-Kerry et al. 2015).

As a result, I modified my study protocol to allow the IMPACT paperwork to be distributed bv the practice, either by post with help from me, or given in person to the parent when attending the practice for their child's dental appointment. Only 15% (n=4) of practices chose to hand out the IMPACT invitation packs within the dental practice; the preferred method of distribution (n=23) was by post. This pragmatic approach to modifying the IMPACT study protocol, to allow the IMPACT paperwork to be distributed with help from me, was in-keeping with FiCTION design as a pragmatic trial.

Despite verbal agreement with practices over the telephone, three practices forgot that my support visits for posting the IMPACT paperwork out to parents had been arranged, requiring visits to be rescheduled to another day. Additional confirmation of appointments via text, email or letter may have reduced the likelihood this breakdown in communication. By acknowledging the challenges to running a dental practice, and modifying the IMPACT protocol, it is probable to conclude that this stopped any dental practices from withdrawing from the IMPACT study. My visits to the dental practices to assist with IMPACT mailings, significantly reduced the burden on practice personnel within the dental practices. However, the logistics associated with visits to practices was challenging, in terms of travelling, and accessing the relevant information without affecting the practice's running of day-to-day activities.

All but one of the dental practices used a computer-based medical record system. The need to gain access to parent information within the dental practices was challenging at times and had to be navigated around the accessibility of a suitable computer in a busy dental practice. Often the computer was within a clinical area and access was restricted. Since I am a clinician and familiar with the running of a dental practice I was able to predict some of the challenges; I explored the dental team's work schedules and tried to attend practices at quieter times e.g. weekends, during holiday periods or training/administration sessions so any disruption would be minimised. The need to gain access to information in a way which would involve the minimal upheaval in the practices concerned had to be balanced against the potential reduced sample size which would have resulted from only selecting parents from certain practices where computing facilities were more readily available.

5.6.3.3. Recruitment and retention of parents

Parents were selected based on dental practices participating in the FiCTION RCT in Scotland and north-east England who also agreed to participate in the IMPACT study. It is commonly suggested that individuals from ethnic minorities, lower income, poorly educated or lower socioeconomic status groups are less likely to participate in research and therefore are underrepresented; these assumptions, however, generally appear to be based on the analysis of single trial datasets (Robinson et al. 2016). The FiCTION RCT team have very limited evidence of how representative the catchment populations of the FICTION practices (overall, or for the subset that were approached to and agreed to be in IMPACT) were of the underlying population of Scotland, England and Wales. Of the 72 practices in the UK that randomised at least one child to the FiCTION RCT, 23 (32%) were in the first (most deprived) quintile, 21 (29%) in the 2nd, 10 (14%) in the 3rd, 12 (17%) in the 4th and 6 (8%) in the 5th (Maguire et al. 2020). The applicability of this information to individual participants is limited, however, as it is based on the dental practice postcodes; some practices are likely to have had large and heterogeneous catchment areas for patients. Ideally the index of deprivation should have been based on the child's home postcode and could have been used to distinguish between all the parents of children involved in the FiCTION RCT and the parents of children involved in the IMPACT study.

There was little baseline difference between parents in the FiCTION and Non-FiCTION groups in terms of their age, relationship to the child or ethnicity. The majority of questionnaires, irrespective of FiCTION status, were completed by mothers and by participants who identified themselves as white. Analysis of this data set would suggest the IMPACT study was more representative of the ethnic mix of Scotland and north-east England than it would initially appear (Section 5.5.2). It is not certain that the findings of the Scottish and north-east England FiCTION participants reflect those of the other FiCTION participants in the rest of the UK as the ethnic mix may be different across the country, including in London. Whilst the FiCTION RCT team have data on the ethnic mix of the FiCTION children, and ethnic mix could have been calculated for the subset of IMPACT parents, the problem that parents may self - identify as being of one ethnic group but identify their child as being of another was acknowledged. This seems likely as the population of England, Wales and Scotland has become increasingly ethnically diverse in recent decades. (Office for National Statistics 2014). It is unclear whether supplying the questionnaires in different languages would have been advantageous but this option was not provided by either

the FiCTION RCT or the IMPACT study. It was felt collectively by the researchers that the component instruments may not have been cross-culturally adapted and validated in other languages and the results based on such sub-scales questionnaires may therefore not have accurately reflected what they were supposed to measure.

Asking participants to complete the questionnaires at home empowered them by allowing completion at a time and in a setting of their choosing. If either the baseline or 18 month questionnaire was not returned to me within four weeks of initial posting, a reminder letter, including a duplicate questionnaire, was posted to the parent and a follow-up telephone call was made to parents who had provided a contact telephone number. Providing non-respondents with a second copy of the questionnaires has been found to improve questionnaire response rate (Edwards et al. 2002). Some parents were very slow in returning the baseline questionnaire, but did so before they could have received the reminder questionnaire. As discussed in Section 5.5.1.2, most parents returned the initial questionnaire without a reminder (n=188, 72%), but for some parents (n=73, 28%) the reminder may have helped trigger the return of the questionnaire. Given the time interval between the baseline and 18 months from baseline questionnaires being sent, issues arose with participants moving home and the questionnaires being returned unopened to me. Dental practices were contacted when a questionnaire was 'returned to sender' to confirm whether a different address was held by the practice; where applicable questionnaires were re-issued. This introduced further additional burdens for both dental practices and myself. It is unclear whether an online questionnaire may have reduced the loss to follow up of participants as likewise it is easy for online questionnaires to be deleted or ignored. Issues could arise with participants changing email addresses or internet providers over the intervening time period.

There were incidences where parents, particularly FiCTION parents, appeared to be confused as to whether the questions related to them or their child (as noted when they gave their child's DOB instead of their own). As mentioned previously (in Section 5.4.9.3.3) as part of the data checking process, the parent's date of birth and relationship to the child was cross-matched across paired baseline and 18 month questionnaires. Instances of mis-matched parents (Table 5.11) were discussed by the study team and a decision reached on a case-by-case basis on whether to

exclude the participant at follow-up or to allow them to remain in the dataset. The most common source of mis-match was where the parent reported their own date of birth on one questionnaire but their child's on the other (n=21). This resulted in a greater burden for the study team in terms of data cleaning and analysis.

The method of issuing the IMPACT information did not to seem to influence recruitment or retention of parents within the study. Upon reflection, sending the IMPACT invitation pack meant, in principle at least, that it would be received by some families who were never going to eligible for the IMPACT study, as their child was not brought to the FiCTION screening appointment. As discussed in Section 5.5.1.2 this did occur; two children were not brought to their FiCTION RCT screening dental appointment and therefore were not eligible to participate in the IMPACT study but both parents had in any case declined to take part on the returned IMPACT consent form. As reported in Section 5.5.1.2, the FiCTION practice screening logs were not always completed consistently and I was therefore unable to determine how many IMPACT ineligible parents were contacted by the 23 practices who posted out the IMPACT packs.

The inconsistent completion of FiCTION practice screening logs, coupled with resource constraints, meant that I was unable to cross-check all IMPACT pack recipients against practice FiCTION screening logs. Instead, FiCTION status was confirmed only for parents who returned the IMPACT consent form, either opting in or opting out of participation in the IMPACT study. If I had been able to cross-check all IMPACT pack recipients against practice FiCTION screening logs, I could have looked at whether there was bias, in respect to the age and gender (variables which were meant to be recorded on FiCTION practice logs for each child), in respect to return of IMPACT consent forms.

5.6.3.4. Target sample size and response rates

Although the achieved sample included participants with a range of demographic and socio-economic differences, all with experience of being approached and screened for FiCTION, the revised target sample size of 66 per group was not achieved in the FICTION group but was well exceeded in the Non-FiCTION group. As discussed in Section 5.4.5, a total of 3214 children were expected to be screened for FiCTION across these 27 practices. Based on the assumed rates of 85% of those screened

being excluded from the FiCTION RCT because they did not meet eligibility criteria and a further 20% meeting trial eligibility criteria but declining FiCTION participation, it was calculated that 2732 would be ineligible for FiCTION, 96 would be FiCTION eligible but declined, and 386 being FiCTION eligible and enrolled. Given the requirement for equal numbers per FiCTION and Non-FiCTION groups, it was acknowledged that the target sample size (initially 255, subsequently reduced to 66) would be reached more quickly for the Non-FiCTION group, as this comprised the larger pool of potential participants.

As the originally proposed method of recruitment for IMPACT was for GDPs to recruit parents in person, ideally at the FiCTION screening visit, the study team did not feel that imbalance in group sizes would exist long-term. Under this approach, each practice was expected to implement a targeted invite approach, recruiting 10 parents (subsequently reduced to 2-3) who had a child recruited into the FiCTION RCT and 10 parents (also subsequently reduced to 2-3) who did not have a child recruited into the FiCTION RCT, when the parent attended the dental practice for their child's dental appointment. Under this model of recruitment, anticipated IMPACT participation rates for the original sample size of 255 per group were 66% (255/386) and 9% (255/2828) for FiCTION and Non-FiCTION parents respectively, revised downwards to 17.1% (66/386) and 2.3% (66/2828) with the revision of the target sample sizes. Markedly higher participation rates for FiCTION parents were considered plausible, given that this subset of parents had already shown commitment to research by consenting to their child taking part in the FiCTION study.

With the dental practices reporting feeling overwhelmed with the FiCTION RCT, 23 practices chose to send out the IMPACT invitation packs to the parents of all children being invited to take part in FiCTION, some of whom did not subsequently attend for FiCTION screening and were therefore IMPACT ineligible. Across all FiCTION practices, 36% of children (4379/12078) sent a FiCTION invitation, failed to attend for a FICTION screening visit. The parents of such children would have been considered IMPACT ineligible, since their child's FiCTION status (and therefore the parent's IMPACT group allocation) could not be ascertained.

The total number of IMPACT invitation packs issued by the 27 participating practices was 2980, somewhat lower than the 3214 estimated from assumed overall screening,

eligibility and consent rates. The number of IMPACT invites sent by post by the 23 dental practices who chose this method of participant invitation was 2697. Making the simplifying assumption that the rate of non-attendance for FiCTION screening (and therefore IMPACT ineligibility) in these 23 practices was the same as for all FiCTION practices (36%), it can be calculated that 1726 IMPACT eligible parents were invited to take part from these 23 practices, with a further 181 IMPACT eligible parents known to have been invited by the other 4 practices. This suggests that a total of 1907 IMPACT eligible parents were approached. Within the FiCTION RCT, rates of ineligibility for that trial amongst those screened were somewhat lower than expected, at 76% (rather than 85%) for all screened participants. Across all 27 IMPACT practices, a total of 492 children were randomised into FiCTION, and therefore comprised the pool eligible for recruitment into the FiCTION group of IMPACT. Two children (see Section 5.5.1.2) invited to take part in FiCTION and IMPACT, did not attend for their FiCTION screening visit and were therefore deemed IMPACT ineligible. The remaining 1413 IMPACT eligible parents comprised the Non-FiCTION pool. As indicated above (Section 5.5.1.2), consent forms were received from 66 FiCTION and 264 Non-FiCTION parents, response rates of 13.4% and 18.7% respectively (overall consent rate 17.3%). The slightly lower rate of consent in the FiCTION group may reflect the perceived additional burden of taking part in a second study for this sub-set of parents.

As discussed previously (Section 5.6.2.2), given the challenges with recruitment and retention of parents for both studies, and uncertainty regarding whether the HTA would agree to an extension to the FiCTION the IMPACT sample size was recalculated and the revised (reduced) recruitment target was implemented in November 2014. Recognising that more parents than required had already been recruited into the Non-FiCTION group (n=206), the imbalance of numbers of FiCTION versus Non-FiCTION parents could not be rectified. The study team felt that it was unethical not to continue to use all of the Non-FiCTION parent data collected. The baseline study sample therefore comprised 55 FiCTION and 206 Non-FiCTION parents. It was further recognised that by incorporating more Non-FiCTION parents that necessary (206 as opposed to 66), this made any estimates for the Non-FiCTION group more precise and also improved the precision of between group comparisons (FiCTION vs Non-FiCTION).

5.6.3.5. Study size imprecision

As noted in Section 5.4.5, it was difficult to calculate sample size requirements for this study given the lack of previous data. In addition, there were no publications on what comprised a minimal clinically important difference (Cook et al. 2018) for the included measures, meaning it was difficult to determine what might comprise an appropriate change over time.

Most significantly, the data used in the original and revised sample size calculations were for participants themselves undergoing dental treatment, whereas in the IMPACT study the participants were parents observing their children receiving treatment. In hindsight, using a similar difference seen in an interventional study to calculate the difference which might be predicted in an observational study was a poor decision, but these were the only data available at the time. The precision obtained in the final analysis could not be determined *a priori* because the impact of including confounding variables in multivariable analysis was unclear, as were the degree of precision with which key variables could be measured and the extent of exclusion of some parents e.g. loss to follow up.

The initial sample size calculation of 255 per group implied that 85% of FiCTION parents would need to participate in the IMPACT study. Although a high participation rate, this was nonetheless felt to be achievable, based on the results of the FiCTION Pilot and Rehearsal study previously undertaken in 2010-11. Of those eligible for that study, 80% of parents agreed for their child to participate. The study team felt that this suggested parents were keen to participate in primary care research; as the burden associated with the IMPACT study was low this was unlikely to be a significant reason for them to decline participation therein. In addition, the initially proposed method of recruitment for IMPACT was for GDPs to recruit parents in person, ideally at the time of the FiCTION screening visit, suggesting the 85% uptake of FiCTION parents was viable.

In reality, in total, only 332 (11.1%) parents given an IMPACT invitation pack returned the consent form. As described in Section 5.4.4, this comprised of: FiCTION eligible and joined (n=66), FiCTION eligible and declined (n=6) and FiCTION ineligible (n=258) parents. Almost all parents (n=312, 94.0% of those returning a consent form,

10.5% of those contacted) who returned the consent form consented to participate in the IMPACT study. Of the 312 parents consenting to participate in IMPACT, 64 parents (20.5%) were involved in the FiCTION RCT and 248 (79.5%) were not involved in the FiCTION RCT, in almost all cases because their child was not eligible to participate. Unfortunately, as the FiCTION screening logs were not reliably completed, I was unable to determine how many children were ineligible because they were caries-free and how many were otherwise ineligible e.g. because they had pain or sepsis associated with dental caries. Out of those who were calculated as IMPACT eligible, IMPACT consent rates were 13% (64/492) for FiCTION and 18% (248/1413) for Non-FiCTION respectively. Using the totals of 492 and 1413 eligible for FiCTION and Non-FiCTION respectively as the denominators, the percentages of questionnaires by the same parent of both baseline and 18-month questionnaires were 8.3% (41/492) and 10.7% (151/1413) respectively. Low response rates increase the likelihood of non-response bias, but the problems with the screening logs already alluded to make it difficult to compare child-level demographic variables for IMPACT non-respondents and to ascertain whether there were indeed any such biases.

5.6.3.6. Potential biases & lack of external validity

The parents participating in the IMPACT study were self-selected and not a random sample from the children screened for the FiCTION RCT. This could have introduced non-response bias. It would have threatened the external validity of the survey — that is, the extent to which the IMPACT study results could be generalised to the underlying population. The responding parents are likely to have been systematically different to the non-respondents in some way, not least in their motivation to complete the questionnaire. This may have ultimately affected the results of the IMPACT study. For example, parents with a limited literacy or those for whom English is not their first language may have been less likely to return the expression of interest form if they had difficulties understanding the study information leaflets. This would have resulted in the IMPACT study underestimating the interest of parents to participate in a primary care dental research study. The problem may have been exacerbated if the dental practice did not discuss the IMPACT study with families at the same time as discussing the FiCTION RCT.

The sample size calculation for IMPACT was predicated on an implicit assumption that Non-FiCTION parents would not have experienced change over time in MDAS, OHIP-14, DHB or SOC-13, whilst FiCTION parents would have experienced a change of the same magnitude as in Santa-Rosa et al. (2014). With the benefit of hindsight, Santa-Rosa et al.'s (2014) study refers to change over time in OH-RQoL for children and adults who themselves were undergoing dental aesthetic restorative treatment. The present study assessed the likelihood of change over time in OH-RQoL and related measures in parents whose children had received dental treatment. It is impossible to draw firm conclusions whether a child's experience of treatment could be expected to have any marked effect on parental dental health or OH-RQoL.

The recruitment and retention of parents within the IMPACT study was difficult and compounded by being nested with the FiCTION RCT which had a lower than expected participant recruitment rate (Keightley et al. 2014). Based on the assumptions of the FiCTION RCT study team that (a) 85% of those screened would be ineligible for FiCTION and (b) of those who screened eligible for FICTION, 20% would decline participation in the trial (in other words, that 12% of those screened eligible for FICTION would take part), by inviting 2980 parents to take part in IMPACT (and assuming that invited to IMPACT attended for a FICTION screening visit), one would have expected 358 parents in the FICTION pool, and the remaining 2622 parents in the Non-FiCTION pool, 12% and 88% of all those approached respectively. In reality, for the majority of practices, the IMPACT invitation was issued alongside that for FiCTION, and a significant percentage (assumed 36% – see Section 5.6.2.4) of parents receiving these invitations did not bring their child to a FiCTION screening visit, thereby rendering them IMPACT ineligible (since their FiCTION status could not be determined) and reducing the effective size of the overall pool to 1907 (64% of those invited). Furthermore, the observed rates of FiCTION ineligibility (actual rate 76% versus 85% assumed) and FiCTION decline amongst those eligible (actual rate 19% versus 20% assumed) were such that the actual pools of FiCTION and Non-FiCTION parents were 492 and 1413 respectively. In total, of those eligible for IMPACT, 16.3% (312/1907) consented to participate in the IMPACT study with 13.0% (64/492) and 17.6% (248/1413) in the FiCTION and Non-FiCTION groups respectively. Completed baseline questionnaires were returned by 261 parents (83.7%% of the 312 parents consenting to participate in the IMPACT

study); 55 ((85.9% of those receiving a questionnaire) FICTION and 206 (83.1% of those receiving a questionnaire) Non-FiCTION. This imbalance in terms of raw numbers (55 FiCTION vs 206 Non-FiCTION) seemed plausible, since far more of those receiving IMPACT invitation packs and being eligible for IMPACT (1413/1907=74.1%) were only eligible for the Non-FiCTION group. When the sample size was revised to 66 parents per group (66/492 =13.4%% FiCTION and 66/1413 = 4.7% Non-FiCTION) , the strategy changed to specific targeting of only FiCTION parents as the Non-FiCTION parents target sample had already been reached.

The actual IMPACT response rate (baseline questionnaire returned), vis-à-vis invitations issued to IMPACT eligible parents, based on the revised sample size calculation, (was a bit lower than required (55/492 (11.2%) vs 66/492 ((13.4%)) for the FiCTION pool while for Non-FiCTION (it was higher than required (206/1413 (14.6%) vs 66/1413 (4.7%)). This suggests there may have been non-response bias, with those who were already in FICTION less likely (vis-a-vis expectations and relative to Non-FiCTION parents) to also agree to participate in IMPACT. Whilst not what we originally expected, on reflection this is not particularly surprising as FiCTION parents would already have been experiencing significant respondent burden in the FICTION RCT and may not have wanted to take on another study. The return rate of baseline IMPACT questionnaires by consenting parents in the FiCTION group in Scotland (19/100=19.0%) was a little higher than the FiCTION group in north-east England (36/212= 17.0%).

5.6.3.7. Study outcome measures

For this study the parents' previous dental experiences were equally as important as their understanding of research and it was impossible to ascertain, with any degree of certainty, whether one would be more important in a parent's willingness to take part in IMPACT. The study team felt, based on an appraisal of existing published literature and collective judgment, that parents' DA, OH-RQoL and how they valued their life may all be important predictors of their beliefs, values and attitudes towards (their child's) participation in a primary dental care research study. Validated outcome measures to assess parents' DA, OH-RQoL and how they valued their life were then critically appraised. The MDAS (Humphris et al. 1995), OHIP-14 (Locker et al. 2004), DHB (Broadbent et al. 2006) and SOC-13 (Larsson and Kallenberg 1999) measures were the chosen validated instruments, addressing respectively DA, OH-RQoL,

dental beliefs and sense of coherence, because of their reliability, validity and low respondent burden. Reducing research burden to participants was considered essential considering some parents would also be involved in the FiCTION RCT and there was a high risk of study fatigue occurring within the FiCTION RCT as it progressed.

For practical reasons the OHIP-14 was included on the ADHS 2009 survey, but its method of reporting in that study differed from other published work in the field and previous ADH surveys. Seven dimensions of impact of oral condition are associated with OHIP-14; these are functional limitation; physical pain; psychological discomfort; physical disability; psychological disability; social disability; and handicap. Each OHIP-14 dimension consists of two questions and the most frequent response to either question determines the overall frequency of experiencing the problem. For example, a person who responded that they had *occasionally* experienced “painful aching in their mouth” along with a response that they had *hardly ever* “found it uncomfortable to eat any foods” would be classified as having experienced physical pain occasionally. The reporting OHIP-14 by sub-dimension has not been completed at baseline and is an area for further work.

As discussed in Section 5.6.2.3, index of multiple deprivation was based on practice address, not patient address, in the FiCTION RCT. As recognised by the FiCTION team, it would have been preferable, though more burdensome on resources, if this had been calculated at the patient level. The practice populations may not have been representative of the general populations of Scotland and north-east England in the first place (for a whole range of reasons, not least of which is that the census data is now nearly 10 years out of date). If that was the case, then no matter how robust my sampling strategy was and how high my response rate could have been, then my achieved sample would not have been representative of the populations of the areas concerned. In addition, there is a high likelihood of non-response bias, such that my achieved sample is not representative of the underlying practice populations in terms of educational attainment. Educational attainment is perhaps the most widely used indicator of socio-economic status (Shavers 2007). There were large differences between the highest education level attained between the two IMPACT groups, with higher levels of educational attainment amongst the Non-FiCTION group. Baseline highest educational attainment was used for comparison as the classification

changed for a few parents between the baseline and 18 month follow-up questionnaires. This could simply have been a lack of test-retest reliability in the question. It has previously been reported that, in general, those who attained a higher level of education had a more favourable view of medical research (Singhal et al. 2002). Further conclusions cannot be reached regarding the relationship between educational attainment and willingness to participate in dental research as the educational status of parents who were approached but did not agree to participate in IMPACT, nor on those who did not agree to participate in FiCTION, was not ascertained.

5.6.4. *Interpretation of results*

As discussed in Section 2.4.3.3, there is a paucity of evidence on the factors perceived by healthcare professionals to facilitate or hinder recruitment of participants in general medical and dental practices. Whilst there is a growing recognition that dental practices in the primary care NHS sector provide an excellent and relevant environment in which to carry out clinical dental research, and an opportunity for all members of the dental team to develop and expand their roles into the research field, research conducted within primary dental care services is still relatively rare and limited (Dawett 2017). Whilst most IMPACT dental teams understood the general aspects of the IMPACT study, they reported finding it difficult to manage alongside the trial commitments associated with the FiCTION RCT. It was evident that high levels of support were necessary from the FiCTION research support staff and clinical leads for the necessary FiCTION study materials to be collected. Simultaneous evaluation of another area of research involving the same subjects via nested studies, rather than stand-alone studies, could add much value to trials in addition to providing data for secondary objectives. This has been recognised as important, where there is funding available for “Studies Within a Trial” (SWATs) (Health Research Board Trials Methodology Research Network 2019, National Institute for Health Research 2019a). SWATs are designed to address a methodology research question on any aspect of the trial, for example: design, conduct, analysis, reporting or dissemination of trials, for which there is current uncertainty and to explore alternative ways of doing a trial process (e.g. recruiting patients, helping them to stay in the study, or reporting the findings) to provide evidence about how to improve the process (Treweek et al. 2018a) or to evaluate approaches to support trial delivery success within HTA main trials (National Institute

for Health Research 2019a). SWATs have the potential for trial findings to be more significant in terms of policy and practice. Whilst IMPACT did not set out to address a methodology research question, it did add value by highlighting some additional challenges with carrying out a study nested in a RCT in primary dental care.

There is no consensus on a cut-off value at which loss to follow-up is acknowledged as a problem. Nonetheless, it has been suggested that loss to follow-up of 5% or lower is usually of little concern, whereas a loss of 20% or greater means that readers should be concerned about the possibility of bias; losses between 5% and 20% may still be a source of bias (Dumville et al. 2006). Differential attrition is recognised as likely to result in bias, as those lost from one group are more likely to be systematically different from those lost from the other group – by definition, they are systematically different with respect to their 'experience' of the intervention (e.g. FiCTION) than the other (e.g. Non-FiCTION). The retention rate for 18-month data collection amongst parents who returned a baseline questionnaire was only very slightly higher for FiCTION parents (41/55 = 74.5%) than Non-FiCTION parents (151/206=73.3%); it resulted in a total response rate only slightly lower (192/261=73.6%) than anticipated (75%, based on an assumed loss to follow-up of 25%, informed by the FiCTION Pilot and Rehearsal Study (Innes et al. 2013)). It could be argued that more relevant, or at least an equally relevant, retention rates are calculated by the number of those retained to 18 months divided by the number initially eligible for and consenting to IMPACT in the first instance; the retention rate remained higher for FiCTION parents (41/64 = 64.1%) than Non-FiCTION parents (151/248=60.9%). Using both of these calculations, the loss to follow up rate for both FiCTION and Non-FiCTION parents were both greater than the 20% mentioned by Dumville et al. (2006) suggesting that we should consider the possibility of bias. Analysis has shown, however, that, with the possible exception of ethnicity (where numbers were very small anyway), there was little evidence of attrition bias in either group or for the IMPACT sample as a whole. The overall percentage of participants who will either withdraw or otherwise be lost to follow-up should be very carefully considered until the likely impact of research study settings, characteristics of participants and the outcomes being assessed are better understood.

It was acknowledged that those included in a study often differ in relevant ways from the target population to whom results are intended to be applied (Vandenbroucke et

al. 2007). Such participation biases can distort exposure-disease associations if associations differ between those eligible for the study and those included in the study. Although low participation does not necessarily compromise the internal or external validity of a study, it is recommended that transparent information on participation and reasons for non-participation is essential. As this study was interested in change scores, no imputation of 18-month data based on baseline values (e.g. using last observation carried forward) were made where a questionnaire was not returned at 18 months and the parent was “lost to follow-up”. However, the reasons why parents were no longer in the study or why they were excluded from statistical analyses was reported, where feasible, to help readers judge whether the study population was representative of the target population and whether attrition bias was possibly introduced.

Limited resources meant that I was unable to ascertain whether the 312 parents consenting to participate in the IMPACT study were a biased sample of all the parents approached or the parents who were IMPACT eligible. As the FiCTION practice screening logs were not always completed consistently, it was not viable to compare the child characteristics for the 64 children whose parents consented to IMPACT with the 428 (492-64) who were enrolled in FiCTION in those practices but did not consent to IMPACT. The inaccuracy of the FiCTION screening log introduced several further limitations within this study. It may be the case that, for more complex studies, a researcher would need to be on-site full time to fully ensure robust collection of data. As mentioned earlier (see Section 2.4.3.3), the type of staff selected to recruit participants to studies, and how they present themselves, is particularly noteworthy and would warrant further exploration in this incidence.

The mean age of parents in this study was 38.1 years (SD 5.8 years). A previous study reported the 2008 UK population total mean (SD) norm for MDAS for adults 30-39 years old was 11.61 (5.88) (Humphris et al. 2009); the mean baseline MDAS total score (SD) was 11.8 (6.3) for FiCTION parents and 10.9 (4.8) for Non-FiCTION parents. A previous study reported the total mean (SD) norm for SOC-13 for adults 30-44 years old from Glasgow, Liverpool and Manchester was 63.65 (-1.47) (Walsh et al. 2014); the mean baseline total SOC-13 score (SD) was 63.7 (7.8) for FiCTION parents and 62.9 (7.0) for Non-FiCTION parents. For a previous study, the mean of baseline DHB total score (SD) was 10.9 (SD 2.6) at age 15 yrs, 11.1 (SD 2.6) at age

18 yrs, and 11.1 (SD 2.4) at age 26 yrs when assessed in a birth cohort at ages 15, 18 and 26 years old (Broadbent et al. 2006); the mean baseline total DHB score (SD) was 9.2 (1.6) for FiCTION parents and 9.4 (1.9) for Non-FiCTION parents. These result suggests the IMPACT sample is generally representative of the UK population in terms of DA, OH-RQoL and DHB. As mentioned previously in Section 5.6.2.7, direct comparison with the IMPACT sample against the ADHS population is not currently possible for OHIP-14. The most important trend shown in the recent ADH surveys is a decrease in caries experience, shown by a decrease in the average number of teeth per individual with signs of disease or disease experience (fillings) (White et al. 2012). Overall, 92.6% of participants in IMPACT said their general baseline health was good or very good and 74% said that their baseline dental health was good or very good. These key findings are in keeping with the ADHS 2009 where, overall, 81% of adults said that their general health was good or very good and 71% of adults said that their dental health was good or very good (Nuttall et al. 2011). Even with advances in general dental health care in the last 10 years, these results suggest that younger adults feel more positive regarding their general health.

5.6.5. *Implications for research*

The literature review indicated that, as far as I am aware, there are no primary care based dental studies, other than the FiCTION RCT, involving parents and children, and none assessing change over time with specific outcome measures. Reducing barriers to participation in research can: lead to more reliable study data (McDonald et al. 2006); make the research more patient-centric (Fayter et al. 2007); and provide an overall better participant experience (Mann et al. 2018).

> *"The consequences of poor recruitment are: premature closure of trials; trials that are underpowered to answer the main research questions (and the dangers associated with this (Altman and Bland 1995)); wasting of resources; and the end-users of research (patients and clinicians) not benefiting from the intended outcomes of the trial"(Das Nair et al. 2014).*

There is growing support (Martin-Kerry et al. 2015) for the view that multi-site dental clinical trials come with a number of common challenges including difficulty recruiting practices and participants, training staff, multi-site coordination and lengthy periods required to gain approval for studies. I experienced at first-hand lengthy delays in gaining study sponsorship and thus receiving a favourable ethical outcome for the IMPACT study. By modifying my quantitative study protocol, by supporting IMPACT

invitation packs to parents to be posted out by practices with my help, I was able to reduce difficulty in retaining dental practices. The IMPACT study was nonetheless dependent on the success of recruitment of children into the FiCTION RCT. The challenges with recruitment and retention of parents for the FiCTION RCT, and uncertainty regarding whether the HTA would agree to an extension, highlights a potential challenge that the design of future studies (especially if time sensitive studies such as associated with a PhD) should take into account. In this respect alone, the study adds useful information to the current knowledge.

Primary care is a clinical setting that faces particular recruitment challenges with common barriers to general practice trial recruitment including time constraints, lack of funding, lack of interest in research, and a perception that patients need to be protected (Colwell et al. 2012). The dental team had a tendency to focus first of all on the possible benefit to their immediate patients and not on the theoretical benefit to future patients; this has also been reported in paediatric oncology research (De Vries et al. 2011). Whilst it was not the only reason given by FiCTION dental practices participating in the FICTION RCT for their decision not to participate also in the IMPACT study, concerns over the additional burden that research placed on the family was an overwhelming theme which had also been reported by the FiCTION RCT (Keightley et al. 2014). Several dental teams felt concerned about “overloading” FiCTION parents; concern that the doctor-patient relationship would be adversely affected by participation has previously been reported as a barrier to clinicians inviting eligible patients to participate in RCTs of healthcare interventions (Rendell et al. 2007). There was, however, widespread agreement, within the dental practices willing to participate in the IMPACT study and the research ethics committee, that contacting Non-FiCTION parents was acceptable. The degree of non-participation of clinicians is relevant and further knowledge of the reasons underpinning this potential barrier would be helpful to apply results to other settings and populations. For clinicians and policymakers, this suggests that additional research support may be required for nested studies within larger research projects to be successful.

Using questionnaires involving validated scales allowed a significant amount of information to be collected from a large number of participants. Using set questions and validated scales, potentially sensitive subjects could be (and were) explored. Participants were reassured that their answers were being scrutinised objectively and

were not influenced by my values or biases and that the approach adopted ensured that every question was asked even if it was a sensitive area. Whilst it was difficult to recruit participants, a high proportion of parents were motivated to see the study through to completion and there is little evidence of attrition bias. This was a welcome finding given the dearth of published primary dental care research studies.

An avenue not explored in any detail with participants was how much importance they placed on the conduct of dental research in general practice rather than other settings. If participants did not rate dental research in this setting as important, this could account for poorer grasp of the importance of staying within the research study until the end. This is particularly interesting to consider with respect to the ethnic minorities. Only, 4% (10/260) of parents were non-white at baseline and a higher proportion of non-white parents were lost to follow up (7/68 = 10.2%) than remained in the study to the end (3/192 = 1.6%). Whilst these numbers are very small, this highlights the need to further explore their socio-cultural influences in terms of research participation.

Chapter 6: Qualitative Study – In-Depth Semi Structured Interviews

6.1. Background

Parental views towards participating in clinical dental research, and RCTs in particular, is unclear. The goal of this qualitative study was therefore to identify concepts that would improve our understanding of this social phenomenon, using in-depth semi-structured interviews (see Section 4.10).

6.2. Aim

To investigate parents' views, knowledge and experience around their child participating in dental research.

6.3. Objectives

The objectives associated with the qualitative study were:

1. To investigate parents' views, knowledge and experience regarding their own dental health and their families' dental care and any differences therein between those parents whose children were participating in the FiCTION RCT and those parents whose children were not participating in that RCT.

2. To investigate parents' views, knowledge and experience about participation in research and any differences between parents whose children were participating in the FiCTION RCT and those whose children were not participating in that RCT.

6.4. Methods

6.4.1. *Approach*

The intention of this qualitative study was to investigate parents' views, knowledge and experience of dental research based on their participation (or not) in the FiCTION RCT, and their geographical location, gender, age and ethnicity.

The purpose of each interview was to explore, in depth, a participant's reality, their experiences and how they made sense of them. With the aim of having a 'conversation with a purpose', open questioning was adopted throughout so that each participant's experiences could be explored thoroughly. To ensure that the specific areas of interest were studied, the conduct of interviews was guided by a pre-prepared interview topic guide (see Section 6.4.6 and Appendix F).

The purpose of the interviews was to generate detailed and in-depth descriptions of human experiences; the approach taken included some of the characteristics associated with phenomenological interviewing (Roulston 2010) (see Section 4.9). In keeping with phenomenological interviews, I took a neutral stance and refrained, as far as possible, from evaluating or challenging the participant's responses, to enable the interviewee to feel comfortable in providing in-depth descriptions of the areas of interest. However, as I used a semi-structured approach and only interviewed each participant once, the qualitative study did not comply with all the principles associated with phenomenological interviewing (see Section 4.9).

6.4.2. *Ethical Committee opinion and R&D approval*

The conduct of this project was carried out in accordance with the ethical principles set out in the Declaration of Helsinki (2013) (World Medical Association 2013). A favourable ethical opinion was obtained from NRES Committee North East – Newcastle and North Tyneside 1 (REC Reference 13/NE/0180, Date: 21/04/2015) prior to commencement of the study. R&D management approval was obtained in north-east England from NECS. For Scotland, R&D approval was from the NRS Permissions Coordinating Centre with SSI forms generated for NHS Ayrshire & Arran, NHS Borders, NHS Grampian, NHS Greater Glasgow & Clyde, NHS Lanarkshire, NHS Lothian & NHS Tayside.

6.4.3. *The sample – selection of participants*

The sampling method chosen was purposive (Tongco 2007) to ensure that the knowledge, views and experiences of chosen participants were explored in detail and that a full range of participants was included. For the purposes of the study, all study participants were required to have had their child screened for the FiCTION RCT as this was central to the research question. A number of relevant factors were also considered (Table 6.1) when designing the sampling strategy.

Table 6.1: Parameters used to select participants for the qualitative study

Variable	**Description**
Participation in RCT (FiCTION)	Participating, Not participating
Geographical location (UK)	Scotland, England
Ethnicity of parent	White, Other
Gender of participant	Female, Male
Age of participant	24 years or under; 25-44 years; 45+ years

Maximum variation selection (Palinkas et al. 2015) of participants was used as it was felt that this enabled all the variables to be incorporated while maximising the diversity of data collected to address the research question. Each variable is briefly discussed below and the reasoning behind its inclusion in given:

- Participation in RCT (FiCTION): –I sought to include parents involved in the FiCTION RCT and parents not involved in FiCTION (due to ineligibility for or unwillingness to take part in FiCTION) in order to explore if these two groups viewed their own dental health dental care, that of their children, or (dental) research differently.
- Geographical location: – The FiCTION RCT was conducted across five centres, in England, Wales and Scotland. I chose to sample from two of these centres, Scotland and north-East England. As discussed in Chapter 1.3, Scotland and England have quite different dental service and remuneration systems. Scotland and North East England are also exposed to different dental prevention programmes in primary care, which may influence the dental health of children and their parents as well as the importance a parent places on going to the dentist. It was felt these factors had the potential to influence parental decisions regarding participation in a research study. The FiCTION RCT was also managed slightly differently in Scotland and North East England, for example, with general dental practitioners who were recruiting patients to FiCTION being exposed to different study team members (each clinical centre had their own Clinical Lead and Clinical Lead Secretary responsible for supporting the dental teams with any training, recruitment and retention support they needed). It was not known whether this would have any indirect impact at the patient level.
- Ethnicity: – I aimed to recruit participants of different ethnicities in the sample group as previous research as concern had previously been raised over the

lack of ethnicity minorities choosing to be involved in research (Robinson et al. 2016).

- Gender: – I sought to include participants of both genders in order to explore if men or women experienced research or dental health dental care differently.
- Age: – Participants of a range of ages were included as concern had previously been raised over the lack of older people choosing to be involved in research (McMurdo et al. 2011). Whilst this generally is directed to the upper end of the age spectrum, it has been suggested that researchers opt for arbitrary upper age limits without offering a scientific justification (McMurdo 2012) and thus all ages should be included unless there is a clear justification. As were focusing on parents, the age range was naturally restricted but efforts were made to include some younger and some older parents.

6.4.4. *Proposed sample size*

Non-probability sampling is traditionally used in qualitative research. Sampling is linked to data saturation, i.e. it stops when further interviewing generates no additional themes (Palinkas et al. 2015). In planning the study, it was anticipated that the data saturation point would be reached at between 14-25 interviews; however, the actual number of interviews undertaken was determined by the achievement of data saturation.

6.4.5. *Recruitment*

Participants who had returned the baseline questionnaire for the IMPACT quantitative study (see chapter 5) and had signed the consent form agreeing to be contacted regarding the qualitative study were eligible to participate. I initially contacted eligible participants by using the contact details provided on the consent form. A covering letter explaining the IMPACT qualitative study, and including the Parent Information Sheet and Consent Form (for information purposes only), was sent to potential participants (see Appendix G) and a follow up telephone call made two weeks later. Further written consent was obtained from all parents who agreed to participate prior to the interview commencing (see Appendix G). The choice to participate in the qualitative study did not affect participation in the quantitative study; however, to be eligible for the qualitative study participants had to have completed a baseline IMPACT questionnaire. Due to the lack of robustness associated with the FiCTION

screening logs, the timing between FiCTION screening and the IMPACT qualitative interviews could not be ascertained.

6.4.6. *Topic Guide*

The topic guide was developed via discussion with the study team and in light of findings from the FiCTION pilot study (Marshman et al. 2012), another study (Hutchinson et al. (2007)) which had looked at medical patients' understanding and knowledge with respect to participation in a RCT for cancer and work by Gibson et al. (2000) who concluded that people's pattern of dental attendance was similar to those suffering from other chronic disease.

6.4.7. *Pilot*

Prior to commencing the main qualitative study, I conducted two pilot interviews using two volunteers; one familiar and one unfamiliar with the FiCTION RCT. Neither were familiar with the IMPACT study. This process involved recruiting, setting up and undertaking two interviews which enabled any practical issues with the methods of the study to be tested. In addition, it helped to develop my interviewing and transcribing techniques. Based on the pilot interviews, and then their transcription and subsequent discussion with the study team, the suitability of the topic guide was tested (see Appendix F). No unexpected emerging topics were identified at this stage and the data collected were discarded. Based on findings from these pilot interviews, the topic guide was slightly amended and re-organised to improve the natural flow of conversation. Topics relating to a participant's experience and views were explored before topics that tested a participant's knowledge/comprehension, to help each interviewee feel more at ease with me (and vice-versa). The resultant topic guide ensured that all participants were asked about the anticipated areas of interest, but it evolved further as the study interviews continued and additional related subject areas and emerging topics were identified.

6.4.8. *Interview style*

All interviews were conducted by me. Prior to this qualitative study, I had no experience of qualitative interviewing and therefore underwent training at Newcastle University before commencing the qualitative study.

As a clinician, I was familiar with questioning patients as part of a clinical assessment to derive a diagnosis from a list of possibilities based on evidence (e.g. signs, symptoms, examination and special investigations). However, qualitative interviews are different as they seek to discover the framework of meaning that the participant has assigned to a particular experience. It was critical, therefore, to remain open to the possibility that concepts and themes may emerge that were completely different to those expected at the outset. To ensure that themes emerging from one interview were processed and used to inform the next interview in a consistent way, I conducted all the interviews and the transcription and analysis thereof. By reviewing each interview during transcription, data entry, coding and afterwards, together with some secondary review with the study team, ways to improve the interview style were highlighted. For example, revisions were made to the interview structure and plan, to help reduce the risk of 'stage fright' emerging in either the interviewee or me.

6.4.9. *Interview location*

Each semi-structured face-to-face interview involved me and a single participant. The interviews were carried out at a convenient time and location for the interviewee; either in the interviewees' home, or in a public place. Since interview location has been shown to affect the content of the interview (Elwood and Martin 2000, McDowell and MacLean 1998), a non-clinical environment was selected and the interviews were conducted in a comfortable venue with any costs to the interviewee minimised.

6.4.10. *Introductions at the beginning of the interview*

As previously stated, the results produced in any qualitative study may be affected by the individual collecting and analysing the data. The way in which a researcher presents themselves, for example, either as a clinician or as a postgraduate student, to interviewees may influence data. In this study, I was presented as a 'PhD student/researcher'. By the presenting myself solely as a student/researcher, rather than as a qualified dentist, it was hoped that the interviewees would be more likely to talk freely without worrying about discussing any negative experiences in relation to their dental care and attitudes to dental health. However, in instances where I was asked directly, I disclosed that I was a dentist and accepted that the data collected may have been influenced by this.

6.4.11. *Data handling*

I recorded each semi-structured interview using a digital recorder then transcribed the interview verbatim and anonymised it (Easton et al. 2000, Wellard and McKenna 2001). The transcribed data were entered into NVivo Version 11 (QSR International Pty Ltd 2012) and the transcript was checked against the original audio recordings to ensure accuracy. In addition, for quality control purposes, 300 words from two interviews were transcribed twice and the transcripts compared to ensure standards were being maintained. The digital recordings were stored on a Newcastle University password-protected PC.

6.5. Data analysis

Thematic Analysis of qualitative data does not require the detailed theoretical and technological knowledge necessary for alternative approaches such as grounded theory and discourse analysis, it has been suggested as suitable for those early in their qualitative research career.

> *"Thematic analysis can be an essentialist or realist method, which reports experiences, meanings and the reality of participants, or it can be a constructionist method, which examines the ways in which events, realities, meanings, experiences and so on are the effects of a range of discourses operating within society. It can also be a "contextualist" method, sitting between the two poles of essentialism and constructionism, which acknowledge the ways individuals make meaning of their experience, and, in turn, the ways the broader social context impinges on those meanings, while retaining focus on the material and other limits of "reality". Therefore, Thematic Analysis can be a method which works both to reflect reality, and to unpick or unravel the surface of "reality" (Braun and Clarke 2006, p. 81).*

I used an essentialist method initially when exploring participants; dental experiences and a constructionist method when discussing participants' decisions regarding their children's dental journey and entry into screening for the FiCTION RCT. I then used a contextualist method with participants when summarising my understanding of the information they had given, to enable further discussion. Coding involved using NVivo as a tool to carefully examine the transcripts and selecting and labelling sections of dialogue to create a method of indexing. Highlighting sections and grouping them together into electronic files enabled the data to be collated into potential themes. This enabled me to become familiar with the data collected. The Framework Method

(Spencer et al. 2014) was then applied to the dataset which involved a further 5 steps (Gale et al. 2013):

1. Coding to classify all the data.
   After familiarisation with the interviews, I read each transcript line by line, applying a label to describe the important data. Some codes were pre-defined with agreement with the study team e.g. relating to specific areas of interest such as a participants' views about potential barriers to research engagement. After scrutiny of the first transcript, the study team provided a form of secondary review, to offer alternative viewpoints regarding the codes and as a means of validating the codes.
2. Development of a working analytical framework where codes were grouped into clearly defined categories,
   After I had coded a few more transcripts, the study team discussed the codes applied. Codes were amended and a set of codes were agreed to apply to subsequent transcripts. 'Other' codes were created for data that did not fit with the existing codes.
3. Application of the analytical framework to transcript data
   The framework using the existing codes was applied to all the remaining transcripts.
4. Data entry into the framework matrix
   The data were entered into the matrix for all the transcripts.
5. Interpretation of the data
   At several points during the interviewing and transcribing processes, I discussed potential themes with the rest of the study team. This, in combination with the development and application of the framework matrix to the data set, allowed theoretical concepts (both prior concepts and ones emerging from the data) to be explored.

6.6. Increasing credibility

Once analysis was finalised, participants were sent a summary of the themes that had been formed during the study team's analysis of the complete data set. They were asked to contact me if they felt the themes were not an accurate representation of the data.

6.7. Validity

There is a risk with qualitative research that it can be subjected to bias from both the researcher and the participant (Mays and Pope 1995). To ensure bias was not introduced into the qualitative research, required recognition that my position as a dental clinician could bring potential bias; I reflected upon this and attempted to minimise it. In addition, to ensure that participants did not feel the need to hold back on complex or sensitive conceptions they had, I ensured that none of the participants interviewed were under my care as a dentist.

All of the data generated in the qualitative study were examined independently by the study team to ensure the themes generated were valid. Where there was disagreement, this primarily related to coding of the data and this was resolved through discussion.

6.8. Results

6.8.1. *Study participants*

I approached nineteen participants to take part in the research to provide a range of different views, at different locations within Scotland and north-east England. In total, data were collected from 18 of these participants; one participant was uncontactable as they did not answer their telephone on repeated occasions. I confirmed with each participant that they personally had been responsible for completing at least a baseline questionnaire. All participants had accompanied their child to their dental appointments. I stopped collecting data after 18 interviews as data saturation was deemed to have been achieved. Characteristics of interview participants are given in Table 6.2.

Sixteen out of the 18 interviews were conducted in the parent's home and the remaining two were conducted in coffee shops close to their homes. The interviews ranged in duration from 20 to 90 minutes. Key findings are reported under each main theme using appropriate verbatim quotes to illustrate findings. Quotations from participants in the qualitative study are presented to strengthen each themes' credibility in terms of fairness and accuracy (Single and Biotext Pty Ltd 2009). These are accompanied by a linking discussion section (Section 6.10) in this chapter in which the findings are discussed in relation to existing research.

Table 6.2: Characteristics of interview participants

ID	Participation in FiCTION	Geographical location	Ethnicity of parent	Gender of parent	Age of parent	Highest level education completed
1.	FiCTION	North-east England	Other (Iraqi)	Male	Not reported	Not reported
2.	Non-FiCTION (child not eligible)	North-east England	White	Female	43	Some additional training
3.	Non-FiCTION (child not eligible)	North-east England	Indian	Male	41	Postgraduate
4.	Non-FiCTION (declined)	North-east England	White	Female	47	Some additional training
5.	FiCTION	North-east England	White	Female	32	Undergraduate
6.	FiCTION	Scotland	White	Female	34	Undergraduate
7.	Non-FiCTION (child not eligible)	Scotland	White	Female	34	Undergraduate
8.	FiCTION	Scotland	White	Female	42	Undergraduate
9.	Non-FiCTION (child not eligible)	Scotland	White	Female	33	Postgraduate
10.	Non-FiCTION (child not eligible)	Scotland	Mixed race (Pakistani/White)	Female	44	Some additional training
11.	Non-FiCTION (child not eligible)	Scotland	White	Male	31	Postgraduate
12.	Non-FiCTION (child not eligible)	Scotland	Indian or Pakistani	Female	Not reported	Undergraduate
13.	FiCTION	Scotland	White	Male	51	Postgraduate
14.	FiCTION	North-east England	White	Male	Not reported	Primary
15.	Non-FiCTION (child not eligible)	North-east England	White	Female	35	Secondary
16.	Non-FiCTION (child not eligible)	North-east England	White	Male	43	Some additional
17.	FiCTION	Scotland	African	Male	Not reported	Primary
18.	Non-FiCTION (child not eligible)	Scotland	White	Male	56	Undergraduate

6.8.2. *Dental health*

6.8.2.1. Introduction

To generate detailed and in-depth descriptions of experiences it was important to explore, in detail, parents' historical and current dental knowledge, views and experiences regarding their own dental health and their families' dental care. This section discusses the participants' dental history from childhood into adulthood, and

the effect this may have had on their dental experiences and their decision to have their child participate in the FiCTION RCT or not (due to ineligibility for/unwillingness to take part in FiCTION). During the analysis of the parent's views, knowledge and experiences, the data collected revolved around three major themes and associated sub-themes which were identified including:

1) Good dental health is important; it means that dental issues have been dealt with and individuals are educated about dental health;
2) Poor dental health impacts on nutritional, psychological and social performance, and;
3) Participants' dental practice selection and their dental attendance have nothing to do with research.

In the following sections, each theme identified is discussed generally with all parental responses considered. Subsequently, the narrative compares the differences between FiCTION and Non-FiCTION parents to address the objectives associated with the qualitative study.

6.8.2.2. Good dental health is important; it means that dental issues have been dealt with and individuals are educated about dental health

6.8.2.2.1. Participants view of term "good dental health"

There was much discussion by participants on what "good dental health" meant. Whilst all participants agreed that this would include "healthy pink gums" and the teeth being clean, their views varied on whether any teeth could be restored or missing. All participants, except Participant 11, reported having fillings. However, even Participant 11 felt that the presence of a few fillings did not mean an individual would not have good dental health. Instead, almost all participants felt that if the necessary filling had been placed, and there were not too many fillings, this still resulted in the individual having good dental health.

"Fillings that are required are there to stop any decay going into the teeth." (Participant 2, Non-FiCTION, Female, 43 years old)

However, no participants stated the number of fillings that would be deemed acceptable to still maintain good dental health status.

Participants' opinions regarding the acceptability of crowns and maintaining good dental health status was also similar between participants.

"I'm sure some people, you know, end up with crowns and…not saying through no fault of their own, but, you know, obviously…people I do know that have crowns and stuff, it's often the rest of the mouth is fine." (Participant 18, Non-FiCTION, Male, 56 years old)

Participants' opinions regarding the acceptability of false teeth were more varied. A couple of participants felt that any form of denture automatically excluded the individual from having good dental health, as demonstrated by Participant 11.

"So I'd assume that, at some point, their health was so bad that they had to have it replaced with a denture." (Participant 11, Non-FiCTION, White, 31 years old)

However, a handful of participants felt that the reason for missing teeth had to be considered fully before an individual's dental health status could be determined.

"Because some of those are unavoidable like my sister has a bridging tooth because she hit...she was on bump cars years ago. Hit a tooth and it killed a nerve. So, she has like a fake tooth at the front. That's not her. That was not due to neglect…." (Participant 15, Non-FiCTION, Female, 35 years old)

The number of remaining teeth was also discussed when defining dental health status. Again, there was variation between parents with the vast majority stating that all teeth should be present for dental health to be good.

"I would have thought that a full set of…teeth." (Participant 5, FiCTION, Female, 32 years old)

Where having some missing teeth was perceived by some participants as being acceptable for the definition of good dental health, the number of missing teeth allowed was minimal.

"Partial denture, perhaps. But if you've got a mouthful, then…a complete top and bottom set…then I guess you've got to say no." (Participant 18, Non-FiCTION, Male, 56 years old)

6.8.2.2.2. Participants views of how "good dental health" is obtained

Almost all participants discussed the importance of parents, particularly mothers, "ingraining" good habits into their children at a young age. They felt that without

regular parental attention that children would not have the motivation or insight to look after their mouth properly.

> *"I think that's my mum. Because she was always, always very hot on making sure we brushed our teeth properly, em, in an evening, and there was almost a competition going on between me and my brothers and sisters that we had to get the (laughs) the…we had to have the cleanest teeth. So it was a little bit of competition factor, and a little bit of my mum saying this is the right way to do it. Em, in that." (Participant 5, FiCTION, Female, 32 years old)*

Interestingly, a few participants went as far as being critical of their own parents for not prioritising their childs (i.e. their) dental needs.

> *"I think it is the responsibility of the mum… of the parents for the child and for when he get older so he can take his own responsibility. For me, I lost most (of) my teeth and my teeth (are) not healthy… my parents ignored me at that time." (Participant 1, FiCTION, Male, age not reported)*

Other factors that might influence an individual's likelihood of achieving good dental health were also discussed. A couple of participants discussed financial constraints and whether they felt this would decrease an individual's ability to maintain good dental health.

> *"I mean, the kids are getting them free in nursery and things as well. So, I don't think it should be a reason now. I think it's more...kind of a- can be more of an excuse, I don't think it should be a reason..." (Participant 7, Non-FiCTION, Female, 34 years old)*

The majority of participants felt that external pressures, such as the ability to attend dental appointments regularly, could impact on dental health status. This could be broken down further into transport difficulties, such as those stated by Participant 15.

> *"Whereas we've just got a car though, and we're there. We're lucky in that sense. But yeah, if you didn't have that and you didn't have a dentist local. Then, yeah, it can have an effect." (Participant 15, Non-FiCTION, Female, 35 years old)*

Another external pressure or barrier identified by a small number of participants related to potential access problems to the dental practice.

"I mean this dentist I have just now that's up a flight of stairs and it's quite difficult when you've got a little one. So you need to…some of it we can access quite easily, yeah." (Participant 12, Non-FiCTION, Female, age not reported)

The impact of disabilities on the ability for a patient to clean their mouth to maintain a good dental health status was also highlighted. Interestingly, there was more disagreement between participants here. A couple of participants reported that with the multiple cleaning devices available now, optimal oral hygiene was achievable.

"Because I mean, you can get one of those toothbrushes that have got...or even a finger toothbrush, the ones that stick on your finger. I wouldn't say so. I mean you could at least brush your teeth once a day." (Participant 8, FiCTION, Female, 42 years old)

However, a couple of other participants anticipated that certain groups with, for example, mobility, access and manual dexterity issues, may struggle more to achieve optimal dental health.

"If they were less physically able to get to the dentist and things then that makes a huge difference to someone em..depending on how easy accessible the dentist was." (Participant 6, FiCTION, Female, 34 years old)

Half of the participants discussed the potential impact of education, or a lack thereof, on dental health status. All participants who mentioned education felt it was critical to ensure the correct information was being delivered. Participant 1 felt that dental health education should be included in religious events as another way to deliver the message as he felt it was not being given within schools.

"We have religion and we have like, we listen to the religion rather than the doctor so it's problem. So the doctor tell something ignore it. If the religious man, say something ok we should stop it. So religious. So you know we have a Friday, the Friday prayer? Yeah, so they tell the people political and religious issue. I tell, if they told them about health or dental health, it would be better. …. But you know our teacher in the school they don't tell us about, they don't tell us how to brush your teeth in primary school, in secondary school or even in the University so from where can get our information? If our school is bad

and our colleges is bad and our religious man is also bad, then we suffer." (Participant 1, FiCTION, Male, age not reported)

Two other parents felt it was essential to educate people on all aspects and factors in life that could impact on dental health status, rather than simply providing oral hygiene advice.

"I think some people have poor dental health just either…not because they don't brush them. It's, um, I mean, you watch things on the TV and things and you could see like malnutrition and stuff could cause like poor dental health that there…because things that they're not eating properly and things like that." (Participant 6, FiCTION, Female, 34 years old)

6.8.2.2.3. Participants views of the importance of their own dental health

All participants reported their own dental health was important to them. The majority of participants reported giving their dental health the same weighting as their general medical health.

"Yeah, I would say because there's…even though it's you go to get your teeth checked, there's other things that they could find in your mouth and cancer things like that. Like that gum disease early signs and things." (Participant 6, FiCTION, Female, 34 years old)

A handful of participants however, did distinguish between general and dental health and attributed more importance to their medical health.

"Um, probably in the past, I viewed it as not as important as probably my physical health like going to the doctors and things, I mean, I wouldnae… really have a problem and then not go to the doctors, I would. So, I suppose, you should view it in the same way but I think it's just one of those things where you think, well, they're okay, I'm no in pain, they're fine". (Participant 10, Non-FiCTION, Female, 44 years old)

Interestingly, participants who reported chronic medical conditions attributed more importance to physical health. For example:

"Well, I suffer from depression and I have real bad bouts of it, you know? Like over the weekend I spent the whole weekend in bed. If I get stressed it seems

to trigger it. And I would far rather have no teeth at all and not be depressed, than the other way around." (Participant 18, Non-FiCTION, Male, 56 years old)

A few participants compared the importance of their dental health to health-related illnesses or luxury goods. It was felt that teeth, whilst more important than non-essential items, were not as important as serious health issues.

"Yep. I'd rather have my teeth than a new dress." (Participant 2, Non-FiCTION, Female, 43 years old)

"If you're going to need a quadruple bypass or, you know, some teeth extracted, you know, they don't measure one against the other." (Participant 18, Non-FiCTION, Male, 56 years old)

6.8.2.2.4. Participants views of how their own opinions on dental health might differ from other people

Participants were divided on how their own views on dental health compared to that of the general population. Considering that all participants reported that dental health was important, about a third of participants felt that the population as a whole would show the full spectrum of views on dental health.

"A lot of people, ehh they are quite as we've just discussed about that they just don't care about it. So you'll have a few people who are extremes that go every six months for dental care and everything which is fine as well from their point of view. So there is nothing wrong with that. So you have both extremes people who never bother about their dental care and who people you see extremes as well. I'm one in between." (Participant 3, Non-FiCTION, Male, 41 years old)

Another third of participants felt that dental health status would be viewed as very important by the population at large.

"I think nowadays, people's attitudes have changed. I do and I think, you know, people realise that they need to have good dental health." (Participant 14, FiCTION, Male, age not reported)

The remaining third of participants felt that dental health status would be viewed as being of secondary importance to other things going on in their lives.

"I think people regard their teeth as a secondary, it's nice to have but it's not a necessity. Which is not the way you should think about it. People think teeth as, oh you can get dentures, you can get replacements, it's not the way to think about it. It's part of you." (Participant 5, FiCTION, Female, 32 years old)

6.8.2.3. Poor dental health impacts on nutritional, psychological and social performance

Most participants identified the impact of poor dental health on the chewing of foods. Several participants elaborated further to highlight that this may result in an unbalanced diet which would impact on their wellbeing.

"I know my mum and dad have got dentures now and they can't eat things like a lot of fruit and things like that, like sort of apples and things. They won't eat because of…they can't, basically." (Participant 7, Non-FiCTION, Female, 34 years old)

A couple of participants reported that poor dental health could have a psychological impact on the individual.

"Also embarrassment, humiliation, depression." (Participant 10, Non-FiCTION, Female, 44 years old)

Two participants expanding on this identified that poor dental health could impact on an individuals' verbal and non-verbal communication.

"It could affect your speech." (Participant 12, Non-FiCTION, Female, age not reported)

Overwhelmingly, most participants reported that poor dental health status would feed into other people's preconceptions.

"You can't help but make assumptions if someone sort of got like the front teeth missing. It's like they've maybe had been in prison or that happens during a fight or you can't help do but...." (Participant 9, Non-FiCTION, Female, 33 years old)

Views were discussed within the context of employability. A common perception reported by several participants, is best described by Participant 10.

"If your face is filled with a broken fence, So if you go get a job, they can say well, if you can't look after yourself, you can't look after my company." (Participant 10, Non-FiCTION, Female, 44 years old)

Participants were then asked if they felt the nature of the job would influence this preconception. Many participants reported that a frontline job involving the public or clients might be harder to obtain due to possible negative perceptions from the interview panel.

"If you do have poor dental health and you do have funny breath, you are not going to want that person to meet people and represent your company." (Participant 15, Non-FiCTION, Female, 35 years old)

Participants' views regarding non-frontline jobs, for example working within a factory or office, were more split. A few participants felt that individuals with bad teeth could be completely hidden or that individuals with bad teeth could be incorporated more readily into the workforce if they worked behind the scenes. Other participants felt that poor dental health would still have a detrimental effect on employment irrespective of the setting of the employment if the role involved any social interaction.

"I think if you're going to be working on the shop floor, in a factory or whatever, um, it, it's not going to affect you as much as if you happen to be in management." (Participant 14, FiCTION, Male, age not reported)

"I think that it will affect all employment whether you are back stage or whether you are front stage. Because even then you are working with people, you know." (Participant 17, Non-FiCTION, Male, age not reported)

One participant also reported not wishing to employ an individual with poor dental health status due to the threat of required time off to attend dental appointments:

"If you have got bad teeth, you're going to be wanting more…pass outs or half days or whatever. For dentists aint you? "(Participant 4, Non-FiCTION, Female, 47 years old)

6.8.2.4. Participants' dental practice selection and their dental attendance have nothing to do with research

The importance participants placed on research involvement when selecting a dental practice was discussed. The majority of participants reported that a practice recommendation from friends and colleagues and the location of the practice would largely influence them in selecting a dental practice. Research involvement was not a factor for participants when deciding which dental practice to attend.

> *"It wouldn't persuade us to go there and I wouldn't say oh I'm avoiding going there. I just…wouldn't... it wouldn't affect me. It wouldn't stop us going there… somebody's got to do research so." (Participant 4, Non-FiCTION, Female, 47 years old)*

> *"It (research) wouldn't actually concern me. I would actually just look for the dentist that was locality wise and best offered, the best healthcare for them." (Participant 5, FiCTION, Female, 32 years old)*

> *"Probably again the locality. Um, I think, as well, the number of dentists within the practice because sometimes getting an appointment can be quite hard if you're… if there's an emergency of anything like that. And I think, for me as well, I tend to kind of ask family and friends and ask for… like, by reputation and things like that and how good they are." (Participant 7, Non-FiCTION, Female, 34 years old)*

All participants, except Participant 15, now attended a different dental practice to the one they went to as a child. The seminal features that dictated attendance at their current dental practices were: proximity of the practice to their home or place of work, word of mouth and/or NHS availability.

> *"I mentioned that issue to my Health Visitor… She didn't give me a list, she just mentioned those few, oh, you know, 'cause it's not a big town, but I think probably, like, two/three names and I thought that was closest to us, that's why." (Participant 11, Non-FiCTION, Male, 31 years old)*

6.8.2.4.1. Historical dental attendance

Participants were asked to consider how frequently they went to the dentist as a child. Just over half of participants reported going on a fairly regular basis, either on a

six monthly or yearly basis. For the remaining participants that did not go on a regular basis, their experiences as a child were largely to resolve problems that had arisen.

> *"Rarely, very, very rarely. I just don't know. I don't know, it wasn't in the family routine. I've no idea why the dentist wasn't a big priority. But it just wasn't." (Participant 10, Non-FiCTION, Female, 44 years old)*

Participants were asked to reflect on their visits to the dentist when they were a child and to consider the treatment they had been given. About half of the participants had fairly neutral memories of attending the dentist.

> *"I think it was okay. And it was an okay experience. I didn't…I wasn't worried about it necessarily." (Participant 13, FiCTION, Female, 51 years old)*

The remaining participants had mainly negative memories.

> *"Um, and what put me off the dentist when I was younger was they hadn't told me that they had change from the gas and air to injections. And just went right ahead and done it. And I remembered get in the chair. And I remember hitting him. And then, I remember not going back after that. And that was my only, that was my youngest memory of the dentist so… torture chamber. Oh, horrific. I think out of everything I remember was the fear"(Participant 10, Non-FiCTION, Female, 44 years old)*

More negative childhood experiences were reported by participants who had attended irregularly in their childhood.

6.8.2.4.2. Current dental attendance

All participants currently attending the dentist regularly reported that the frequency of recall appointments was dictated by the dental team. Only four participants were not on a regular maintenance programme with their dentist, through their own choosing.

> *"Still probably as and when. I think, the last time I was there was about two years ago. It was like, I always think I'll make an appointment, I'll go for a check-up and I never kind of do it… "(Participant 7, Non-FiCTION, Female, 34 years old)*

The vast majority of participants reported attending regularly to enable the dentist to identify problems within their mouths early.

"I think…vital…I think every six months. And if you've got problems, then, you need to be able to step that to three months to make sure that there's no recession back in, or regression. Sorry, not recession." (Participant 16, FiCTION, Male, 43 years old)

A few participants, who reported that they attended regularly, admitted that they were only diligent in this regard as they wanted to be a positive role model for their children.

"Yes. Well it's more the fact that I want them to see that I'm doing it so they should do it as soon as they get older they still….For me, probably not quite as frequently needs but I do it for them. For their benefit." (Participant 5, FiCTION, Female, 32 years old)

All participants reported that their child attended for dental check-ups regularly. Where participants were themselves regular attenders, they commonly attended at the same time as their offspring.

"Yeah, I think it's like loads of – it's, like, the first thing, because it's easier for them, so you can go all together. We don't have anyone, like, to look after them, so I could go, like, happily, you know, like, relaxing there, it's not the case. No, we just go together and even set the example, you know, it's nothing that bad, you know. I open the mouth, we talk about it, you know, the dentist will just count your teeth, he'll have a look at those, nothing like, you know, nothing wrong or, he will ask you if it's painful and, you know, all that stuff and tell you how we can improve how to keep your teeth like healthy, all that stuff. Like, give them examples as well, that's why I probably go with them as well and it's easier, in a way, to go…" (Participant 11, Non-FiCTION, Male, 32 years old)

All participants, irrespective of their own dental attendance pattern, wanted their child to attend regularly for a variety of reasons. These varied from wanting to establish a clear routine for children, to getting them used to the dental setting and wanting to pick up potential problems early.

"To make sure everything's ok really. And em just to get (name) used to it as well. I think she was about 2 when we first took her." (Participant 2, Non-FiCTION, Female, 43 years old)

6.8.2.5. Comparison between FiCTION and Non-FiCTION parents views, knowledge and experience regarding their dental health and their families' dental care

The findings from the two groups of participants (FiCTION and Non-FiCTION) were broadly similar. There was no noticeable difference between participants' definitions of good dental health or their perception of the facilitators and barriers to obtaining good dental health. Participants' views on the impact of poor dental health on nutritional, psychological and social performance were very similar. Only two participants, one from each group, identified that poor dental health could impact on an individuals' verbal and non-verbal communication.

> *"It could affect your speech." (Participant 12, Non-FiCTION, Female, age not reported)*

Whilst the FiCTION participant discussed laughing (a form of non-verbal communication) and the Non-FiCTION parent discussed talking (a form of verbal communication), this is unlikely to be of great significance.

National guidelines for attendance recommend that patients whose disease activity continues unabated may need a shorter interval and closer supervision. If practices follow these recommendations, then it would be anticipated that FiCTION children attend dental practices more frequently. Interestingly, only those participants whose children were not participating in a RCT in primary dental care were not themselves on a regular maintenance programme, highlighting a potential difference between FiCTION and Non-FiCTION participants. This could simply be due to the frequency of the FiCTION recall appointments acting as a prompt for participants to also attend for their own dental check-up. However, all FiCTION participants reported their own dental health status was very important to them. In contrast, some Non-FiCTION participants did not rate their dental health as anything other than "normal" and did not give it any increased consideration within their lives. When analysing this further, complacency was only noted within the Non-FiCTION group when justifying irregular dental attendance for themselves. There was no complacency noted with the FiCTION participants. This could be because their child having decay had subsequently altered their dental attendance by making them more vigilant.

> *"It's important – you know, even though I haven't been to the dentist, it's important to me and if I got – if I had a problem, I would get it sorted and I'd be*

– probably if I did have a problem, I would probably then become much more, you'd go much more regularly and start to – I almost need to actually have a problem to make me feel that I personally need to make more of an effort and there's maybe how I feel about it. At the same time, I'm, kind of, I'm pleased that my teeth – I've never had a filling ever, for example. I think I must have looked after them when I was younger and I can't be doing anything too wrong but I think I'd change if I actually had a problem." (Participant 11, Non-FiCTION, Male, 31 years old)

More negative childhood experiences were reported by participants who had attended irregularly in childhood, irrespective of their current attendance pattern. Only two participants considered their childhood experiences positively; and both had limited dental treatment as a child. Interestingly both were male and neither's child was involved in the FiCTION RCT (due to ineligibility).

"I preferred going to the dentist than getting my hair cut. That tells you everything. The dentist was fine. The pain was fine." (Participant 16, Non-FiCTION, Male, 43 years old)

All participants reported that their child went to their dental check-ups regularly and the reasons given were the same for FiCTION and Non-FiCTION participants. Current and historical dental practice selection criteria were similar between both groups of participants.

6.8.3. *Participation in research*

6.8.3.1. Introduction

This section will discuss the participants' journey from being introduced to the FiCTION RCT by their general dental practitioner and associated dental team, their journey through joining the IMPACT study and the effect of participating in research on their everyday lives. During the analysis of the participant's views, knowledge and experiences, perceptions revolved around four major themes and associated subthemes which were identified including:

1) Research needs to be justified.
2) Participants do not always have complete knowledge or understanding of a research study in which they are participating.
3) Research engagement can be challenging.

4) Participants will engage with further research if it is timely and relevant.

Each theme identified is discussed generally with all participants' responses considered. Subsequently, the narrative compares the differences between FiCTION and Non-FiCTION participants to address the objectives associated with the qualitative study.

6.8.3.2. Research needs to be justified

There was much discussion on the importance of research, the responsibility of the public to participate in research and how research studies should be conducted. Whilst participants agreed that research would provide data to the researchers, their views varied on the wider impact this knowledge would have. Quite a few participants, like Participant 13, felt that research would enable a service to be evaluated to ensure that existing care is assessed and improved where necessary.

> *"Research is about evaluating what you've done, looking back seeing where your data has proven something and you're happy with it because you've systematically run…your methodology has been good, but also a time to reflect on where perhaps, the data doesn't deliver. You want to try and make sure that is corrected for another cohort of research." (Participant 13, FiCTION, male, 51 years old)*

A couple of participants, demonstrated by the reflections of Parent 11, felt that research would help inform those planning policies that are adopted by governments, businesses or other institutes, while Participant 18 reflected that the conducting of research promotes the professional duty of candour.

> *"To find out root causes of things and then that information can be used by the people who make policy decisions to do things in a different way… Research should be unpolitical, it should just be, these are the facts, you know, and then it should be up to policy makers to decide what to do with the facts." (Participant 11, Non-FiCTION, male, 31 years old)*
>
> *"Its culture of openness now rather than just…well, you don't know whether a dentist is good or bad and you don't know if dentistry as a whole is good." (Participant 18, Non-FiCTION, male, 56 years old)*

One participant expressed a different view to everyone else; she felt that participation in research could empower participants to feel more in control of their own health and the care they receive.

> *"I think.....if the public can get involved, it means they can learn and educate their self, it takes a lot of fear away for things as well because they know that a lot of big cancer campaigns and things like that, they've been quite successful and things. So, big drives for screening and things like that. So, I think it's got to a positive thing." (Participant 7, Non-FiCTION, female, 34 years old)*

6.8.3.2.1 Justification of dental practices being involved in research

The majority of participants viewed dental practices which participate in research favourably.

> *"I think if the dental practice have a research practice, I think they are better from the other. Could be they give me a better service." (Participant 1, FiCTION, male, age not reported)*

This is interesting given that research activity did not influence their selection of dental practice.

One participant mentioned that a practice's participation in research would not concern them due to the regulatory safeguards that are in place before patients are recruited into research studies.

> *"Yeah, it won't affect me. Yeah I won't change my mind based on whether they are doing research or not…. Before doing any research people go through ethical and everything so they check for the safety and everything so I wouldn't bother too much about that" (Participant 3, Non-FiCTION, male, 41 years old)*

Interestingly, another participant reported that a practice's participation in research would not influence them as the practice's research involvement fundamentally relied on a patient's choice to participate.

> *"Um, to be honest, it probably wouldn't make any difference. If I was one that done research and they asked me to take part, I think it's entirely up to you whether you done it or not." (Participant 6, FiCTION, female, 34 years old)*

Participants were asked why they felt dental practices were involved in research. A substantial proportion of participants felt that involvement in research was good at attracting patients to receive treatment at their practice:

> *"I suppose it makes them look better as well. I would say that they're taking part in all in this stuff." (Participant 6, FiCTION, Female, 34 years old)*

Participant 1 was more cynical and reported dental practice involvement in research was because "they don't have anything to do". A couple of participants felt that by conducting research the practices would learn more about their patient base:

> *"Well basically I think they want to improve dental health for people. Maybe this country is not so good, I don't know. Maybe.. I mean it's lifestyles or diets are playing a part in causing poor dental health. Any maybe recent initiatives and research more available because they have prove things." (Participant 12, Non-FiCTION, Female, age not reported)*

A few participants felt that there may be additional regulatory reasons why dental practices were participating:

> *"I think they probably have a legal requirement to do so. They've got a duty of care to look after their patients and look after them well." (Participant 14, FiCTION, Male, age not reported)*

6.8.3.3. Participants' do not always have complete knowledge or understanding of the study in which they are participating

When participants' were asked what they understood about the focus of the FiCTION RCT, a diversity of understanding was reported. It was hoped that all participants, regardless of FiCTION participation status, would be able to give a valid description of the FiCTION RCT since they had previously been provided with detailed literature on that study.

Participants' degree of understanding varied, however, with one or two participants giving a fairly accurate account of the three different treatment options available in the FiCTION RCT.

> *"I think that was three different kinds for like three different types in they were needing treatment. It was a proper filling, a cap, and I think it was the other thing was like a fissure sealant thing that they kind of got…..And I think it's just*

because they want to look into the way that they could treat the kids' teeth. Um, what's actually better for them" (Participant 6, FiCTION, female, 34 years old)

A handful of participants were less certain, but still showed some understanding of the principles laid out by the FiCTION RCT:

"One was treatment. One was drilling and filling, I think? One was, um, I can't remember…one was just leaving it…and watching it. And there was a third one." (Participant 15, Non-FiCTION, female, 35 years old,)

A high number of participants did not understand the purpose of the FiCTION RCT and openly reported this:

"Still don't understand it, to be honest. I'm assuming that they are looking at dental health from, obviously, from children's points of view. And how to improve that for this generation, and then, for future generation. That's what I'm assuming that's coming out of it." (Participant 8, FiCTION, female, 42 years old)

The primary outcome measures for the FiCTION RCT was the incidence of either pain or infection related to dental caries, and the number of episodes of pain or infection, and the secondary outcome measures related to the incidence of caries in primary and permanent teeth, quality of life, cost-effectiveness, acceptability of treatment strategies to patients and parents and their experiences, and dentists' preferences.(Innes et al. 2013) A few participants were unable to articulate the finer points associated with the FiCTION RCT, but were very broadly able to summarise the objective of the FiCTION RCT.

"I think they are also looking for healthy teeth for young generation." (Participant 17, FiCTION, male, age not reported)

6.8.3.3.1 What is a "randomised controlled trial" (RCT) and randomisation?

A RCT has been defined previously as:

"An experiment in which two or more interventions, possibly including a control intervention or no intervention, are compared by being randomly allocated to participants. In most trials one intervention is assigned to each individual but sometimes assignment is to defined groups of individuals (for example, in a household) or interventions are assigned within individuals (for example, in different orders or to different parts of the body)."(Cochrane Community 2019)

When asked to express what they understood by the term “randomised controlled trial” a number of views emerged from the participants. Their children had all been screened for eligibility into a RCT (FiCTION) and a diversity of understanding was perhaps surprising. It could be hoped that all participants, but in particular FiCTION participants, would be able to be able to give a valid informed response about RCTs. This was not the case though with a diversity of understanding, from a cautious grasp to little understanding. However, it is important to acknowledge, especially for Non-FiCTION parents, that some of the qualitative interviews may have been held a considerable time after the FiCTION RCT material was distributed.

There were a few comments, like that given by Participant 11, that show participants had confused random selection with random allocation but showed good understanding of it.

> *“So I think that means that people are picked randomly and then there’s a control group that is also picked randomly. I would assume that there’s some control over getting a, sort of, a cross section of society, you know, so a cross-section of ages and associates there, kind of, backgrounds and things. I assume there’s some control element that’s just randomly picked.” (Participant 11, Non-FiCTION, male, 31 years old)*

There were a few more comments, like those given by Participant 1, which, whilst not articulated quite as well, still grasped the overall concept of random allocation rather than random selection.

> *“They pick randomly, its working, a statistical thing. So from a statistical point of view, you random sample. Random – different ages, different nationalities, different I think places. So just erh varies the diversity.” (Participant 1, FiCTION, male, age not reported)*

There were a few comments, like given by Participant 12, which suggested participants had heard the term of randomisation before but their level of understanding was hard to judge.

> *“It’s random selection em and then a controlled set of treatment for each of the arm selection so you say I’m going to pick one out of a hat, they’ll get that treatment.” (Participant 5, FiCTION, female, 34 years old)*

A few participants showed they did not understand the term, like Participant 9.

> *"Randomised controlled trial um, anybody could be selected for it. Um, and the, I'm trying to think how to, I'm trying to think the control part. Um, like randomised, anybody you know what it means. Um. In a certain number of case studies like you know what I mean. ....I don't think this is in the dictionary definition. You know how like in the adverts like 72% of a hundred people agreed with us that's like the controlled trial." (Participant 9, Non-FiCTION, female, 33 years old)*

These four extracts reflect the diversity of understanding of the term RCT, none of which were particularly accurate. Interestingly, almost all parents' definition contained the term "random".

It is important to recognise that participants struggled to differentiate between the concepts of random sampling and random allocation. Random sampling, which was not used within the FiCTION RCT, occurs when subjects are being selected for a study where subjects are selected randomly from the population and each subject in the population is equally likely to be selected. Meanwhile random allocation, which was used within the FiCTION RCT, occurs in experimental settings where subjects are randomly assigned to various treatments and any observed effect can be attributed to the treatment.

6.8.3.3.2 Can I withdraw from the FiCTION RCT?

The majority of participants felt comfortable with the concept of letting the research team know that they would like to either withdraw from the FiCTION RCT entirely or asking to change the treatment approach being used. However, whilst most felt comfortable with prioritising their child's needs above the research aims, there were mixed thoughts about the actual practicalities of how to do this from the Non-FiCTION participants. One participant (Non-FiCTION), who had an imperfect understanding of the FiCTION RCT, felt bureaucracy associated with the RCT may restrict the dentist's ability to provide their preferred choice of care and thus they may need to come up with a private agreement with the practice.

> *"I wouldn't be accepting of it, I'm not that kind of parent. I don't know whether they'd be able to change it, cause they are working to their rules and*

guidelines. They might offer a private service that would be different that I could pay for." (Participant 2, Non-FiCTION, female, 43 years old)

Another parent (Non-FiCTION), who also showed an imperfect understanding of the FiCTION RCT, felt that bureaucracy associated with the RCT might mean that they needed to withdraw their child from the practice and register elsewhere.

"Well I suppose if you're not happy with it then you would have to…. Either talk to your dentist or if there is nothing he can do then I suppose you would… if it effects these, me I'd move dentist. My kids come first so it's as simple as that" (Participant 4, Non-FiCTION, female, 47 years old)

A few more participants felt that by complaining, perhaps loudly, they would be able to withdraw from the study entirely or change the treatment approach being used with their child.

"I would discuss it with the dentist or whoever I need to approach. You know and see if they can change it to an alternative treatment or something or…obviously I'm not to kind of keep quiet especially when it comes to my children…I think most parents will. I think when it comes to children, you really want what's best for them." (Participant 12, Non-FiCTION, female, age not reported)

Interestingly, a couple of participants did report that they felt that they should remain with the allocated treatment even if they had reservations. This was either due to a reluctance to question the dentist or feeling that they should be loyal to their initial agreement.

"He's the expert there and I don't think to interfere personally." (Participant 17, FiCTION, male, age not reported)

A common view held by several participants was they felt that challenging the dentist could be difficult for participants.

"Me personally, I'd be okay, But I suppose, there is maybe a lot of people who are not confident, maybe challenging somebody with that kind of authority, maybe so…..that could be a problem, I think." (Participant 7, Non-FiCTION, female, 34 years old)

6.8.3.3.3 Reasons why participants joined a dental research study

The majority of participants reported participating in IMPACT, and FiCTION where applicable, for largely altruistic reasons. Many wished to increase the knowledge basis to help drive change for the future:

> *"Em, next generation. So, their kids when it comes to dental treatment." (Participant 5, FiCTION, female, 32 years old)*

A few participants reported participating in IMPACT to aid completion of the project:

> *"Because I just think it's important for you, as a researcher to find out a bigger picture. Because there's obviously an end goal to this, and you're doing it for a purpose. So, I just think, in that way, I could help you to be able to complete your research project. Whereas if you've not got a good enough count of people, then, you're not going to get a true story of what you're trying to put into your research project." (Participant 8, FiCTION, female, 42 years old)*

One parent reported curiosity as a reason why her child wished to participate. Interestingly, this was the parent who declined to participate in the FiCTION RCT, but no reason was given for this.

> *"I think that was one of the reasons why she wanted to take part was she was curious, uh, what it would be and what she would get and things." (Participant 4, Non-FiCTION, Female, 47 years old)*

The decision processes to take part in FiCTION varied for parents whose children were eligible to participate. A few parents felt that the decision to participate should lie solely with the clinician whilst others felt that the decision to participate, or not, was the child's. Only one parent reported that they felt it had been a joint decision between parent and clinician. One parent felt the decision regarding participation had already been made by the clinician:

> *"It wasn't as if there was an option for him to be part of it. It was, he is part of this and that's it type of thing. So, it was a case of right, okay then."(Participant 8, FiCTION, female, 42 years old)*

6.8.3.4. Research engagement can be challenging

The majority of participants were not surprised to be asked to participate in a research study by their dentist. In fact many described it as "normal". Of the minority

of participants who were surprised to be asked, the vast majority reported they still felt it was acceptable that they had been approached.

> *"I thought it was, it was, it was nice. You know, to think that I'm doing something positive, you know." (Participant 14, FiCTION, male, age not reported)*

The decision to participate in the IMPACT study was reported by all participants to be a fairly quick decision that they made without consulting others. Participants who were participating in the FiCTION RCT, largely reported that it felt logical to also take part in the IMPACT study.

> *"I don't know. I just, you know, I've done one, I might as well do the other." (Participant 5, FiCTION, female, 32 years old)*

However only one parent felt suspicious about the recruitment process:

> *"I was asking the question, how many kids who come to this practice will be taking part. So I was wondering I heard things like random selection. I kind of think, well, actually, I know how that works. It's not always random, you know? That's me being a bit cynical. So, that was a question that came to my mind." (Participant 13, FiCTION, male, 51 years old)*

6.8.3.4.1 Confidence with random allocation

Unconcealed random assignment can lead patients with particular characteristics receiving a certain allocation, thereby biasing the allocation. Because of this, random allocation is ideally done off-site by someone not involved in delivering care to the patient. This can cause uncertainty to parents and therefore parents' views regarding random allocation was an important area to explore. Participants' views about random allocation, in this case using a computer, generated a wide range of views. A few participants, like Participant 14, wanted to minimise bias and felt that the computer provided a robust method.

> *" I think it's probably...that seems to be a more fair process because I think, maybe...well people shouldn't be biased towards some people but I suppose, they may see that certain kids are coming in who they might prefer or they might like better for some reason, might get a better standard treatment. So, I think, it's more...that's a more fair process doing it that way." (Participant 7, Non-FiCTION, female, 34 years old)*

However, one participant reported concerns over the reliability and robustness of using a computer:

> *"You see, a computer, there can always be a programming error, there can always be a reboot problem. There can always be...we all work on Microsoft computers. And every one of us knows how bloody unreliable they are. Microsoft for all its millions and billions, still cannot make a computer that will do four things at once without going, "Oh, I'm just going to stop now.""*
> *(Participant 16, Non-FiCTION, male, 43 years old)*

Other participants openly felt unhappy with the concept of random allocation and their comments suggested they did not understand the principle of equipoise:

> *"Probably wouldn't like it, to be honest….Um, because it's what I've said, I would want the right treatment at the right time……for him. Um, and I think my dentist, uh, can see, um, and make that judgement better than a computer can." (Participant 15, Non-FiCTION, female, 35 years old)*

A few participants reported no preference initially, but subsequently changed their mind as seen with Participant 10:

> *"Again, it probably doesn't bother me….Type of thing so that did put me off a little bit because I thought, "Surely, it should be up to the parents to decide as well, even in consultation with the dentist as to..." Because again, we know our children, and so does the dentist. Whereas somebody miles away that have decided who's getting what treatment, um they don't know them. And certainly, a computer doesn't know them. In a way, it doesn't bother us, but it does from the point of view that I think it should be discussed in some way. "*
> *(Participant 10, Non-FiCTION, female, 44 years old)*

Lastly, a couple of participants reported no preference to the computer selecting a treatment arm rather than the clinician, as long as the concept of equipoise was followed:

> *"I think as long as they are all valid approaches that have shown, em, success in the past then that's fine. If you're talking about then, em, one has been shown to have better outcomes than the other, then I'd feel a little bit different about that."(Participant 5, FiCTION, female, 32 years old)*

These extracts reflect a diversity of knowledge of the random allocation concept and clinical equipoise. Interestingly participants had very different perceptions of random allocation, from very favourable to very negative.

6.8.3.4.2. Representation of the population

All participants involved in the study showed clear positive opinions about the purpose of research with no negative opinions reported. However, importantly, one participant, from an ethnic minority herself, felt a different approach was required to recruit and retain ethnic minorities in research studies:

> *"In respect to ethnic minorities, I've worked with quite a lot of them as well. Em. Translation is massive. And, the thing with ethnic minorities is that their cultures are different. It's easy to presume em the way, say for example, a culture doesn't brush their teeth but they will chew cinnamon sticks. Well, that's their way of brushing their teeth, that's our version of it. But it's very easy eh to misunderstand with em the communication, very very easy." (Participant 10, Non-FiCTION, Female, 44 years old)*

This participant felt that it was necessary for different recruitment techniques to be utilised to overcome these misinterpretation barriers, especially for first or second generation migrants.

> *"Explain the reason for the question. Make sure they or the translator understand the reason for the question and they will give you an answer, it might not be that question, but it's what you are looking for…The other thing is with foreign cultures, is especially in the West, people from different lands feel that the west look down on them. And they've almost all got: you think you're better than us. So there must be an awareness of that, as an interviewer…. First generation ethnic minority, my dad…he used to think the British people were so stupid. Because he says: you do business with them, they shake your hand, they trust you, you don't know what (laughs) what we're doing to them. But they just had an entirely different way of doing business and it was a literally a complete lack of understanding on either part. Second generation you have the child that's seen the parent being treated unfairly, so you have maybe an anger issues and don't you dare, but they've got the knowledge to turn around and give a good slap in the chops [laughs]. Third generation doesn't care."(Participant 10, Non-FiCTION, Female, 44 years old)*

Interestingly, this feeling was not reported by the other minority participants, three of whom were first generation migrants.

Regarding the factors which impact on participation in research, participants were in agreement that time constraints may make people less able or willing to participate.

> *"Again, I suppose it depends on people's lifestyles. How busy they are and you know, we've got a few friends that.. neighbours... that work sort of all over the world and I don't think they'd have the time or the… where I am home based so... em, it depends on the individual." (Participant 2, Non-FiCTION, female, 43 years old)*

A few felt people were more protective of their time in terms of donating it to participate.

> *"I think it would just depend on whether individual people are willing to give up their time and to participate or not." (Participant 6, FiCTION, Female, 34 years old)*

The rest felt that if participants wanted to participate in research strongly enough they would manage to accommodate it within their busy lives.

> *"If somebody wants to do it, they're going to do it." (Participant 9, Non-FiCTION, female, 33 years old)*

However, participants had conflicting opinions, from all ethnicities, about involving retired people, generally assumed to have more free time, in research. The majority of participants felt elderly people would have more time to participate in research and would welcome the opportunity to talk to researchers for companionship. However, some reported the design of the study may need to be adapted.

> *"I think old people you might, you know, especially if you were going to go to their door because it's somewat to do isn't it." (Participant 14, FiCTION, male, age not reported)*

*S*ome participants reported that, whilst age itself may not be a motivating factor to aid or hinder research uptake, older generations' attitude to trust the information given without questioning may itself lead to less interest in research participation.

"Um, I think, nowadays, I think we have a more a more open attitude to things like that. But then, I think...I know my mum and dad's generation is very much, "Oh, no, we don't know. Leave it to professionals," type of thing whereas, I think, we're a lot more open-minded now. "(Participant 7, Non-FiCTION, female, 34 years old)

Some participants reported socio-economic status would influence whether people were willing to participate in research.

"The lower socioeconomic group would probably not so involved and then being questioned on a lot of things that they perhaps realise they're not performing well at, they'd be less likely to want to get involved in the study…." (Participant 18, Non-FiCTION, male, 56 years old)

6.8.3.4.3. Involvement of children in research

Participants' thoughts regarding involving children in research studies were varied. As all participants had allowed their children to be screened for the FiCTION RCT, it was perhaps unsurprising that all parents believed that children should be involved in research. It was perceived that the quality and quantity of data gathered would be greater if children were involved:

"You'll get completely different answers" (Participant 4, Non-FiCTION, female, 47 years old)

Conflicting statements were given regarding younger children's suitability to participate in research. A few participants felt that age linked to the child's ability to understand what they were asked to agree to:

"I think yeah, age matters." It matters… at least they should understand what he said". (Participant 17, FiCTION, male, age not reported)

A few participants felt the researcher-child conversation would be affected by the age of the child, but the interaction could be adapted based on their age.

"I wouldn't say so….. There are different ways of targeting them depending on the age range." (Participant 8, FiCTION, female, 42 years old)

Children under the age of 16 can consent to their own treatment if they are believed to have enough intelligence, competence and understanding to fully appreciate what is involved in their treatment. The majority of participants felt that the child being

asked to participate in research should get to make the final decision. However, some participants felt it was the child's parent or guardian that ultimately was responsible for making the final decision.

> *"Basically the parents are making the decision, are making the call, so erh it's fine." (Participant 3, Non-FiCTION, male, 41 years old)*

It was important for several participants that they should be present if research was being conducted on their child.

> *"With the parent, like present, it doesn't have to be sitting on the sofa with them, but nearby just to keep an eye on it." (Participant 11, Non-FiCTION, male, 31 years old)*

One participant felt legally it was important to differentiate between an adult and a child.

> *"Well if they're still minors in the eyes of the law". (Participant 18, FiCTION, male, 56 years old)*

Due to the cohort of participants involved, the aspect of their children having to miss school to conduct research was a regular talking point. Participants' views varied greatly, from concerns that missing school was not a viable option, "*"Definitely not" (Participant 7, Non-FiCTION, female, 34 years old)* to acceptance that missing school for a short time was ok. The majority of participants felt that missing school was not ideal but may be willing to make some concessions, depending on the circumstances. A few participants did consider the stage of schooling their child was at when making that decision:

> *Um. It just well now he's only primary 2. Um, obviously depending how long the research would be. Um, but maybe leaving school an hour early, that's not exactly a huge amount. (Participant 9, Non-FiCTION, female, 33 years old)*

Participant 10 considered their child's intelligence when they decided to take their child out of school:

> *"Miss school in a heartbeat, absolutely… For me personally, this is gonna sounds horrible it really is. But at the moment eh my son is exceptionally switched on. And a lot of times he's bored out his skull, so if he misses…*

three weeks he'll catch up in two seconds" (Participant 10, Non-FiCTION, female, 44 years old).

A few participants also felt that removing their child from school would just create additional problems, either relating to a change in their normal routine or with liaising with the school:

"It wouldn't concern me if the research was communicating with the school and it was more formally arranged that way. I wouldn't worry about them missing education or anything like that". (Participant 11, Non-FiCTION, male, 31 years old)

6.8.3.4.4. Research participation restrictions

A minority of participants reported initial concerns with the practicalities, in terms of time or the location, of the qualitative interviews:

"It's not so bad cos you came to the house… I mightn't of have had time meself to go to meet you… I wouldn't have drove... Because you won't get me to the town for love nor money in a car... I get lost, it's as simple as that." (Participant 4, Non-FiCTION, female, 47 years old)

"Just the time… The face-to-face cause the questionnaire I can do that it the evening when I've got time, it's the face-to-face fitting in with". (Participant 5, FiCTION, female, 32 years old)

However, one participant appreciated being able to justify to herself having some personal time:

"I do love the fact that it made me sit down and do nothing, it's wonderful. [laughs]" (Participant 10, Non-FiCTION, female, 44 years old)

The only participant that reported difficulties with the interview process also had an infant she was caring for at the same time:

"Well it's not as smooth as I would have liked to be but it's all right. It's fine….Just getting the little one settled as well so....And it's just I get very limited time to get work done I think.... Like phone calls to do and shopping and all the rest of it just everything that that makes a house run." (Participant 12, Non-FiCTION, female, age not reported)

6.8.3.5. Participants will engage with further research if it is timely and relevant

Participants were asked, based on their experiences with the IMPACT study and FiCTION RCT, whether they would be willing to take part in subsequent dental research studies. No participants reported that their experiences would stop them participating in further research. The factors influencing their decision to participate in further research remained the same as at the start: namely the nature of the research and its relevance to them. A few participants reported that they may delay in participating in further research studies as they felt they had contributed to the IMPACT study:

> *"I would feel more inclined in a sense that I know what it's about and if it was a similar format, I think, if I could fit it in, but if another one came next week, I'd think, oh I've just done one, so I'm not…" (Participant 11, Non-FiCTION, male, 31 years old)*

Encouragingly one participant reported how well they felt their dentist had done in discussing relevant information with them:

> *"If feels like it's been controlled quite well at the dental, you know, the dentist just kind of disseminating things. And I think, again, if it came through them that would be okay."*

Interestingly, several participants reported feeling more positive about themselves by their participation in research:

> *"I felt positive about it but I wasn't thinking about it would help me in any way." (Participant 11, Non-FiCTION, male, 31 years old)*

The majority of participants had not participated in research before being approached by the FiCTION RCT. This was reported to be largely due to a lack of opportunity rather than any aversion on their behalf, as stated by Participant 18.

> *"No, I don't think so…. Never been approached." (Participant 18, Non-FiCTION, male, 56 years old)*

Delivering study material using a method in line with parental preferences may aid with recruitment and retention. As part of the face-to-face interviews, parents were asked about their personal preferences regarding their preferred route of being

approached to participate in research studies. A small number of parents reported an preference for online contact, due to ease of return, security of the data set and cost effectiveness. Overwhelmingly, however, parents preferred to be asked by post. Some participants, like Participant 9, felt mail was more professional:

> *"No, no, post is fine. I was thinking a letter is more official than like an email or a text message or something like that" (Participant 9, Non-FiCTION, female, 33 years old)*

Another participant, Participant 10, preferred post as they felt it was less likely to be forgotten than other forms of electronic delivery systems:

> *"The post is probably better, but because a text you can easily dismiss it and forget it. But post, you always have a pile of papers and you know I need to look through these things. Post I pay attention to, because I don't know why, I just do. Email, I view that a wee bit similar to the text, it can slip my mind." (Participant 10, Non-FiCTION, female, 44 years old)*

Another participant, Participant 14, preferred post as he felt it was more inclusive to the population:

> *"Post is fine. I really don't like the way this e-mail crap's going because if you haven't got a printer, you're knackered….Um, I think this digital technology only's great, you know what I mean, if, if you've got access to good, good equipment." (Participant 14, FiCTION, male, age not reported)*

6.8.3.6. Comparison between FiCTION and Non-FiCTION participants views, knowledge and experience regarding participation in research

To investigate participants' views, knowledge and experience about participation in research and any differences between those parents whose children were participating in a RCT in primary dental care (FiCTION) and those parents whose children were not participating, the narrative subsequently was compared for similarities and differences between FiCTION and Non-FiCTION participants. For the reporting of this, the data were considered in the context of the major themes and subthemes.

6.8.3.6.1. Research needs to be justified

Parents' views about the impact of their participation in research, via the dental practice, was the same between both groups of parents. However there was a noticeable difference between FiCTION and Non-FiCTION participants with respect to their thoughts about their dental practices being involved in research. Most participants participating in the FiCTION RCT reported that dental practices participating in FiCTION were doing this either as a regulatory requirement for those members within the dental team or to increase knowledge around the FiCTION topic, either locally to influence their own practice or nationally. Non-FiCTION participants were more likely to report that participation in the FiCTION RCT was to make the practice more attractive to patients but this may have been a spurious finding, since for most the reason for non-participation in FiCTION was ineligibility of their child, rather than unwillingness of the child and/or parent to take part.

6.8.3.6.2. Participants do not always have complete knowledge or understanding of the study in which they are participating

The screening process for identification of participants for the FICTION RCT was through routine dental examination ('check-ups'). Participants were identified and invited to participate through two routes (FiCTION Trial 2017):

- "The recruited FiCTION practices carried out simple searches on their practice databases in order to identify potentially eligible children using a date of birth query. Potentially eligible children due for a recall appointment were invited to participate by letter of invitation from the child's GDP. This letter, together with an information sheet for parents and an information sheet for the child, was sent with their dental appointment card at least one week in advance of the scheduled recall appointment.
- Opportunistic recruitment of participants who presented to recruited FiCTION practices and had caries into dentine in at least one primary tooth. Parents of children presenting opportunistically, and identified as being potentially eligible for participation, were invited to participate. Unless they declined, parents were given the invitation letter and the parent and child information sheets and time was allowed (minimum of 24 hours) to consider participation in the trial before consent was sought."

As expected, higher number of IMPACT participants whose children were participating in FiCTION were more likely to have better understanding of the

screening process than those whose children were not participating in FiCTION. In addition, the vast majority of FiCTION participants remembered receiving written information whilst most Non-FiCTION participants did not; this difference may partly explain why FiCTION participants had more understanding regarding the FiCTION RCT. Given that the patient information leaflets were given before the child's screening appointment, it might be assumed that both groups should have had the same level of understanding. However, FiCTION participants may have read the patient information leaflet more thoroughly after the screening appointment leading to better understanding.

All participants, except one, felt it was either "normal" to have been asked to participate in the FiCTION RCT, or reported neutral feelings about being asked. A higher proportion of FiCTION participants reported neutral feelings than Non-FiCTION participants. Rather unexpectedly, Non-FiCTION participants were slightly more inclined to see it as "normal" to have been asked. There was not a noticeable difference between FiCTION participants and Non-FiCTION participants in terms of their rationale for participating in IMPACT.

The diversity of understanding regarding of the term RCT, none of which were particularly accurate, was noticed with both FiCTION and Non-FiCTION participants. FiCTION participants were perhaps unsurprisingly, comfortable with random allocation. However, interestingly one FiCTION participant was unhappy with the concept of random allocation and thought he had chosen the arm his child was on:

> *"No, no I should decide. I will not let the computer choose. I should choose. (Participant 1, FiCTION, male, age not reported)*

Participant 4, who was FiCTION eligible but declined, was unhappy with the concept of random allocation and felt that the dentist should make the final decision:

> *"Well to me the computer would do some of it but I think……it's the dentist cause he's actually seeing what, how bad the decay is so to me, I would have said it's him that makes the final choice….cause he's the one that's actually looking at it." (Participant 4, Non-FiCTION, female, 47 years old)*

This also highlights the important of clinical equipoise and this statement could also reflect that not all dentists were in clinical equipoise. Non-FiCTION participants

showed the full range of opinions on random allocation with a fairly even spread of very favourable to very negative comments given.

There was a noticeable difference between parents whose children were participating in FiCTION and those parents whose children were not participating in FiCTION when considering the withdrawal process. Only one FiCTION parent, Participant 17, reported reluctance about withdrawing, whereas several Non-FiCTION participants reported concerns:

> *"Well I suppose if you're not happy with it then you would have to….either talk to your dentist or if there is nothing he can do then I suppose you would….if it effects…these, me I'd move dentist." (Parent 4, Non-FiCTION, female, 47 years old)*

This is interesting, as the main reason for non-participation was ineligibility rather than unwillingness, and so the issue of withdrawal was essentially a non-issue for these participants.

FiCTION participants were also more self-assured that withdrawing from the RCT completely or changing arm was acceptable, in comparison to Non-FiCTION participants. This may be due to increased discussion with the FiCTION participants and dental teams as treatment was undertaken around withdrawal and changing trial arms.

> *"You can change your mind and opt out of it at any point. She always reminds you about that if, um, if (name) struggled." (Participant 6, FiCTION, female, 34 years old)*

There was no noticeable difference between FiCTION participants and Non-FiCTION participants in terms of who would make the final decision to participate in FiCTION; parent, child, clinician or a combination of interested parties. What was noticeable, was that FiCTION participants had clearly experienced the journey through the decision-making process, whereas Non-FiCTION participants were only considering the decision in the abstract whilst the interview was being conducted. Since giving consent is an on-going active communication process throughout the RCT, it was hoped that the FiCTION participants would have been thoroughly informed at all

stages. Participants, such as Participant 7, commonly reported trying to take their child's thoughts into account when considering whether to become involved:

> *"I think we would probably override any decision because obviously we are adult. But I think, if I knew they definitely weren't happy with it, I wouldn't push them". (Participant 7, Non-FiCTION, female, 34 years old)*

6.8.3.6.3. Research engagement can be challenging and participants will engage with further research if it is timely and relevant

Both FiCTION and Non-FiCTION participants showed a range of opinions regarding the public's willingness and ability to participate in research. This trend was also seen when discussing the possibility of a child missing school to participate in research.

FiCTION and Non-FiCTION participants' willingness for children to participate in research was mixed. FiCTION participants were largely unconcerned about the age of the child while Non-FiCTION participants were a little bit more guarded in their willingness for young children to participate in research.

Interestingly, FiCTION and Non-FiCTION participants did have different past research experiences. FiCTION participants were much more likely to have been involved in research previously than Non-FiCTION participants:

> *"She was coming out and asking him a series of questions and that's, uh, we took part in that survey and I, that was, that was, that was three year ago now like. But, ah, I can't remember the questions we're asked, we were answering to be honest with you but, ah, I do know that she found it very beneficial because we got a nice thank you letter at the end of it. (Participant 14, FiCTION, male, age not reported).*

However, the willingness of both groups to participate in future research studies was similar although the reasons given were different.

The majority of parents reported participating in IMPACT to increase the knowledge base. FiCTION participants were more inclined to report taking part in IMPACT as it might give a deeper understanding of the issue:

> *"To find out a bigger picture." (Parent 8, FiCTION, female, 42 years old)*

"You know, I've done one, I might as well do the other." (Participant 5, FiCTION, female, 32 years old)

Non-FiCTION participants were more likely to participate as they personally found the topic of the research interesting, or because I was interested in the topic, and because the results may be helpful to the dental community in the future:

"I'm interested in the fact that you're interested" (Participant 10, Non-FiCTION)

6.9. Discussion

The discussion first presents a summary of the principal findings of the qualitative study. Then the strengths and weakness of the design of the qualitative study are discussed with subsequent comparison to other relevant published articles. The principal findings of the qualitative study are then considered in terms of potential impact on clinicians and/or policymakers. Finally, areas where further research may be needed are identified.

6.9.1. *Statement of principal findings*

The first objective associated with the qualitative study was to investigate parents' views, knowledge and experience regarding their own dental health and their families' dental care, and any differences therein between those parents whose children were participating in the FiCTION RCT and those parents whose children were not participating in that RCT. Participants' views regarding their own dental health were varied but there was no noticeable difference between participants' definitions of good dental health or their perception of the facilitators and barriers to obtaining good dental health between FiCTION and Non-FiCTION participants.

All parents reported that their child went to their dental check-ups regularly and the reasons given were the same for FiCTION and Non-FiCTION participants. Considering that child attendance has been linked to a parent's attendance (Holmes et al. 2016), it was a little surprising to find that not all participants reported that they themselves also attended the dentist regularly. The interviews highlighted that, whilst the majority of the participants, irrespective of trial status, attended their dentist regularly, a significant minority were irregular attenders.

Perhaps not unexpectedly, only participants whose children were not participating in a RCT in primary dental care were not on a regular maintenance programme themselves, highlighting a potential difference between FiCTION and Non-FiCTION participants in terms of attendance patterns. This suggests that participants who are regular attenders may be more likely to involve their child in research or that participants' motivation for attending regular dental check-ups may have increased because of their child's involvement in the FiCTION RCT.

The second objective associated with the qualitative study was to investigate parents' views, knowledge and experience about participation in research and any differences between parents whose children were participating in the FiCTION RCT and those whose children were not participating in that RCT. Most participants had selected their current dentist by word of mouth and the convenience of the locality of the practice, with none having made the decision to join their dental practice based on the dental practice's research profile. Therefore research involvement does not appear to be a major incentive to attend a particular practice.

Most FiCTION participants understood the general aspects and advantages of participating in that study such as the nature of the study, the potential benefit to other children, the notion of voluntary participation and the possibility of withdrawal at any time. By contrast, a greater proportion of Non-FiCTION participants struggled with these concepts, which might be expected in view of their limited exposure to the FiCTION RCT. Participants' views, knowledge and experience about participation in research were influenced by participation in the FiCTION RCT, but some of the more complex concepts around RCTs were not really understood by either group. FiCTION participants' knowledge around the process for withdrawal from the trial was better than Non-FiCTION participants and this is likely due to their experiences within the FiCTION RCT, especially as dentists became more immersed in the RCT and became more familiar with trial processes themselves. This was likely to have a "knock-on" effect on the practice's FiCTION families becoming more aware and familiar with trial processes as the trial progressed. Both groups of participants included some individuals who had struggled with explaining the concept of random allocation to a trial arm as well as the need for the clinical trial team to use random allocation rather than clinician and/or patient choice.

In the IMPACT study participants from ethnic minorities were interviewed and, on the whole, ethnic minorities felt ethnicity was not a barrier in research participation. However, one ethnic minority participant reported that under-representation of minority ethnic groups in research may be an issue as they felt that it was easy for ethnic minorities to be misunderstood both in terms of how they respond to questions and their interaction with the researcher. This may result in a reluctance to participate in research, especially for first or second generation migrants.

The participants interviewed in the qualitative study came from a range of educational backgrounds. There did not appear to be a relationship between willingness to participate in the FiCTION RCT and educational background. Educational level did not seem to be related to parent's ability to define a RCT or the process of random allocation of participants.

6.9.2. *Strengths and weaknesses in relation to other studies, discussing particularly any differences in results*

This section will first discuss the strengths and weaknesses of the design of the qualitative study and then relate the findings to other studies, discussing particularly any differences in results.

6.9.2.1. Strengths and weakness of the design of the qualitative study

Using semi-structured interviews, involving predetermined questions and altering or explaining questions as necessary, allowed a fairly flexible and sensitive approach to be adopted. This was particularly useful given that it was my first experience of undertaking qualitative research. However, the use of open ended questions made the analysis more challenging when comparing participants' answers between and within groups. There were also occasions, especially early on in the interview series when I was honing my interviewing skills, when very long, seemingly rambling answers were given by some participants. This resulted in a greater transcription and analysis burden for me and a greater burden on participants due to a longer interview time.

However, the semi-structured interview design enabled potentially sensitive subjects to be explored delicately. By using some set questions I felt participants were reassured that their answers were not being over-scrutinised by my values or biases,

even if they did get quite emotional, and ensured they answered every question even if it was a sensitive area. It is unclear whether this would have been the case if participants had been participating in an unstructured interview where there was no set expectation for emotive topics to be covered and therefore participants may have avoided discussing these.

By conducting the interviews face-to-face, I was able to empower participants by putting them at ease before beginning the interview and by explaining that it was their experiences that were of interest. It was important to consider the best way to maintain the balance of power between the parent and myself, since by being responsible for introducing the topics and guiding the interview, I could be seen as 'having the upper hand'. However, it was important to remember that it was the participant who had encountered the personal experience and thus was the "expert". Given my limited experience of qualitative research, the face-to-face approach made it simpler for me to pick up on non-verbal communication by participants. In addition, the breadth of data could not have been collected if a telephone interview had been arranged instead. However, face-to-face interviews were logistically more challenging, in terms of travelling, and may have been more of a burden on participants than a telephone interview would have been. Despite verbally agreeing interview arrangements with participants over the telephone, two participants forgot I was coming but fortunately were able to complete the interview the same day. If this had not been the case, there would have been additional burden and expense re-arranging the interviews to another suitable time and location. Additional consideration to confirming appointments via text, email or letter may have reduced the likelihood of interviews being forgotten. As mentioned earlier, I am a clinician and familiar with questioning patients as part of a clinical assessment to derive a diagnosis from a list of possibilities based on evidence. The majority of participants presumed I was employed as a researcher and were surprised, if they asked for clarification, that I was also a clinician. As such I felt the influence on the qualitative data was largely positive as I was able to respond more precisely to collect additional data and make further comparisons.

Participants were selected using purposive sampling which allowed the interviewing of several ethnic minorities, participants from different social backgrounds and mothers/fathers to take place. Although I would have preferred to include more

younger participants to increase the age range, this option was limited since the vast majority of participants recruited into IMPACT were in their 30s or 40s. Likewise, it would have also been advantageous to interview more participants who were eligible to participate in the FiCTION RCT but had declined, but this option was restricted by the very small number of IMPACT participants that fitted into this category.

An avenue not explored in any great detail with participants was who took their child to dental appointments. Most participants mentioned within the interview that they themselves took the child to the dentist for check-ups, for practical reasons, but it was not possible to ascertain whether the FiCTION participants took their children to the treatment sessions. If participants were reliant on other guardians to take their child to the dentist after the initial recruitment which required parental attendance, this could account for poorer grasp of knowledge and understanding around some of the research aspects included in the qualitative interview.

I examined my qualitative interviews using thematic analysis. Thematic analysis does not require the detailed theoretical and technological knowledge necessary for alternative approaches such as grounded theory or discourse analysis, and it has been suggested as suitable for those early in their qualitative research career (Braun and Clarke 2006). However, I initially struggled determining the ‘themes’ and was inclined to look simply at my topic guide. This resulted in me initially stringing a collection of extracts together and thus failing to make sense of the patterning of responses across the entire data set. Review of my coding and analysis was required by a second person to avoid the data only being taken at face value. I suspect this is part of the learning process for those new to qualitative research, but it is unclear whether a different method of analysis would have reduced or increased this secondary review burden.

Whilst this is not uncommon in qualitative interview analysis, various features, for example, stress on certain syllables or sounds, intonation (raise/lower voice), emphasis or slow/fast speech were not captured. This more in-depth form of analysis, called discourse analysis not only captures what was said, but also how it is said. (Shaw and Bailey 2009) However, I was more interested in what was being said rather than how it was said and therefore I made the decision not to use discourse analysis. I conducted all the interviews and the transcription and analysis thereof.

Amore in-depth discourse analysis would have presented a considerable extra demand on resources and was unfeasible for me to do and in addition, it is unclear whether it would have been worthwhile.

Methodologically, I believe that I followed accepted practice in fieldwork, analysis and interpretation. However, there are a number of limitations. Firstly, although the sample did include participants with a wide range of anthropometric and socio-economic differences, all with some FiCTION experience, I only interviewed participants who returned a completed IMPACT baseline questionnaire. No claims can be made about participants who would have been willing to participate in the qualitative study but not engage in the quantitative study. Secondly, I cannot be certain of the extent to which the experiences of the 18 study participants reflect those of the 261 who completed the baseline questionnaire, although maximum variation sampling was used to include a wide range of participant factors. Third, the study lacks precise data about levels of participation in the FiCTION RCT. I therefore cannot draw specific conclusions about the effects on parental dental anxiety (DA), OH-RQoL or attitude to their dental care and that of their children with respect to intensity and duration of FiCTION RCT experience. These areas are important for further research.

6.9.2.2. Relating this qualitative study to other studies, discussing particularly any differences in results

Dental health can affect general health by causing considerable pain and suffering and by changing what people eat, their speech, quality of life and well-being and has an effect on other chronic diseases (Petersen 2003). Most participants identified the impact of poor dental health on chewing foods with several participants elaborating further to highlight that this may result in an unbalanced diet which could impact on their wellbeing. Both groups of participants felt that dental health was perceived poorly by the population in general and that poor dental health impacted both psychologically and socially. Interestingly, only two participants observed that poor dental health could impact on an individuals' verbal or non-verbal communication. None of the participants reported pain and/or suffering when discussing the impact of poor dental health. Whilst pain and missing teeth are the more obvious consequences of poor dental health, it is unclear if the full impact of poor dental health is understood by the public.

This qualitative study supported the findings of another survey (British Dental Trade Association 2012) which showed that having a recommended/trusted dentist was a major factor and very important to people when considering/choosing a dentist. Trust in the dentist was far more important than how specialised/experienced the dentist was. From a study involving 50 in-depth face-to-face interviews of a range of adults living within Southern England, a third believed that expense generally restricted how often they visited the dentist. Other main reasons cited for not attending the dentist in the past were having no dental problems, difficulty paying for dental care, fear of dentist, reluctance to pay for dental care and difficulty obtaining NHS treatment. The dentist's manner and the dentist's technical skills were also highly motivating factors that influenced dental attendance (Calnan et al. 1999). The findings of this qualitative study would support those findings.

Research conducted within primary dental care services is still relatively rare (Dawett 2017). As far as I am aware, there is no published evidence to suggest research was a factor considered by patients when selecting a medical or dental facility. Given that research participation is not within the public domain, unless the dental practice chooses to advertise their involvement, this is perhaps unsurprising. Considering that it is stated in the NHS Constitution that the NHS commits "to inform you of research studies in which you may be eligible to participate" (Department of Health 2015, p. 8) and that this should extend to dental patients as well, it will be interesting to see whether dental practices' research participation profiles enter the public domain in future. For the majority of dental practices involved in the FiCTION RCT, this was their first experience of undertaking research. There is growing support for all clinical registered trials to be required to publish their results (Chalmers et al. 2013). If it does, it would be interesting to note whether research involvement does begin to become a factor in the public's decision to register with and attend certain dental practices.

The difficulty that participants had in describing randomisation, in expressing the purpose of the research or specific details about the FiCTION RCT's 3-arm design mirrors findings from previous medical RCTs involving children (Chappuy et al. 2013). As mentioned earlier, both groups of participants (FiCTION and Non-FiCTION) included some individuals who struggled with explaining the concept of

random allocation to a trial arm as well as with understanding the need for the clinical trial team to use random allocation rather than clinician and/or patient choice. This echoes the findings of a clinical trial involving parents of critically ill babies (Snowdon et al. 1997) where some parents gave seemingly appropriate descriptions of the trial but further examination highlighted areas of confusion. Interestingly, the parents in the present study also used or responded to terms such as “random” or “randomisation” as if they were familiar with them but further unpicking identified some uncertainty or incorrect interpretations of the terms.

It has been claimed that racial and ethnic minorities, especially in the USA, are less willing than non-minority individuals to participate in health research but these assumptions generally appear to be on the basis of analysis of single trial datasets (Robinson et al. 2016). Within the present qualitative study, ethnic minority participants largely felt ethnicity was not an issue for the associated FiCTION RCT. Reasons for perceived exclusion of minority ethnic groups are complex and previous medical research has reported that it is unclear whether the real issue is one of planned exclusion, inadvertent exclusion, non-participation or a mixture of these (Redwood and Gill 2013), all of which would result in under-representation of ethnic minorities in research studies. We know from previous medical research (Gill et al. 2013, Rooney et al. 2011) that engagement with communities and more personalised approaches are beneficial to increase the recruitment and participation of patients from all communities, including minority ethnic communities and the same approach is necessary for dental research studies. For qualitative interviews, specific adjustments can include; the use of the same interpreter (to provide as much consistency as possible), briefing the interpreter about the project’s aims and their role in the interview, getting the interpreter to provide feedback at the end of each interview which is then used to inform subsequent interviews, getting the study recruiter to approach religious and community organisations to talk to people directly about the research, collecting data in different ways e.g. using focus groups and/or using an open-surgery type arrangement (Gill et al. 2013). For quantitative studies, the translation of materials into appropriate languages is a key adjustment.

It has previously been reported that, in general, those who attain a higher level of education had a more favourable view of medical research and were more aware of the approval processes (Singhal et al. 2002). From the IMPACT interviews, there did

not appear to be a relationship between willingness to participate in the FiCTION RCT and educational background, however it was acknowledged that these patients had opted into the study and therefore may not be completely representative of the population.

6.9.3. *Meaning of the qualitative study: possible mechanisms and implications for clinicians or policymakers*

The World Health Organization (WHO) stated in 1992 that the retention, throughout life, of a functional, aesthetic, natural dentition of 20 or more teeth and not requiring recourse to prostheses should be the treatment goal for dental health (World Health Organization 1992). The perception of participating in the IMPACT qualitative study largely concur with this but it is important to acknowledge two areas where there was slight disagreement: most parents felt that most or all teeth should be retained (i.e. significantly more than 20 teeth) and opinions regarding dentures differed, with few parents able to differentiate between teeth lost to dental disease and teeth lost to other factors (e.g. trauma related). In Western cultures, individuals who are missing anterior teeth may experience significant barriers to personal and social success e.g. dating (Willis et al. 2008). The IMPACT qualitative study participants all felt that poor dental health impacted on nutritional, psychological and/or social performance and this is supported by the literature where the number of teeth in the mouth, alongside age and cultural background, has been found to influence OHRQoL (Sheiham et al. 2001, Steele et al. 2004). This suggests that, if the qualitative group is representative of the public that the WHO statement of the retention of only 20 teeth (or more) may not be in keeping with the public's current expectations and aspirations regarding their dentition. This has significant "knock on" implication on policy and practice as the retention of more teeth has the potential to increase burden and expenditure on current dental resources and funding.

Previous studies (Sbaraini et al. 2012, Calnan et al. 1999) along with this current qualitative study have reported that all patients, irrespective of their risk of developing dental caries, valued a caring dentist who respected them and listened to their concerns without "blaming" them for their dental health status. There were three main barriers which they reported could discourage them from following normal preventative home care regimes: uncertainty about prevention, competing priorities and existing habits. Home care activities (tooth brushing and flossing) were seen as

time-consuming and not a priority and it was reported that entrenched bad habits were also hard to change. Participants within the IMPACT qualitative study also felt other families did not prioritise tooth brushing, due either to a lackadaisical routine established by their own parents which they had themselves adopted or to perceived time barriers, and that these habits were difficult to change. For clinicians and policymakers, this suggests further support to encourage good practice to maintain dental health may be beneficial during both antenatal and postnatal stages for families. The IMPACT qualitative study interviewed both mothers and fathers who had an active role in their child's dental attendance. Some mothers felt that their child's dental attendance was more a "mother's role", but the fathers and other mothers felt this was more a "parent's responsibility". There was widespread agreement that a child's access to dental service was influenced by the motivation of a primary carer, both in terms of scheduling the appointment and ensuring their child presented for care on the appointed day and time, and was largely outwith the control of the child, a finding supported within literature. In previous research, barriers reported by parents, even when an appointment had been scheduled, related to a lack of family resources, compromising their ability to attend the appointment, as well as the lack of emphasis some parents placed on attending for dental care (Dodd et al. 2014). For clinicians and policymakers, this suggests additional social support may be required for some children to support regular dental attendance.

Although some research, predominantly from the USA, reports that ethnic minorities are under-represented in clinical and health research (Hussain-Gambles et al. 2006), the data from this UK study did not provide any clear evidence that this was viewed a major issue by the majority of parents. More often, parents perceived time restrictions, disinterest or socio-economic status as barriers to participation in research rather than a subject's ethnicity. From an online survey of a representative (in terms of age, sex, socioeconomic class and educational qualifications) UK sample, it was suggested that patients preferred professionals of the same ethnic origin or of cultures that are similar to their own, as this improves professional-patient communication (Furnham and Swami 2009). However, some studies conducted in England among university students have shown that patients are now more open to accepting professionals that come from different ethnic groups. Whilst not explicitly asked within the IMPACT qualitative study, participants did not report any ethnic or cultural preferences with respect to the dental practice they attended, suggesting that

this is less of a concern or priority for parents when it involves their child, or for policymakers or clinicians within primary dental care.

In an Australian qualitative study of 17 patients previously enrolled in a preventive care program RCT (Sbaraini et al. 2012), patients suggested that there were two types of dentists and two different ways of practicing dentistry which were categorised as “old-school dentistry” and “new-school dentistry”. Patients described the “old-school” dentist as one who had a “mandate for doing fillings”, would not give patients preventive options and lacked communication skills. Some patients wondered if there was an “old-school institution” that graduated dentists without any knowledge of preventive options (Sbaraini et al. 2012). These findings were echoed by some of the participants within the IMPACT qualitative study. Several participants discussed how dentistry had changed in recent years with one participant going as far as reporting that their restorations were done as it was “fashionable” at the time. Several participants reported receiving preventative care as a child, but the general consensus within both FiCTION and Non-FiCTION participants was that preventative care now had a more prominent focus within the dental setting. It is unclear at this stage whether this sentiment will be maintained as these participants age, or whether the next generation will echo similar statements.

6.10. Conclusion

This qualitative study set out to investigate parents’ views, knowledge and experience regarding their own dental health and their families’ dental care and any differences therein between those parents whose children were participating in in the FiCTION RCT and those parents not participating in that RCT. The FiCTION and Non-FiCTION participants were very similar in terms of their previous dental experiences and the dental attendance of their child. An interesting finding was that Non-FiCTION participants approached their dental attendance as a matter of routine i.e. they went because they felt it was “normal” that they should or they had failed to attend regularly having become complacent due to a history of good dental health. FiCTION participants attended more out of a sense of duty to be a positive role model to their child.

This qualitative study identified positive parental experiences and reported parents were happy to be involved in the FiCTION RCT if it had minimal impact on their child

and would lead to improved treatment for future children. Parents were less concerned about knowing which arm their child was recruited to in the RCT as long as they could change their mind about being involved. However parents felt that the attitudes and motivations of the dentists themselves were particularly important in recruiting them into research studies, and perhaps more important than the written information packs given to them. These findings should be particularly interesting for policymakers given the dearth of published primary dental care research studies involving children.

There is a growing recognition that dental practices in the primary care NHS sector provide an excellent and relevant environment to carry out clinical dental research and an opportunity for all members of the dental team to develop and expand their roles into the research field. In addition to evaluating treatment outcomes, understanding the practicality, feasibility, acceptability, expense and cost-effectiveness of a new treatment regimen are crucial to its overall deliverability in NHS dentistry.(Heasman et al. 2015) With regard to the conduct of research trials in primary care, it has been reported that research dedicated to identifying the best methods to achieve engagement with patients as potential participants is lacking and clearly needed.(Domecq et al. 2014)

Most FiCTION participants understood the general aspects and advantages of participating in the RCT, the nature of the RCT, the notion of voluntary participation, the possibility of withdrawal at any time and the potential benefit to other children. By contrast, a greater proportion of Non-FiCTION parents struggled with these concepts. Although there was a noticeable range of views, knowledge and experience about participation in primary care research within the cohort of participants, this did not seem to be greatly influenced by the FiCTION status of the participant. This suggests further education of the public is required within primary care settings to ensure generalisability of study findings and reduce inequities in access to healthcare and research participation.

Chapter 7: Triangulation

7.1. Background

The central research question investigated in this thesis was: does participating in a RCT impact on a parent's dental anxiety (DA), oral health-related quality of life (OH-RQoL) and attitude to their dental care and that of their children? This central question was then broken down into several objectives for the quantitative and qualitative studies.

The objectives of the quantitative survey were:

1. To quantify the difference at baseline, with respect to parental DA (MDAS), OH-RQoL (OHIP-14), dental health beliefs (DHB) and sense of coherence (SOC-13) regarding their own dental care and that of their children, between parents of children with active caries and participating in an RCT in primary dental care (FiCTION) and parents of children without active caries and not participating in an RCT.
2. To quantify the difference in change from baseline to 18 months between these two groups of parents in parental DA (MDAS), OH-RQoL (OHIP-14), dental health beliefs (DHB) and sense of coherence (SOC-13) regarding their own dental care and that of their children.

The objectives of the qualitative study were:

1. To investigate parents' views, knowledge and experience regarding their own dental health and their families' dental care and any differences therein between those parents whose children were participating in the FiCTION RCT and those parents whose children were not participating in that RCT.
2. To investigate parents' views, knowledge and experience about participation in research and any differences between parents whose children were participating in the FiCTION RCT and those whose children were not participating in that RCT.

Chapters 5 and 6 described the quantitative and qualitative studies respectively, in isolation. When the separate analyses of the quantitative and qualitative datasets were completed, some differences in the findings became apparent. The quantitative study showed little evidence that participating in a RCT impacted on a parent's DA, OH-RQoL or attitude to their dental care and that of their children. The qualitative study found several interesting findings, and participants reported that their experiences with the FiCTION RCT and/or IMPACT Study would not stop them participating in further research (see Section 6.8.3.5). This led to much discussion

and debate with the study team, as a result of which further exploration of the data was undertaken.

In this chapter, the findings of both the quantitative and qualitative studies, have been combined in a process sometimes called triangulation. The term triangulation can be confusing because it has two meanings (Sandelowski 1995). It can be used to describe corroboration between two sets of findings or, alternatively, to describe a process of studying a problem using different methods to gain a more complete picture (O'Cathain et al. 2010). The process of triangulating findings from different methods takes place at the interpretation stage of a study when both data sets have been analysed separately and several techniques have been described (O'Cathain et al. 2010). Findings from each method which agree (convergence), offer complementary information on the same issue (complementarity), or appear to contradict each other (discrepancy or dissonance) can be considered and this was the approach taken in this project (O'Cathain et al. 2010). Looking for dissonance between findings from different methods is an important part of this process and is not a sign that something is wrong with a study; it may lead to a better understanding of the research question (Moffatt et al. 2006).

7.2. Comparing the quantitative and qualitative studies

It is standard practice at the data analysis and interpretation phases of any study to scrutinise methodological rigour.

Some parents reported during the qualitative interviews that they felt the questionnaires were complicated and that they were not always sure whether the questionnaire was directed towards them or their child. In addition, a number of issues important to parents, in particular around participation in research, were not captured in the questionnaire, which simply reflects the complexity of fully capturing the richness of what people want to say using quantitative measures alone. Despite best efforts, the recommended sample size for the Non-FiCTION parent group was not achieved in the IMPACT quantitative study. In addition, there were three important sources of dilution effects: firstly, fewer parents than expected (10.9%) of those sent the IMPACT invitation pack returned the consent form; secondly, fewer parents (84% of those consenting to IMPACT) who met the IMPACT criteria returned the baseline questionnaire; and thirdly, slightly fewer than expected parents

remained in the study to the end (due to loss to follow-up or exclusion). The recruitment of very few parents whose children were FiCTION eligible but declined (n=6) was a significant limitation of the quantitative study, as these parents may have provided very different responses. All of these factors provide a possible explanation for the lack of a measurable effect in terms of participation on a change in parent's MDAS, OHIP-14, DHB and SOC-13 over time for either parent group in the IMPACT quantitative study.

The number of participants in the qualitative study whose children were participating in the FiCTION RCT was small (n=7). Nonetheless, I would argue that the sampling method, analysis and interpretation were sufficiently rigorous to ensure that the findings were an accurate reflection of what was being studied. Within the quantitative study there was evidence of an ethnic minority under-representation that is of practical and clinical interest. When ethnic minorities, already recruited into the quantitative study, were approached to take part in qualitative interviews, they did so enthusiastically. When asked if they felt ethnicity was a barrier to research participation, they disagreed. One participant, from an ethnic minority herself, felt a different approach may be necessary to recruit and retain ethnic minorities in research studies. The qualitative study also showed little evidence from white parents that they perceived that ethnicity was considered a major issue to participation in research, with them identifying time restrictions, lack of interest or socio-economic status cited as more important barriers to participation in research. Limkakeng et al. (2013) undertook a systematic review of literature between 1985-2009 to understand Chinese patients' motivations and concerns to participate in clinical trials and demonstrating shared values between cultures with regard to research (see Section 2.3.1). IMPACT would suggest that further work is required to maximise engagement with ethnic minorities within dental research studies with specific targeting for recruitment of ethnic minority participants.

7.2.1. *Exploring sample corroboration*

All 18 members of the qualitative sample were fully enclosed in the larger sample of 261 parents providing baseline quantitative data. The full sample of parents was informally compared with the data from the 18 members of the qualitative sample on a number of demographic and anthropometric characteristics at baseline (Tables 7.1 – 7.4) and found to be broadly comparable in terms of age and education. There was

a higher proportion of fathers and ethnic minorities within the qualitative sample when compared against the quantitative study as a whole, but this was unsurprising given that the sampling strategy used in the qualitative study sought to maximise the diversity of data collected. There was also little evidence that the qualitative sample of parents differed from the full quantitative sample, when compared in terms of general and dental health outcomes measures at baseline.

Table 7.1: Demographic and anthropometric characteristics of IMPACT participants in the full quantitative sample at baseline and the qualitative sample

	Full quantitative sample of parents (n=261)		**Qualitative sample of parents (n=18)**	
	n		**n**	
Age (years) Mean (SD)		38.1 (5.8)		39.4 (7.5)
Total responses	244		14	
Relationship to child				
Mother	228	(88.7%)	10	(55.6%)
Father	23	(8.9%)	8	(44.4%)
Other	6	(2.3%)	0	(0.0%)
Total responses	257		18	
Ethnicity				
White	250	(96.2%)	13	(72.2%)
Indian, Pakistani or Bangladeshi	5	(1.9%)	2	(11.1%)
Mixed race	3	(1.2%)	1	(5.6%)
Other	2	(0.8%)	2	(0.8%)
Total responses	260		18	
Highest level of education completed				
Primary school	9	(3.4%)	2	(11.8%)
Secondary school	25	(9.6%)	1	(5.9%)
Some additional training	75	(28.7%)	4	(23.5%)
Undergraduate university	74	(28.4%)	6	(35.3%)
Postgraduate university	67	(25.7%)	4	(23.5%)
Total responses	250		17	
Country of Residence				
North-east England	170	(65.1%)	10	(55.6%)
Scotland	91	(34.9%)	8	(44.4%)
Total responses	261		18	

Table 7.2 compares the full (quantitative) sample of parents against the data from the 18 members of the qualitative sample on a number of outcome measures i.e. baseline mean (standard deviation) MDAS, OHIP-14, DHB and SOC-13 scores for all participants in IMPACT at baseline. There was little evidence of differences between the full sample of parents against the data from the 18 members of the qualitative

sample of any practical importance and demonstrates corroboration between the full sample of parents and the 18 members of the qualitative sample.

Table 7.2: Baseline mean (standard deviation) MDAS, OHIP-14, DHB and SOC-13 scores for the full quantitative sample of parents against the data from the 18 members of the qualitative sample at baseline

Total score	Full quantitative sample of parents (n=261)	Qualitative sample of parents (n=18)
MDAS		
Mean (SD)	11.1 (5.1)	10.3 (5.2)
Total responses	250	18
OHIP-14		
Mean (SD)	6.7 (6.4)	7.0 (6.6)
Total responses	243	16
DHB		
Mean (SD)	9.4 (1.9)	10.3 (2.4)
Total responses	261	18
SOC-13		
Mean (SD)	63.1 (7.2)	60.1 (7.4)
Total responses	256	18
SOC-13 comprehensibility		
Mean (SD)	25.5 (4.0)	23.8 (4.6)
Total responses	256	18
SOC-13 manageability		
Mean (SD)	17.8 (2.7)	17.4 (1.9)
Total responses	256	18
SOC-13 meaningfulness		
Mean (SD)	19.8 (3.0)	18.9 (3.0)
Total responses	256	18

Tables 7.3 and 7.4 report the baseline characteristics of all 261 participants in the IMPACT quantitative study and the 18 members of the qualitative sample at baseline and shows their similarity.

There was little evidence (Table 7.5) that the qualitative sample of parents differed from the full quantitative sample, when compared in terms of change over time in MDAS, OHIP-14, DHB and SOC-13; for the qualitative sample, the sample size is reduced from 18 to 12 or 14, because scale scores at both time points could not be calculated for some respondents.

The mean change from baseline to 18 months was an increase in MDAS of 0.3 for the full sample of parents and a decrease of 0.4 for the 12 members of the qualitative sample for whom MDAS scores at both time points could be calculated. The mean change for both groups was small, suggesting that the full sample of parents got slightly more anxious over time on average and the qualitative sample of parents got slightly less anxious over time on average. The mean change in MDAS scores for both groups would not be considered clinically meaningful (Humphris et al. 2009).

The mean change from baseline to 18 months was an increase in OHIP-14 for the full sample of parents and a decrease in OHIP-14 for the 12 members of the qualitative sample. The mean change for both groups was small, suggesting that the full sample of parents OH-RQoL got slightly worse over time on average and the qualitative sample of parents got slightly better over time on average. The mean change for both groups would not be considered clinically meaningful (Slade 1997).

The mean change from baseline to 18 months was a decrease in DHB of 0.1 for both the full sample of parents and the 14 members of the qualitative sample. The mean change for both groups was slightly negative, suggesting that both had slightly less favourable dental beliefs over time on average. The mean change in DHB scores would not be considered clinically meaningful (Broadbent et al. 2006).

The mean change from baseline to 18 months was a decrease in SOC-13 of 0.3 for the full sample of parents and an increase of 0.5 for the 14 members of the qualitative sample. The mean change for both groups was small, suggesting that the full sample of parents got slightly less able to deal with the stressors of everyday life over time on average and the qualitative sample of parents got slightly better at being able to deal with the stressors of everyday life over time on average. The mean change in SOC-13 scores for both groups would not be considered clinically meaningful (Eriksson and Lindström 2005).

These comparisons indicated that the difference in change over time from baseline to 18 months in MDAS, OHIP-14, SOC-13 and DHB between the full sample of parents and the 18 members of the qualitative sample data was inconsistent but negligible.

Table 7.3: General and dental health of the full sample of parents against the data from the 18 members of the qualitative sample parents at baseline

Baseline health				
	Full quantitative sample of parents (n=261)		**Qualitative sample (n=18)**	
	n	**(%)**	**n**	**(%)**
How is your health in general? Would you say it was…				
Very good	126	(48.8%)	7	(38.9%)
Good	113	(43.8%)	10	(55.6%)
Fair	15	(5.8%)	1	(5.6%)
Bad	2	(0.8%)	0	(0.0%)
Very bad	2	(0.8%)	0	(0.0%)
Total responses	258		18	
Would you say your dental health (mouth, teeth and/or dentures) is…				
Very good	61	(23.6%)	2	(11.1%)
Good	130	(50.4%)	11	(61.1%)
Fair	59	(22.9%)	4	(22.2%)
Bad	6	(2.3%)	1	(5.6%)
Very bad	2	(0.8%)	0	(0.0%)
Total responses	258		18	
How many natural teeth have you got? Is it…				
None at all	0	(0.0%)	0	(0.0%)
At least 1 but less than 10	1	(0.4%)	0	(0.0%)
Between 10 and 19	6	(2.3%)	1	(5.6%)
20 or more natural teeth	244	(95.3%)	16	(88.9%)
Some natural teeth but don’t know how many	5	(2.0%)	1	(5.6%)
Total responses	256		18	

Table 7.4: Dental experiences of the full sample of parents against the data from the 18 members of the qualitative sample parents at baseline

Baseline dental experience				
	Full quantitative sample of parents (n=261)		**Qualitative sample (n=18)**	
	n	**(%)**	**n**	**(%)**
Dental care/treatment				
Have you ever had fillings?				
Yes	225	(90.7%)	17	(94.4%)
No	23	(9.3%)	1	(5.6%)
Total responses	248		18	
Have you ever had any wisdom teeth extracted (taken out)?				
Yes	91	(36.7%)	8	(44.4%)
No	157	(63.3%)	10	(55.6%)
Total responses	248		18	
Have you ever had any teeth extracted (taken out)?				
Yes	172	(65.9%)	15	(83.3%)
No	76	(30.6%)	3	(16.7%)
Total responses	248		18	
Have you ever had a tooth crowned?				
Yes	78	(31.6%)	6	(33.3%)
No	169	(68.4%)	12	(66.7%)
Total responses	247		18	
Have you ever had a dental bridge?				
Yes	22	(8.9%)	0	(0.0%)
No	225	(91.1%)	18	(100.0%)
Total responses	247		18	
Have you ever had an implant to replace a missing tooth?				
Yes	9	(3.6%)	2	(11.1%)
No	239	(96.4%)	16	(88.9%)
Total responses	248		18	
Have you ever had sedation (that is something that relaxes you but does not put you to sleep) for dental treatment?				
Yes	94	(37.9%)	5	(27.8%)
No	154	(62.1%)	13	(72.2%)
Total responses	248		18	

Table 7.5: Mean (SD) change (18 months - baseline) for the full sample of parents against the data from the 18 members of the qualitative sample parents at baseline for MDAS, OHIP-14, DHB and SOC-13.

Total score	Change over time	
	Full quantitative sample of parents (n=192)	Qualitative sample (n=14)
MDAS		
Mean	0.3	-0.4
SD	2.7	3.0
Total responses	168	12
OHIP-14		
Mean	0.1	-2.2
SD	3.8	3.0
Total responses	167	12
DHB		
Mean	-0.1	-0.1
SD	1.7	1.6
Total responses	191	14
SOC-13		
Mean	-0.3	0.5
SD	7.8	10.9
Total responses	186	14
SOC-13 comprehensibility		
Mean	-0.7	0.9
SD	4.3	5.7
Total responses	187	14
SOC-13 manageability		
Mean	-0.1	-0.4
SD	3.4	4.0
Total responses	186	14
SOC-13 meaningfulness		
Mean	0.5	-0.1
SD	3.2	3.5
Total responses	186	14

7.2.2. *Studying a problem using different methods to gain a more complete picture*

As mentioned in Section 7.1, I considered where findings from the quantitative and qualitative studies agreed (converged), offered complementary information on the same issue (complementarity), or appeared to contradict each other (discrepant or dissonant) (O'Cathain et al. 2010). Key findings are reported under the dental health and research themes identified in the qualitative study to provide additional insight into the research question being investigated.

7.2.2.1. Dental health - Agreement or partial agreement

Almost all participants in the qualitative study discussed the importance of parents, particularly mothers, “ingraining” good oral habits into their children at a young age. Whilst the rationale for completing the questionnaire was not explored within the quantitative study, it was interesting to note that the vast majority of respondents were mothers. It could be postulated that mothers were also responding to the IMPACT quantitative study as another way of being a positive role model to their children.

Research has shown consistent inequalities with individuals in lower socioeconomic positions more likely to have poorer dental health, as measured by both clinical and subjective indicators (Guarnizo-Herreño et al. 2014). Analysis of the 2009 ADHS indicated that there were clear socioeconomic inequalities (using educational attainment, occupational social class and household income as indicators) in subjective dental health (using self-rated dental health, OHIP-14 and OIDP as outcome variables) amongst UK adults in England, Wales and Northern Ireland (Guarnizo-Herreño et al. 2014). The quantitative study found whilst there were large differences in the highest education level completed between the two IMPACT groups, with higher levels of educational attainment amongst the Non-FiCTION group (29.5% Non-FiCTION completed postgraduate education versus 16% FiCTION), overall this was a higher percentage than that for the UK population (Office for National Statistics 2012a, National Records of Scotland and Scottish Government 2014a). All but one participant reported having fillings within the qualitative study. This confirmed findings from the quantitative study where 90.7% of both FiCTION and Non- FiCTION participants reported receiving a filling at some point in their life. Whilst this is hardly a surprising finding as the qualitative sample was fully enclosed in the larger sample of parents in the quantitative study, it is almost certainly by chance variation, that the percentage who had ever had a filling was higher in the qualitative sample. In terms of complementary information, participants within the qualitative study reached the consensus that as long as the necessary fillings had been placed and there were not too many fillings, the individual could still be considered to have good dental health. It is probably reasonable to conclude the larger sample of parents in the quantitative study would have reached the same consensus. Half of the participants in the qualitative study discussed the potential impact of oral health education, or a lack thereof, on oral health status, with all

participants who mentioned education feeling that it was critical to ensure the correct information was being delivered but these feelings did not appear to be linked to educational attainment.

Within the qualitative study, all participants reported that their own dental health was important to them, but some differences were noted in terms of its relationship to general health (see Section 6.8.2.2.3).

> *“If you're going to need a quadruple bypass or, you know, some teeth extracted, you know, they don't measure one against the other.” (Participant 18, Non-FiCTION, Male, 56 years old)*

In the quantitative study, higher proportions of participants rated their general health as very good or good, than rated their oral health as very good or good. The majority of participants within the qualitative study were attending the dentist regularly and did so to enable the dentist to identify problems within their mouth early. This would partially support the quantitative finding that the majority of participants felt their dental health was very good, good or fair but does not explain why, on average, participants reported their general health to be better than their dental health in the quantitative study.

7.2.2.2. Research - dissonance

Some participants in the qualitative study perceived that socio-economic status would influence research participation, but based on their employment status reported during their interviews, it did not seem to make a difference. However, by definition, these participants had opted in to participate in a research study and so may not be representative of the average population. Socio-economic status encompasses not just income but also educational attainment, financial security and subjective perceptions of social status and social class. The quantitative data revealed that participants involved in the IMPACT study were more educated when compared to national populations suggesting that there may have been participation bias but this cannot be confirmed definitively as we were unable to compare this data against the socioeconomic status for participants who were eligible to participate in the IMPACT study but who declined.

It has been claimed by some researchers, especially in the USA, that racial and ethnic minorities are less willing than non-minority individuals to participate in health

research (Wendler et al. 2006). Within the qualitative study, one ethnic minority participant felt that under-representation of minority ethnic groups in research may be an issue. However, this feeling was not reported by other minority participants within the qualitative study. The quantitative study highlighted that the vast majority of respondents were white and that a very high proportion of the small number of ethnic minority parents who initially consented to IMPACT were lost to follow up. As demographic data were not obtained on those who were approached for but who declined IMPACT, it was not possible to confirm whether there was participation bias (a) in respect of FiCTION vis-à-vis the underlying populations of the FiCTION practices and (b) in respect of IMPACT, with regard to ethnicity or socio-economic status. It was reported that FiCTION practices were selected from areas reflecting ethnic diversity, fluoridation status and funding system differences but the applicability of this information is potentially limited as some practices are likely to have had large and heterogeneous catchment areas for patients.

7.3. Discussion

Undertaking triangulation had the potential to strengthen the validity of interpretations based on the large, rich quantitative data set. By triangulating the findings from different methodological approaches, both datasets were explored further.

Despite the apparent simplicity of the concept of triangulation, it is a complex process to undertake, presenting several challenges. First, due to the differences in the data set (i.e. different focus), their content varied. This had implications on how the data sets were analysed and the extent to which the content of the data set directly related to the central research question. Despite this, I would advocate treating qualitative and quantitative datasets as complementary rather than in competition. This is primarily due to the infancy of primary care research within dentistry, since standardised measurement tools may not measure the impact of interventions fully. Both quantitative and qualitative elements are needed in these studies to increase the likelihood of a better understood set of results.

7.4. Conclusion

Participating in a RCT does not appear to impact on a parent's dental, OH-RQoL and attitude to their dental care and that of their children but caution is required in interpreting these findings, since the Non-FiCTION group in IMPACT was almost

entirely (200 out of 206) comprised of parents whose children were FiCTION ineligible, not those whose children were eligible but had decided against their child's participation in FiCTION.

The qualitative study identified positive parental experiences and reported that parents were happy to be involved in the FiCTION RCT if it had minimal impact on their child and would lead to improved treatment for future children. Although the quantitative and qualitative studies did not identify any obvious discord between parental age, ethnicity and socio-economic groups, triangulation highlighted the importance of exploring and understanding disagreements in data sets. The participants in the quantitative study were not fully representative of the underlying general population in terms of age, ethnicity or socio-economic status. The project had significantly more success in terms of exploring diversity within research participation with the qualitative study and was able to incorporate the viewpoint of ethnic minorities and differing socio-economic groups more successfully. This suggests that whilst we "feel our way" with primary dental care research, qualitative studies may support this journey better.

Chapter 8: Discussion and conclusions

This final chapter discusses key findings in the context of the literature, alongside strengths and weaknesses from each of the strands of the IMPACT study. It explores implications for clinical care and concludes with the impact of the research to date and a proposal for future research.

8.1. Key findings

8.1.1. *Quantitative study findings*

Of the 312 participants sent an IMPACT baseline questionnaire, 261 (83.7%) completed and returned it (see Section 5.5.2.1). Overall, 200 follow-up questionnaires were returned (response rate 76.6%) and 192 of these (73.6% of those providing a baseline questionnaire, 96% of those returning a follow-up questionnaire) were included in the analysis of change over time (see Section 5.5.2.1).

The quantitative study examined the difference at baseline, with respect to parental dental anxiety (MDAS), oral health-related quality of life (OHIP-14), dental health beliefs (DHB) and sense of coherence (SOC-13) regarding their own dental care and that of their children, between parents of children with active caries and participating in an RCT in primary dental care (FiCTION) and parents of children without active caries and not participating in an RCT. The analysis for all participants in IMPACT suggested there was no difference between the groups at baseline for any of these four outcome measures (MDAS, OHIP-14, DHB SOC-13) (see Section 5.6.1). The analysis of covariance (ANCOVA) models to assess change over time in outcome, and controlling only for baseline score, showed that FiCTION status alone was not statistically significantly associated with change from baseline to 18 months in parental MDAS, OHIP-14, DHB and SOC-13 (see Section 5.6.1). The analysis was then expanded to include a number of additional possible confounders (e.g. age, gender, education) to the models that included baseline score and FiCTION status only. None of the possible confounders, either when included one at a time or when added simultaneously to the multivariable models, were statistically significantly associated with change from baseline to 18 months, and their inclusion had only a very minor effect on the estimated between-group differences (see Section 5.6.1).

Parents' dental anxiety (DA) remained below the MDAS cut-off score of 19 for "very dentally anxious" at baseline and 18 months from baseline, representing low-moderate DA (Humphris et al. 1995). A previous study reported the 2008 UK

population total mean (SD) norm for MDAS for adults 30-39 years old was 11.61 (5.88) (Humphris et al. 2009); the mean baseline MDAS total score (SD) was 11.8 (6.3) for FiCTION parents and 10.9 (4.8) for Non-FiCTION parents. As mentioned previously in Section 5.6.2.7, direct comparison with the IMPACT sample against the ADHS population is not currently possible for OHIP-14. Parents' OHIP-14 remained low throughout the study indicating that parents were satisfied with their own dental health (Slade 1997); the mean baseline OHIP-14 total score (SD) was 6.7 (6.1) for FiCTION parents and 6.7 (6.5) for Non-FiCTION parents. Parents' DHB also remained low throughout the study, indicating favourable oral-health-related beliefs (Broadbent et al. 2006); the mean baseline DHB total score (SD) was 9.2 (1.6) for FiCTION parents and 6.7 (6.5) for Non-FiCTION parents. Parents' SOC-13, including for all sub-domains, remained strong throughout the study, indicating that parents were "likely to feel less stress and tension and to believe they can meet demands" (Eriksson and Lindstrom 2007); the mean baseline SOC-13 total score (SD) was 63.7 (7.8) for FiCTION parents and 62.9 (7.0) for Non-FiCTION parents. The total SOC-13 scores obtained for the IMPACT study are comparable to mean (SD) norms previously recorded for a sample of adults from Glasgow (67.6), Liverpool (63.1) and Manchester (59.3) (Walsh et al. 2014). SOC-13 had also been compared in Glasgow among deprived and affluent groups in the city, with fairly similar results: the SOC-13 score was 59.6 for the deprived group and 70.3 for the affluent group (Packard et al. 2012). As mentioned earlier (see Section 5.6.2.3), of the 72 practices in the UK that randomised at least one child to the FiCTION RCT, 23 (32%) were in the first (most deprived) quintile, 21 (29%) in the 2nd, 10 (14%) in the 3rd, 12 (17%) in the 4th and 6 (8%) in the 5th based on the dental practice postcodes (Maguire et al. 2020). IMPACT total SOC-13 scores suggest that parents from deprived and affluent groups were captured. These outcome measure findings indicate that a parent's participation in this study had a negligible impact on their perception of their own dental health.

A lack of effect is not sufficiently established by a failure to demonstrate statistical significance. However, a failure to reject the null hypothesis of no effect may be the result of low statistical power when an important effect actually exists and the null hypothesis of no effect is in fact false (Hoenig and Heisey 2001). There is a large, current literature that advocates the inappropriate use of post-experiment power calculations as a guide to interpreting tests with statistically non-significant results (Hoenig and Heisey 2001). However, once a confidence interval has been

constructed, power calculations yield no additional insights. Post hoc power based on observed data has not been calculated here as it is directly related to the P-value and will always be less than 50% when the P-value is greater than 0.05 (Hoenig and Heisey 2001). The 95% CI provides the range of 'true' (population) mean differences that are statistically compatible with the observed data. Narrow CIs that don't include differences that would be considered clinically meaningful would be considered to indicate adequate power. The revised target sample size of 66 participants per group, to detect as statistically significant a mean difference between groups of 4 points in OHIP-14 scores at 18 months, was based on a t-test and used a standard deviation of 6 points (and the 66 allowed for 25% attrition and so equated to an achieved sample size of 49 per group). The ANCOVA model utilised was a more efficient analysis than a t-test and the pooled SD for the comparison of the means from the model was 3.7 points, smaller than the 6 points used in the sample size calculation. For the OHIP-14 outcome, we required an achieved sample size of 98 (49 per group); we achieved 167 (31 in the FiCTION group and 136 in the Non-FiCTION group) (See Table 5.1). This resulted in a small loss of power associated with the FiCTION group (31 actual vs 49 required) but a gain in power associated with the Non-FiCTION group (136 actual vs 49 required). The smaller observed SD and the larger overall achieved sample size would support the conclusion that the study was adequately powered to assess the stated hypothesis. In line with STROBE guidelines (Vandenbroucke et al. 2007), I reported 95% confidence intervals (CI) for the quantitative study allowing open interpretation of the findings to be considered along with study size. For all outcomes, the 95% confidence intervals for the adjusted mean difference in the change from baseline are 'narrow' and did not include a difference in change of score between groups for each outcome measure that would be considered clinically meaningful (Cook et al. 2018):

- After adjustment for baseline MDAS, the estimated mean change from baseline to 18 months was an increase in MDAS of 0.23 for FiCTION parents and of 0.31 for Non-FiCTION parents, with the mean difference in the change being -0.08 (95% CI, -1.02 to 0.87), p>0.9.
- After adjustment for baseline OHIP-14, the mean change from baseline to 18 months was an increase in OHIP-14 of 0.18 for FiCTION parents and a decrease of 0.02 for Non-FiCTION parents, with the mean difference in the change being 0.21 (95% CI, -1.24 to 1.65), p=0.8.

- After adjustment for baseline DHB, the mean change from baseline to 18 months was a decrease in DHB of 0.20 for FiCTION parents and of 0.10 for Non-FiCTION parents, with the mean difference in the change being -0.11 (95% CI, -0.63 to 0.43), p=0.7.
- After adjustment for baseline SOC-13, the mean change from baseline to 18 months was a decrease in SOC-13 of 0.39 for FiCTION parents and of 0.32 for Non-FiCTION parents, with the mean difference in the change being -0.06 (95% CI, -2.50 to 2.37), p>0.9.

Previous research, albeit of varying quality and design, has identified parent-related barriers and facilitators such as ethnicity, cultural, gender, socio-economic status and the health status of the child, to the child's RCT participation, though findings are not consistent across studies (see Section 2.3). Findings from the current study suggest that these variables are not associated with participation. However, it cannot be confirmed that they do not affect decisions regarding participation, since the Non-FiCTION group in IMPACT was almost entirely (200 out of 206) comprised of those who were FiCTION ineligible, not those who were eligible but whose parents decided against participation in FiCTION. Further research may be needed to examine more closely the barriers and facilitators of the decision by parents to allow their child to take part in research for which they are eligible.

8.1.2. *Qualitative study findings*

Informal discussions, along with findings from the literature review (see Section 2.3.6), with dental care teams when discussing the IMPACT study illustrated some concern about the potential time commitments on parents to conduct the qualitative interviews, and how they might interfere with work and child-care commitments. This concern was not borne out in practice. Of the 19 families approached to take part in this element of the research, 18 agreed, with only one parent not participating in an interview. Although there was some anecdotal suggestion of the qualitative interviews interfering with parents' normal day-to-day activities when scheduling them, my flexibility made the burden acceptable. Anecdotally, the interviews being held during the daytime were more likely to be viewed as convenient. Although not vocalised when arranging the meeting, there was a suggestion that fathers did not feel comfortable having me, a female, attend their home unaccompanied; all fathers who

participated in this element of the research either arranged the interview to be held in a public place or had a chaperone in their home during the interview. This concern was not evident with mothers and it remains unclear whether they would have responded similarly with a male researcher.

The FiCTION and Non-FiCTION parents were very similar in terms of their previous dental experiences and the dental attendance of their child. An interesting finding was that the sampled Non-FiCTION parents seemed to have established a routine with their approach to dental attendance i.e. they went because they felt it was "normal" that they should or alternatively they had become complacent due to a history of good dental health (see Section 6.8.2.5). This is interesting as, whilst traditionally dentists have encouraged the practice of recommending 6 monthly dental check-ups, there is, however, little information to either support or refute this practice, or to advise either patients or dentists of the best dental recall interval for the maintenance of oral health. This is being investigated by a National Institute for Health Research (NIHR) funded national RCTs in primary dental called INTERVAL (Dental recalls trial) (see Section 1.6.4); meanwhile, IMPACT suggests that Non-FiCTION parents may have become complacent and assumed there would be nothing wrong, making them less likely to attend the dentist. FiCTION parents appeared to attend more out of a sense of duty (see Section 6.8.2.5).

There was a significant range in views, knowledge and experience about participation in primary care research amongst the cohort of parents interviewed. This did not seem to be greatly influenced by their FiCTION status (see Section 6.8.3.6). This is not wholly surprising, given that the Non-FiCTION group in IMPACT was almost entirely comprised of those who were FiCTION ineligible usually because their child had no active decay.

Almost all parents perceived the importance of parents, particularly mothers, "ingraining" good habits into their children at a young age and they felt that without regular parental attention that children would not have the motivation or insight to look after their mouth properly. The vital importance that parents have in "caring for your baby's teeth is one of many important responsibilities as you become a parent" (British Society of Paediatric Dentistry 2016, p. 2) is already widely recognised by dental professionals.

Considering that it states in the NHS Constitution that the NHS commits "to inform you of research studies in which you may be eligible to participate" (Department of Health 2015, p. 8) and that this should extend to dental patients as well, it will be interesting to see whether dental practices' research participation profile enters into the public domain. I was unable to find any evidence that would suggest this is being considered. If dental practices' research participation profiles were to enter into the public domain, it would be interesting to explore whether parents attitudes towards "ingraining" good habits into their child would extend to them routinely participating in research studies.

Parents reflected on why I was investigating the study topic. A few parents understood that the FiCTION RCT might show one management strategy to be better (see Section 6.8.3.3). Nonetheless, they expected dental teams to continue to draw on what they knew about an individual child and their family as well as their own clinical experience in order to decide how to best manage their child (see Section 6.8.3.6.1). This was also a finding of the FiCTION RCT qualitative evaluation with parents/guardians where the: 'treatment arm was felt to be generally acceptable to children and parents but trust in the DP played a significant role' (Maguire et al. 2020).

The findings from the IMPACT and FiCTION qualitative studies, echoed findings from Snowdon et al. (1997) who completed in-depth interviews with parents who had previously agreed for their critically ill baby to participate in a potentially lifesaving but also potentially risky treatment which might lead to the death of their child. This study (Snowdon et al. 1997), along with the IMPACT qualitative study, highlighted that not all patients understood randomisation and that many parents were not comfortable with the concept. Patient concerns regarding randomisation have been reported by other researchers within other healthcare specialities (Featherstone and Donovan 2002, Slevin et al. 1995).

8.1.3. *Key findings in relation to the literature*

As outlined in Section 5.6.3, funding is available for Studies Within a Trial (SWATs) (Health Research Board Trials Methodology Research Network 2019, National Institute for Health Research 2019a) to address a methodology research question on

any aspect of a RCT for which there is current uncertainty (Treweek et al. 2018a) or to evaluate approaches to support trial delivery success within HTA main trials (National Institute for Health Research 2019a). The added value to RCTs of qualitative research, by solving problems at the pretrial stage, explaining findings, and increasing the utility of the evidence generated by the trial has previously been reported (Lewin et al. 2009). The IMPACT Study did highlight some additional challenges with carrying out a study nested in a RCT in primary dental care. The added value of qualitative research to RCTs has been classified by three different relationship models: 'the peripheral', in which the purpose of the qualitative research was not to provide value for the RCT but to address another need such as to support a research degree for a researcher; 'the add-on', in which the qualitative researcher understood the value of the qualitative research but felt the study was considered by the RCT lead investigator(s) and wider team as a separate project which did not add value to the RCT but rather generated knowledge that was complementary to the RCT; 'integral', in which the study lead viewed the qualitative research as essential to the RCT due to complexities and uncertainties about the RCT or intervention (O'Cathain et al. 2014). Using the same descriptors, I would describe the IMPACT study as largely having an 'add-on' relationship with the FiCTION RCT.

As outlined in Chapter 2, in the UK only a small proportion of trials actually recruit successfully to time and target (McDonald et al. 2006, Martin-Kerry et al. 2015). The majority of research studies investigating recruitment and retention challenges in RCTs are focused on adult populations (Eiser et al. 2005). It is commonly suggested that being young, less educated, of an ethnic minority and having low SES are barriers to participation in some RCTs, although there is little agreement between studies and these characteristics are not always considered (Robinson et al. 2016). As the population of England, Wales and Scotland is becoming increasingly ethnically diverse (Office for National Statistics 2014), the potential implication of ethnicity on research participation was important to consider in the IMPACT study. The lack of ethnic diversity in the FiCTION practices introduced some limitations in exploring the implication of research participation namely the participants were largely considered simply as 'white' or 'other' and their diversity and variations in cultural background not fully explored. Whilst it is possible that those who were not recruited to FiCTION, either because they were ineligible or did not consent, were from a more ethnically diverse background, I suspect that this is unlikely, given that

the main reason for non-participation was ineligibility. To support further exploration of the implication of ethnicity on research participation, I incorporated ethnic diversity when sampling for the qualitative element of IMPACT study. However, ethnicity is largely a matter of self perception rather than objective fact (Allmark 2004). This leads to a further problem of how people end up in particular categories - for example, people categorised as Afro-Caribbean may have very different ethnic backgrounds; some may have one “white” parent. It has been reported that accurate definitions regarding ethnicity are impossible “because of the absence of meaningful boundaries (Allmark 2004). It is up to users of research, including clinicians and policy makers, to appraise study findings and decide themselves whether the results are applicable to the population they are interested in.

As also outlined in Chapter 2, previous research has reported that decision-making by an adult on behalf of a child is recognised to be a different experience to an adult making a decision for themselves (Shilling and Young 2009). Whilst we are moving more towards research conducted “with children” rather than “on children” (Marshman et al. 2015), parents are likely to wish to retain some degree of proxy control for their children, in addition to their being legal and regulatory expectations that this is the case. The perception of a study’s risks and benefits is amongst the most important determinants of a parent’s decision to allow his or her child to participate in a medical research study (Tait et al. 2004). Parents’ thoughts about involvement in a primary dental care-based trial has not been explored previously, which may be partially due to the persistent separation of dentistry from medicine which, in the case of Britain, started to occur in the early to mid-20th century. By essentially “separating the mouth from the body” (Nettleton 1988) this may have created challenges, hindering the transfer of information and education between healthcare professionals and indirectly impacted on the importance that parents place on their children participating in a dental research study (rather than a medical research study). Whilst it could be argued that dental research projects could be considered less risky than trials of drug interventions, and this might influence decision making, the qualitative data tentatively shows this would require further investigation.

8.2. Strengths and limitations

8.2.1. *Strengths*

The size of the IMPACT study, with 261 parents recruited across 27 dental practices across Scotland and north-east England is a significant strength and the findings will add to the vast amount of quantitative and qualitative data collected within the FiCTION RCT from a range of different perspectives (dental teams, children and parents participating in the FiCTION RCT). FiCTION did not, however, collect any data from parents whose children were not participating in the RCT. IMPACT primarily adds the voices of those parents who would otherwise be silent, by reason of their child not participating in the FiCTION RCT. There is a lack of published studies undertaken in dentistry, using either quantitative or qualitative methods, to assess parental barriers or faciliators to their child participating in a RCT (Keightley et al. 2014, Martin-Kerry et al. 2015) and very few PhD studies have taken the pragmatic approach of bolting onto a primary care dental research study in the UK with the RCT study forming the basis of study recruitment. Efforts were made to recruit from every FiCTION-participating dental practice within Scotland and north-east England to give a representative sample of parents from the two chosen areas.

Although the rate of recruitment to IMPACT was relatively slow, there was good balance between both FiCTION and Non-FiCTION groups in terms of their age, relationship to child and ethnicity. Whilst there was a large difference in the highest education level completed between the FiCTION and Non-FiCTION parents, the study team felt this could be a reflection of a confounding factor in respect as to why their child was not participating in the FiCTION RCT i.e. that children of better educated parents were more likely to be ineligible to participate in the FiCTION RCT because they did not have active caries.

Retention rates in IMPACT were good. Overall, 200 parents were followed up for over 18 months and 192 of these could be included in the final analysis of change analysis set. Characteristics of both groups of parents were similar in terms of age, relationship to child, ethnicity and education level.

In the quantitative study, it was recognised that structured questionnaires were a useful and quick method of obtaining straightforward data from a large number of parents. The questionnaire was piloted to test the questions, their wording and

format, the sequence, transition statements and skip questions as it was recognised that questions must be clear, concise and to the point to avoid them being misunderstood or misinterpreted. Following this pilot, a parental date of birth question was incorporated to check that the 18 months after baseline questionnaire had been completed by the same intended respondent and not someone else in the family; this facilitated matching of baseline and follow-up data.

The clarity of the instructions in the covering letter, and the layout and length of the questionnaire were deemed appropriate once the non-validated questions relating to dental treatment were moved to the beginning of the questionnaire and demographic data moved to the end of the questionnaire. In addition, well validated instruments were used to collect data on DA (see Section 4.11.1.2), oral health-related quality of life (OH-RQoL) (see Section 4.11.2.1) and attitudes (see Sections 4.11.3.1 and 4.11.3.2) and explicit procedures were used for imputation of missing data (see Section 5.4.9.3.1). Collectively, these processes resulted in a high level of data completion and availability of data for the comparison of scores over time.

I conducted quantitative analysis with two PhD supervisors (one of whom is a statistician) overseeing the more technical aspects of the statistical analysis. Analysis followed a pre-defined statistical analysis plan, informed by the study's aims and objectives.

A purposive sampling (Tongco 2007) strategy was employed for the qualitative element of the research, to ensure diversity of views, and data collection continued to the point of saturation (Palinkas et al. 2015). Efforts were made to minimise any power imbalance that could exist between myself and parents ((Elwood and Martin 2000). Flexibility in respect of time and place of interview was offered, to minimise participant burden. I stressed that the interview could be stopped at any time and I also indicated to parents that I was prepared to make notes if the parent was not willing to be recorded, however no parent requested that the recorded interview was not used. The qualitative study was designed with input from one of my supervisors (with qualitative expertise) and the topic guide constructed to allow parents to tell their story in their own way, while ensuring that the aspects I wanted to explore were covered. The order of the questions was changed following two pilot interviews to put parents more at ease and to help them begin to talk; the pilot participants had felt

that discussing the dental theme first would make parents feel they have something to say. Once rapport between the parents and myself had been established, I then started to ask more detailed questions about the theme of research participation. I was prepared to assess signs of distress or interview fatigue from parents but none was noted. All interviews were conducted and analysed by me, a dentist, with significant input during their analysis from one of my PhD supervisors who is a psychologist (with qualitative expertise). This enabled more technical aspects of dentistry to be explored but ensured socio-cultural aspects were not overlooked.

The inclusion of the qualitative study provided in depth data to address two secondary objectives. First, an understanding of parents' views, knowledge and experience regarding their own and their families' dental care and any differences therein between those parents whose children were participating in a RCT in primary dental care (FiCTION) and those parents whose children were not participating in a RCT in primary dental care. Second, an understanding of parents' views, knowledge and experience about participation in research and any differences between FiCTION and Non-FiCTION parents. By completing the triangulation, it was possible to demonstrate that whilst we "feel our way" with primary dental care research, qualitative studies may support this journey better than using quantitative studies alone.

8.2.2. *Limitations*

The study experienced challenges throughout its course, primarily related to the quantitative component of the study.

Recruitment and retention of participants to the original target sample size within the time originally specified is a recognised challenge (Campbell et al. 2007). Bower (2007) and colleagues found that less than a third of UK primary care trials recruited to their original timescale. The FiCTION RCT was no exception, with slower than predicted recruitment impacting on the length of time individual practices were involved in the RCT. Some practices had high staff turnover resulting in the need for additional training in and reinforcement of the FiCTION RCT (and by extension the IMPACT study). Study fatigue was also anecdotally reported to me by the FiCTION support staff, clinical leads and dental teams. It became evident to me fairly early on

that the plan for practice staff to issue the IMPACT study paperwork to parents whilst in the dental practice was not viable and an alternative option was required. The solution was for dental practices, with my support, to post the material out to parents. Whilst increasing the chance of parents being recruited into IMPACT, this introduced practical limitations in respect of resources (since this approach had not been costed for). It also introduced logistical challenges to me in terms of travelling and accessing the relevant information without affecting the practice's running of day-to-day activities. It also meant that IMPACT packs went to some parents who were not IMPACT eligible, because they never attended a FiCTION screening visit. These parents were ineligible for the IMPACT study and were unnecessarily burdened by receiving the IMPACT packs. This also gave me additional administrative burden and unnecessary expenditure.

The most significant limitation of the IMPACT study was the lack of recruitment of parents whose children were FiCTION eligible but declined to participate in both the quantitative study (n=6) and the qualitative study (n=1). It is unclear whether these parents would have reported different findings. If the FiCTION screening logs had been more robust, we would have been able to estimate how many FiCTION eligible but declined children would have been expected.

The revised target sample size of 66 per group was exceeded for the Non-FiCTION group. However, even with extending my recruitment time and invoking the revised recruitment strategy referred to above, recruitment into the FiCTION group fell short of this target. It may have been possible to achieve the retention of 66 FiCTION parents in the IMPACT study by continuing to recruit up to the end of the FiCTION RCT recruitment period. However, at that time there was a concern that the time-only extension for FiCTION RCT might not achieve the trial's revised target sample size. Due to IMPACT being undertaken as part of a PhD, the decision was made to end recruitment into the quantitative element of the IMPACT study in December 2014 and the smaller IMPACT FiCTION parent group was accepted and acknowledged as a limitation within the IMPACT study. The last child was recruited into the FiCTION RCT in June 2015. This highlights the challenges involved in including small, even underpowered non-randomised observational studies in alongside RCTs. Bolting them on as PhD studies may be problematic if the main study runs into challenges and experiences delays.

In retrospect, as this was a longitudinal observational study, I could have considered repeating the administration of the questionnaire to the pilot subjects after a short interval to assess “test-retest reliability” (Brazier et al. 1992). Whilst it is unlikely the results would have changed, ideally this reliability test should have been completed.

There were several limitations of the qualitative study. Firstly, the “research” theme was not embedded in the quantitative questionnaire. I only interviewed participants who returned a completed IMPACT baseline questionnaire. No claims can be made about participants who would have been willing to participate in the qualitative study but not engage in the quantitative study. As mentioned previously, all interviews were conducted and analysed by me. I am a dentist and this could have introduced a limitation as it is possible that I may have overlooked some research topics that a more dentally-naïve individual would have explored, either in questioning or in data analysis and interpretation. I was unable to find any literature which has considered the implications of background and skill-mix (social scientists vs clinicians) in conducting and analysing qualitative interviews healthcare research.

Patient and public involvement (PPI) in research is advocated on the grounds that people affected by a condition, or the wider public in the case of public health research, have a right to have a say in decisions about research that may affect them. Before the FICTION RCT commenced, a pilot trial was designed and conducted. Service provider (dentists and other members of the team including dental nurses and practice managers) and participant (child participants and their parents) involvement was incorporated into the pilot trial (Marshman et al. 2012). Even with extending my recruitment time and invoking the revised recruitment strategy referred to above, recruitment into the FiCTION group in the quantitative study fell short of its target. It is possible and plausible that discussion and engagement with existing trial participants and participating practices may have suggested strategies to optimise recruitment to and retention in the IMPACT add-on study. However, resource and time constraints precluded conducting separate PPI for the IMPACT study.

8.3. Methodological rigour

8.3.1. *Generalisability*

The demographic and clinical characteristics of the FiCTION practices represented the wide range of characteristics shown by practices operating in UK primary care NHS dentistry. A total of 27 practices, more than half of the dental practices linked to the Scottish and north-east England FiCTION practices, participated in the IMPACT study. Evidenced through the large number of practices and diversity of location shown, including urban and rural areas and in areas with a range of practice deprivation scores, I believe that the findings are generalisable to parents whose children regularly attend primary care dental practices in these parts of the UK.

Dental teams were asked to recruit eligible children to the FiCTION RCT when they attended their routine dental check-up appointments. Ideally parents should have been approached to discuss the FiCTION RCT first, and then, after the screening had been completed and eligibility for FiCTION had been determined, the IMPACT study would have been mentioned. Unfortunately, limited information in the FiCTION screening logs meant that it was unclear whether the IMPACT children were truly representative of the FiCTION RCT and leaves the study open to selection bias (Petrie et al. 2002). In particular, in practices when the FiCTION invitation letters were given out to parents, these may have only been given out to parents the recruiting staff knew well (biasing the sample to regular attendees and those with greater treatment experience) or to those particular groups who they thought may respond better to the FiCTION invitation, which may introduce other demographic biases. The underlying population of the IMPACT study were parents identified and considered for the FiCTION RCT in Scotland and north-east England. If this underlying population has not reflected the entire population of 3-7 years old children in the UK, then the IMPACT study will not be completely generalisable to all parents in the UK with children in this age range. Moreover, as most practices opted for postal recruitment to the IMPACT study, with IMPACT and FiCTION invitations issued together, some parents who did not attend FiCTION screening (estimated at 35%) were also approached. As already noted, very few parents (n=6) who were unwilling for their child to participate in FiCTION agreed to IMPACT participation. In retrospect, I could have revised my approach and asked dental practices to explore whether parents would be willing to discuss another dental research study over the telephone with me first; if in agreement, then the relevant consent could have been

ascertained. The limited information on the FiCTION screening logs means I am unsure whether there was any bias within the practices in terms of who was approached for the IMPACT study.

Major efforts were made to engage with ethnic minorities within the IMPACT qualitative study as it has been suggested that families from ethic minority groups are less likely to participate in research (Wendler et al. 2006). I had good success in recruiting IMPACT parents from ethnic minorities to the qualitative study, but less success in recruiting them to the quantitative study. In quantitative research, the importance of internal validity and external validity (generalisability) has been long accepted and well documented in the literature. In qualitative research, discussions of validity have been more contentious and different typologies and terms have been produced (Pope and Mays 1995). I would argue that the sampling method, analysis and interpretation were sufficiently rigorous to ensure that the findings were an accurate reflection of what was being studied within the qualitative study. Within the quantitative study there was evidence of an ethnic minority under-representation that is of note in terms of generalisability. This research was taking place in the context of ongoing policy concern and academic debate around issues of ethnic diversity, integration, immigration and inequality. I would suggest that further work is required to better understand barriers to quantitative dental research with consideration towards how changing patterns of ethnicity and associated cultural backgrounds relate to recruitment in research studies.

8.3.2. *Choice of outcome measure*

The outcome measures (MDAS, OHIP-14, DHB and SOC-13) included in the quantitative study were diverse but felt by the study team, based on the existing literature (see Section 4.11), to be important potential predictors to quantify if a child's participation in a RCT impacted on their parent's DA, OH-RQoL and attitude to their own dental care and that of their children.

In both the quantitative and qualitative studies, the instruments used to collect the data could have been developed further. Specifically, the quantitative questionnaire could have included more questions regarding participants' previous experience or research and their knowledge and views around the topic of research. After the

IMPACT study began, a report was published, funded in part by the NIHR Clinical Research Network: Wessex, involving the public and healthcare professionals which has explored their attitudes towards clinical research, their likelihood to participate and the drivers and barriers to increasing participation and recommending actions for increasing research participation (Stock and Hickman 2014). Some of the topics discussed within this report could have also been explored with the IMPACT parents and would be a useful source of reference for future research. I could have used a parent-based patient-public involvement group involving parents, clinicians and researchers together to provide suggestions for additional questions to include both in the quantitative questionnaire and in the qualitative topic guide. Although this may have presented a considerable extra demand on resources, this may have been a worthwhile investment since good qualitative and quantitative data is a vital aspect of the triangulation process.

8.4. Recommendations on aspects of research conduct

Research on questions relevant to primary dental care practice, and within primary dental care settings, is an essential component of the clinical research efforts. Whereas over 90% of all NHS dental contacts occur and end in general dental practice, anecdotally only a minority of the clinical research effort is either planned by general dental practice or takes places within this setting. There is a need for research support (see Section 2.4.2), aimed at primary care, designed to give the dental teams confidence and necessary skills in conducting dental research alongside their normal busy day-to-day activities. The Oral and Gastrointestinal health category (UK Clinical Research Collaboration 2015) under which dental research sits, makes it quite difficult to see what is going on in dentistry and whether it is in primary or secondary care.

It is clearly possible for very important research to emerge from the interests and enthusiasm of individual practitioners. However, complementary research opportunities are created by a team approach, which can explore questions that an individual researcher could find difficult to answer. The IMPACT study was not planned when the FiCTION RCT began. My interest in primary dental care research opened a debate with two of the FiCTION Chief Investigators on whether there was need to explore the area further and consequently this PhD topic evolved. Whilst embedding additional smaller research studies may cause additional work for the

core research team, and caution is needed in respect to increasing participant burden, the potential enrichment to the research area of interest should not be overlooked (Health Research Board Trials Methodology Research Network 2019).

Observational studies serve a wide range of purposes: from reporting a first hint of a potential cause of a disease, to verifying the magnitude of previously reported associations (Vandenbroucke et al. 2007). However, reporting of observational research is often not detailed and clear enough to assess the strengths and weaknesses of the investigation (Vandenbroucke et al. 2007). Having a team with the right skill sets is key to ensure observational studies are reported fully and clearly.

The target population for IMPACT were parents whose children had been screened for the FiCTION RCT and therefore recruiting in practices was the most logical and practical method to use. It can be seen, by contrasting the FiCTION RCT and the IMPACT study, that, although primary care can be a good source of research participants, having a researcher on the ground is key to success, and any primary care based study needs to be carefully designed to minimise the impact on practice staff when they are involved alongside running a busy practice. Having clinical studies officers or research nurses, perhaps employed by the NIHR CRNs, who could go into general dental practices and support them in delivery would almost certainly be of value. In all likelihood for the IMPACT study this may have avoided the expenditure of posting the questionnaires, increased the questionnaire response rate resulting in a greater probability of the target sample size being achieved and reduced the recruitment period. The need for training of general dental practitioners involved in primary care research has been widely recognised (Clarkson 2005, Crawford 2005, Hopper et al. 2011) and the additional need for dedicated members of staff or researchers is now also being reported (Keightley et al. 2014, Martin-Kerry et al. 2015).

8.5. Conclusion

Chapters 5, 6, 7 and 8 have addressed all four objectives of the thesis, and the conclusions are summarised below;

8.5.1. *Objective 1*

To quantify the difference at baseline, with respect to parental dental MDAS, OHIP-14, DHB and SOC-13 regarding their own dental care and that of their children, between parents of children with active caries and participating in a RCT in primary dental care (FiCTION) and parents of children without active caries and not participating in a RCT.

Quantitative analysis showed no difference at baseline in MDAS, OHIP-14, DHB or SOC-13, between FiCTION participant parents (Mean (SD) score 11.8 (6.3), 6.7 (6.1), 9.2 (1.6), and 63.7 (7.8) respectively) and FiCTION non-participant parents (10.9 (4.8), 6.7 (6.5), 9.4 (1.9), and 62.9 (7.0) respectively).

8.5.2. *Objective 2*

To quantify the difference in change from baseline to 18 months between these two groups of parents in parental MDAS, OHIP-14, DHB and SOC-13 regarding their own dental care and that of their children.

We failed to reject the null hypothesis of no difference. The basic ANCOVA models, controlling only for baseline score, showed the mean difference in the change (95% CI) for FiCTION and Non-FiCTION parents from baseline to 18 months for MDAS, OHIP-14, DHB and SOC-13 respectively was -0.08 (95% CI, -1.02 to 0.87), p>0.9, 0.21 (95% CI, -1.24 to 1.65), p=0.8, -0.11 (95% CI, -0.63 to 0.43), p=0.7 and 0.06 (95% CI, -2.50 to 2.37), p>0.9. The basic ANCOVA models, controlling only for baseline score, showed that FiCTION status alone was not statistically significantly associated with change from baseline to 18 months in parental MDAS, OHIP-14, DHB and SOC-13.

After extending the ANCOVA model to include a number of additional possible confounders, the estimate of the mean difference in the change from baseline between FiCTION and Non-FiCTION groups for MDAS, OHIP-14, DHB and SOC-13 respectively was reduction from 0.11 points lower in the FiCTION group to 0.003

points lower (95% CI, -1.0 to 1.0), reduction from 0.60 points higher in the FiCTION group to 0.59 points higher (95% CI, -0.97 to 2.14), reduction from 0.20 points lower in the FiCTION group to 0.11 points lower (95% CI, -0.68 to -0.46) and an increase from 1.19 points higher in the FiCTION group to 1.54 points higher (95% CI, -1.12 to 4.20). None of the possible confounders (e.g. age, gender and ethnicity), either when included one at a time or when added simultaneously to the multivariable models, were statistically significantly associated.

8.5.3. *Objective 3*

To investigate parents' views, knowledge and experience regarding their own dental health and their families' dental care and any differences therein between those parents whose children were participating in the FiCTION RCT and those parents whose children were not participating in that RCT.

All participants reported their own dental health was important to them. Just over half of participants reported going to the dentist on a fairly regular basis, either on a six monthly or yearly basis as a child. All parents reported that their child went to their dental check-ups regularly and the reasons given were the same for FiCTION and Non-FiCTION participants. More negative childhood experiences were reported by participants who had attended the dentist irregularly in their childhood. Participants' views regarding their own dental health were varied but there was no noticeable difference between participants' definition of good oral health or their perception of the facilitators and barriers to obtaining good oral health between FiCTION and Non-FiCTION participants.

8.5.4. *Objective 4*

To investigate parents' views, knowledge and experience about participation in research and any differences between parents whose children were participating in the FiCTION RCT and those whose children were not participating in that RCT.

Research involvement did not appear to be a major incentive to attend a particular practice although participants viewed dental practices which participate in research favourably. Both groups of participants (FiCTION and Non-FiCTION) included some individuals who struggled with explaining the concept of random allocation to a trial arm as well as with understanding the need for the clinical trial team to use random allocation rather than clinician and/or patient choice. The majority of participants felt comfortable with the concept of letting the research team know that they would like to

either withdraw from the FiCTION RCT entirely or asking to change the treatment approach being used. A minority of participants reported concerns with the practicalities, in terms of time or the location, of the qualitative interviews.

8.6. Further research

Despite qualitative interviews suggesting that parents value the need for research in primary dental care, the mechanisms for this remain complex and challenging. Primary care dentistry is complex. There is a clear need for better quality evidence on which to base practice and one of the keys to generating this evidence is to conduct primary care dental research studies.

There are several areas where further research may be beneficial:

1. The qualitative study, and the thesis in general, highlights the importance of educating the public in the purpose and practicalities of primary care research. Of the many useful comparisons, one of the more important is the possibility of under-representation of ethnic minorities in primary care dental research studies. This requires further investigation as, if certain research designs are more acceptable to those from ethnic minority populations, then deviation from the “gold standard” RCT may need to be considered.
2. The qualitative study suggested that the decision to participate in research is very personal to individual parents. Some parents did appear to genuinely see the value in participating in research to give their opinion, whereas for others, the value seemed to be based entirely on a sense of obligation to develop future research studies, for benefit to the next generation or to support their dental practice. Although the data collected within this thesis appeared to suggest a variety of parents had been recruited, it is difficult to be conclusive about precisely how parents feel about participating in a primary dental care RCT given the quantitative data collected did not have any research-specific questions. To answer this question definitively, it would be necessary to investigate this further.
3. Further work to explore the practicalities of providing the most appropriate support to primary care research being completed in a timely and more affordable manner would be beneficial.

Appendices

Appendix A: Parent questionnaire

School of Dental Sciences

Newcastle University
Framlington Place
Newcastle upon Tyne
NE2 4BW United Kingdom

Patient identification number:

Research staff only

- ☐ **Baseline**
- ☐ **18 months**

About these questions

In this booklet, you will find some questions about your own teeth and about your lifestyle.

Please answer every question. Most of the questions can be answered by simply circling a number. Occasionally you need to write a number in a box.

Some of the questions may seem to be asking much the same thing, but there are important differences and we need to know how you feel about each.

Don't think too long about any question. What comes into your head first is probably better than a long thought-out answer. If you have problems answering any question, please write that problem beside the question.

Remember that your name does not appear anywhere on this booklet. Only the study team will know who answered the questions. We will not tell anyone else what you said.

Thank you for helping us with this project.

1. How is your health in general; would you say it was…

Very good	……..	1
Good	……..	2
Fair	……..	3
Bad	……..	4
Very bad	……..	5

2. Would you say your dental health (mouth, teeth and/or dentures) is…

Very good	……..	1
Good	……..	2
Fair	……..	3
Bad	……..	4
Very bad	……..	5

3. How many natural teeth have you got?
(Include wisdom teeth – adults usually have up to 32 teeth, including the 4 wisdom teeth. Exclude implants to replace missing teeth) Is it…

None at all	…….	1
At least 1 but less than 10	…….	2
Between 10 and 19	……	3
20 or more natural teeth	……	4
Have some natural teeth but don't know how many	……..	5

4. I would now like to ask you about types of dental care/treatment that you have received from dentists over the course of your whole life. This includes any care or treatment you may have had as a child.

	Yes	No
Have you ever had any fillings?	1	2
Have you ever had any wisdom teeth extracted (taken out)?	1	2
Have you ever had any teeth extracted (taken out)?	1	2
Have you ever had a tooth crowned?	1	2
Have you ever had a dental bridge?	1	2
Have you ever had an implant to replace a missing tooth? (An implant completely replaces a tooth and its root, and is screwed into the bone)	1	2
Have you ever had sedation that is something that relaxes you but does not put you to sleep, for dental treatment? (Sedation can be in the form of gas, air or tablets. Local or general anaesthetic is coded as 'No').	1	2

5. If you went to your Dentist for *treatment tomorrow*, how would you feel?

Not Anxious	……..	1
Slightly Anxious	……..	2
Fairly Anxious	……..	3
Very Anxious	……..	4
Extremely anxious	……..	5

6. If you were sitting in the *waiting room* (waiting for treatment), how would you feel?

Not Anxious	…….	1
Slightly Anxious	……..	2
Fairly Anxious	……..	3
Very Anxious	……..	4
Extremely anxious	……..	5

7. If you were about to have a *tooth drilled*, how would you feel?

Not Anxious	……..	1
Slightly Anxious	……..	2
Fairly Anxious	……..	3
Very Anxious	……..	4
Extremely anxious	……..	5

8. If you were about to have your *teeth scaled and polished*, how would you feel?

Not Anxious	……..	1
Slightly Anxious	……..	2
Fairly Anxious	……..	3
Very Anxious	……..	4
Extremely anxious	……..	5

9. If you were about to have a *local anaesthetic injection* in your gum, above an upper back tooth, how would you feel?

Not Anxious	……..	1
Slightly Anxious	……..	2
Fairly Anxious	……..	3
Very Anxious	……..	4
Extremely anxious	……..	5

10. Have you had trouble *pronouncing any words* because of problems with your teeth, mouth or dentures?

Never	……..	0
Hardly ever	……..	1
Occasionally	……..	2
Fairly often	……..	3
Very often	……..	4

11. Have you felt that your *sense of taste* has worsened because of problems with your teeth, mouth or dentures?

Never	……..	0
Hardly ever	……..	1
Occasionally	……..	2
Fairly often	……..	3
Very often	……..	4

12. Have you had *painful aching* in your mouth?

Never	……..	0
Hardly ever	……..	1
Occasionally	……..	2
Fairly often	……..	3
Very often	……..	4

13. Have you found it *uncomfortable to eat any foods* because of problems with your teeth, mouth or dentures?

Never	……..	0
Hardly ever	……..	1
Occasionally	……..	2
Fairly often	……..	3
Very often	……..	4

14. Have you been *self-conscious* because of your teeth, mouth or dentures?

Never	……..	0
Hardly ever	……..	1
Occasionally	……..	2
Fairly often	……..	3
Very often	……..	4

15. Have *you felt tense* because of problems with your teeth, mouth or dentures?

Never	……..	0
Hardly ever	……..	1
Occasionally	……..	2
Fairly often	……..	3
Very often	……..	4

16. Has your *diet been unsatisfactory* because of problems with your teeth, mouth or dentures?

Never	……..	0
Hardly ever	……..	1
Occasionally	……..	2
Fairly often	……..	3
Very often	……..	4

17. Have you had to *interrupt meals* because of problems with your teeth, mouth or dentures?

Never	……..	0
Hardly ever	……..	1
Occasionally	……..	2
Fairly often	……..	3
Very often	……..	4

18. Have you found it *difficult to relax* because of problems with your teeth, mouth or dentures?

Never	……..	0
Hardly ever	……..	1
Occasionally	……..	2
Fairly often	……..	3
Very often	……..	4

19. Have you been a bit *embarrassed* because of problems with your teeth, mouth or dentures?

Never	……..	0
Hardly ever	……..	1
Occasionally	……..	2
Fairly often	……..	3
Very often	……..	4

20. Have you been a bit *irritable with other people* because of problems with your teeth, mouth or dentures?

Never	……..	0
Hardly ever	……..	1
Occasionally	……..	2
Fairly often	……..	3
Very often	……..	4

21. Have you had *difficulty doing your usual jobs* because of problems with your teeth, mouth or dentures?

Never	……..	0
Hardly ever	……..	1
Occasionally	……..	2
Fairly often	……..	3
Very often	……..	4

22. Have you felt that life in general was *less satisfying* because of problems with your teeth, mouth or dentures?

Never	……..	0
Hardly ever	……..	1
Occasionally	……..	2
Fairly often	……..	3
Very often	……..	4

23. Have you been *totally unable to function* because of problems with your teeth, mouth or dentures?

Never	……..	0
Hardly ever	……..	1
Occasionally	……..	2
Fairly often	……..	3
Very often	……..	4

24. Who completed this questionnaire?

Mother	…….....	1
Father	…….....	2
Other (please state who)		
…….....		3

These questions relate to some things you might do, or have done to you, to keep your mouth healthy and give you a pleasant smile. For each one, we would like your opinion on how important you think it is for people of your age. Please circle the answer which comes closest to how you feel.

25. Avoiding a lot of sweet foods is:

Extremely important (1)	Fairly important (2)	Not very important (3)	Not at all important (4)

26. Using fluoride toothpaste is:

Extremely important (1)	Fairly important (2)	Not very important (3)	Not at all important (4)

27. Visiting the dentist regularly is:

Extremely important (1)	Fairly important (2)	Not very important (3)	Not at all important (4)

28. Keeping the teeth and gums very clean is:

Extremely important (1)	Fairly important (2)	Not very important (3)	Not at all important (4)

29. Drinking fluoridated water is:

Extremely important (1)	Fairly important (2)	Not very important (3)	Not at all important (4)

30. Using dental floss is:

Extremely important (1)	Fairly important (2)	Not very important (3)	Not at all important (4)

Here is a series of questions relating to various aspects of your life. Each question has seven possible answers. Please mark the number, which expresses your answer, with number 1 and 7 being the extreme answers. If the words under 1 are right for you, circle 1: if the words under 7 are right for you, circle 7. If you feel differently, circle the number which best expresses your feeling. Please give only one answer to each question.

31. Do you have the feeling that you don't really care about what goes on around you?

1	2	3	4	5	6	7
very seldom						very often or never

32. Has it happened in the past that you were surprised by the behaviour of people whom you thought you knew well?

1	2	3	4	5	6	7
never happened						always happened

33. Has it happened that people whom you counted on disappointed you?

1	2	3	4	5	6	7
never happened						always happened

34. Until now your life has had:

1	2	3	4	5	6	7
no clear goals or purpose at all						very clear goals and purpose

35. Do you have the feeling that you are being treated unfairly?

1	2	3	4	5	6	7
very often						very seldom or never

36. Do you have the feeling that you are in an unfamiliar situation and don't know what to do?

1	2	3	4	5	6	7
very often						very seldom or never

37. Doing the thing you do every day is:

1	2	3	4	5	6	7
a source of deep pleasure and satisfaction						a source of pain and boredom

38. Do you have very mixed-up feelings and ideas?

1	2	3	4	5	6	7
very often						very seldom or never

39. Does it happen that you experience feelings that you would rather not have to endure?

1	2	3	4	5	6	7
very often						very seldom or never

40. Many people, even those with a strong character, sometimes feel like losers in certain situations. How often have you felt this way in the past?

e p

1	2	3	4	5	6	7
never						very often

41. When certain events occurred, have you generally found that:

1	2	3	4	5	6	7
You overestimated or underestimated its importance						You saw things in the right proportion

42. How often do you have the feeling that there is little meaning in the things you do in your daily life?

1	2	3	4	5	6	7
very often						very seldom or never

43. How often do you have feelings that you are not sure you can control?

1	2	3	4	5	6	7
very seldom						very often or never

44. What is your date of birth? (please write in the date in the boxes below)

D	D	M	M	Y	Y

45. What is the highest level of education that you have completed?

Primary school …… 1

Secondary school …… 2

Tertiary education

Some additional training (e.g. apprenticeship) ……..... 3

Undergraduate university ……. 4

Postgraduate university …… 5

46. To which one of the following ethnic groups do you belong?
(Please circle the number than best describes you)

White……... 1

Black…… 2

Indian, Pakistani or Bangladeshi……..... 3

Chinese……..... 4

Mixed race……..…… 5

Other (please specify)……..... 6

47. I would now like to ask you about types of dental care/treatment that <u>your child</u> has received from dentists over the <u>last 18 months</u>.
Have they had:

	Yes	No
Any local anesthetic?	1	2
Any fillings?	1	2
A tooth crowned?	1	2
Any teeth extracted (taken out)?	1	2
Any radiographs (x-rays) taken?	1	2
Sedation (that is something that relaxes them but does not put them to sleep) for dental treatment?	1	2
A general anaesthetic (that is something that put them to sleep) for dental treatment?	1	2
Any dental or mouth injury (trauma)?	1	2

48. When did you fill in this questionnaire? (please write the date in the boxes below)

D	D	M	M	Y	Y

End of questionnaire. Please make sure you have answered ALL questions.

THANK YOU FOR YOUR HELP

Appendix B: Recruitment letter and Information Sheet to General Dental Practitioners already taking part in FiCTION

Recruitment letter

School of Dental Sciences
Newcastle University
Framlington Place
Newcastle upon Tyne
NE2 4BW United Kingdom

Date 20/05/2014
Title, Initial, Surname,
Dental Practice,
Address
Date

Dear Colleague
Re: Study nested alongside the NIHR-HTA funded FiCTION Trial

Title – IMPACT (Investigating Parental Attitudes to Randomised Controlled Trials in Primary Dental Care)

I am writing to you as I understand your practice is taking part in the FiCTION Trial: Filling Children's Teeth – Indicated or Not. With this in mind, I am writing to ask if you might be interested in taking part in a study that Heather Coventry is undertaking as part fulfilment of an educational qualification (PhD) nested alongside the FiCTION trial in Scotland and north-east England. The main aim of IMPACT is:

- To determine whether participating in a randomised controlled trial (FiCTION) impacts on a parent's dental anxiety, oral health-related quality of life and attitude to their dental care & that of their children.

We are keen to understand the impact of the dental management of children with caries on parents and plan to invite four groups to consent to take part in the IMPACT study:

- Parents of children participating in the FiCTION trial within Scotland and north-east England.
- Parents of children not participating in the FiCTION Trial (due to ineligibility for/ unwillingness to take part in FiCTION) who consent to take part in IMPACT within Scotland and north-east England.
- Children with active caries at baseline (who are participating in the FiCTION Trial) within north-east England.
- Children not participating in the FiCTION Trial (due to ineligibility for/ unwillingnerss to take part in FiCTION) attending dental practices within north-east England.

All parents who participate in IMPACT will be asked to complete a questionnaire regarding their own anxiety, oral health-related quality of life and attitude to their dental care & that of their children. These will be completed at baseline and 18 months later.

In addition, IMPACT will explore the parental questionnaire findings with semi-structured face-to-face interviews involving a small subsample of parents. This would be carried out at a mutually convenient time and venue (either in the participants' homes or the dental practices).

For this study, the chief investigator (Heather Coventry, Clinical Fellow in Paediatric Dentistry and PhD student) would like to recruit and follow up 13 parents whose children are participating in the FiCTION Trial and 13 parents not participating in the FiCTION Trial (due to their child having no active caries at baseline) from each dental practice.

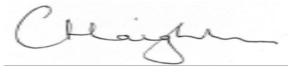
Dentists in your practice not involved with the FiCTION trial can also take part in this study.

I hope you might be interested in taking part in this study. With this in mind, I will telephone in two weeks to discuss it with you, answer any questions you may have and enquire if you would like to take part.

Best wishes.

Yours sincerely.






Heather Coventry | Professor Anne Maguire | Dr Katie Haighton | Professor Jan Clarkson

- Heather Coventry, Clinical Fellow in Paediatric Dentistry, Newcastle University, heather.coventry@ncl.ac.uk, Tel: 0191 208 7829
- Professor Anne Maguire, Professor of Preventive Dentistry, School of Dental Sciences, Newcastle University.
- Dr Katie Haighton, Lecturer in Public Health Research (Evaluation of Complex Interventions), Institute of Health & Society, Newcastle University.
- Professor Jan Clarkson, Director of the Effective Dental Practice Programme, Dental Health Services Research Unit, University of Dundee.

Dentists' and Dental Care Professionals Information Sheet

Scottish Dental PBRN

Newcastle University

School of Dental Sciences
Newcastle University
Framlington Place
Newcastle upon Tyne
NE2 4BW United Kingdom

Version 4.0

Date 20/05/2014

What is IMPACT?

IMPACT is a PhD study nested alongside the FiCTION Trial and its main aim is:

- To determine whether participating in a randomised controlled trial (FiCTION) impacts on a parent's dental anxiety, oral health-related quality of life and attitude to their dental care & that of their children.

We are asking you to consent to take part in IMPACT. However, before you decide whether to take part, we are providing you with the information you will need to understand why the research is being done and what it would involve for you and the practice. Please read the following information thoroughly and feel free to discuss it with colleagues if you wish.

Rationale for this project

Conducting this study within a primary dental care environment alongside the FiCTION trial will help to address some of the knowledge gaps evident with regard to whether conducting research in primary dental care affects a participant's anxiety, quality of life or attitude over time. The results may also inform the best ways to understand and manage parents in the environment where most dental treatment occurs by taking into account parental thoughts and feelings towards dental care. Parents, especially mothers, are key to the adoption of behavioural habits during childhood at home. It is important that this is considered when planning appropriate and effective preventative and treatment strategies for children.

Why have you asked me to take part?

We are inviting practitioners in primary care general dental practices, participating within the FiCTION trial, in Scotland and north-east England to take part in this study.

What will happen if I agree to take part?

Following consent from you that you are happy to take part, we will arrange a convenient time to come to the practice to talk to your team about this study. The FiCTION trial training that you and your dental team have already completed, will have covered most of the training required for this study, but the small amount of additional

study-specific training required can be undertaken in your practice at a mutually convenient time.

What do I need to do?
Your dental practice will search your practice database for child patients, aged 3 to 7 years, who are due a recall appointment as part of the FiCTION Trial. For IMPACT, we request that you also give a covering letter to parents about the IMPACT study along with the IMPACT Patient Information sheet. This paperwork can be either posted or given to the parent when they attend the dental practice for their FiCTION screening appointment. Where the paperwork has been posted, the chief investigator (HC) will ask if a repeat invitation letter to be sent if there is no response after 2 weeks from the parent.

Will taking part generate extra work for the practice?
We would ask your practice to post, with the help of the Chief Investigator, or hand out IMPACT study material to parents of children eligible to be screened for the FiCTION Trial. This will require patients to be identified using a screening number.

How many parents do you want from my practice?
For this study, the chief investigator (Heather Coventry, Clinical Fellow in Paediatric Dentistry and PhD student) would like to recruit and follow up 13 parents whose children are participating in the FiCTION Trial and 13 parents not participating in the FiCTION Trial (due to ineligibility for/ unwillingness to take part in FiCTION) from each dental practice. (n=26)

What happens to the results of this study?
The results from IMPACT will form part of a PhD thesis. All study data will be anonymised. The results may be put online or printed in peer-reviewed dental journals which are read by dentists and their staff. The findings may also be presented at conferences where they can be shared with other dentists, healthcare professionals and researchers.

Are there any risks to my patients and their parents taking part?
This study primarily involves questionnaires which will be completed by parents in their own homes. We also wish to talk to a small sub-sample of the parents using qualitative research methods to supplement the information being captured by the questionnaires. If this involved any parents associated with your practice, the chief investigator may ask to carry this out at your dental practice at a mutually convenient time.

Are there any possible benefits of taking part?
We cannot promise that taking part will benefit these parents or their children. However, you and they might find taking part in this study interesting and will help in addressing some of the knowledge gaps evident when considering the impact of a randomised controlled trial on parents in terms of dental anxiety, oral health-related quality of life and attitude within the primary care environment.

Who is organising IMPACT?
IMPACT is being carried out as a PhD project. It involves:

- Heather Coventry (PhD student), Clinical Fellow in Paediatric Dentistry, Newcastle University, heather.coventry@ncl.ac.uk, Tel: 0191 208 7829

- Professor Anne Maguire, Professor of Preventive Dentistry, School of Dental Sciences, Newcastle University, **anne.maguire@ncl.ac.uk**
- Dr Katie Haighton, Lecturer in Public Health Research (Evaluation of Complex Interventions), Institute of Health & Society, Newcastle University, katie.haighton@newcastle.ac.uk
- Professor Jan Clarkson, Director of the Effective Dental Practice Programme, Dental Health Services Research Unit, University of Dundee, j.e.clarkson@dundee.ac.uk

What if something goes wrong?
The National Health Service complaints mechanism will be available to participants. In the unlikely event that something does go wrong, you have the right to pursue a complaint and seek any resulting compensation through Newcastle University.

Ethical approval
The project has been given a favourable opinion by NRES Committee North East – Newcastle & North Tyneside 1.

What if I have any more questions?
If you have further questions you can contact any of the study team.

Appendix C: Covering letter explaining the IMPACT Study to parents, consent form and parent information sheet

Covering letter

Scottish Dental PBRN

Newcastle University

School of Dental Sciences
Newcastle University
Framlington Place
Newcastle upon Tyne
NE2 4BW United Kingdom

Version 4.0
Date 20/05/2014
Title, Initial, Surname,
Dental Practice,
Address
Date

Dear Parent

Re: Study nested alongside the NIHR-HTA FiCTION Trial

Title – IMPACT (Investigating Parental Attitudes to Randomised Controlled Trials in Primary Dental Care)

I am writing to ask if you might be interested in taking part in a project nested alongside the FiCTION trial in Scotland and north-east England. The main aim of IMPACT is:

- To determine whether participating in a randomised controlled trial (FiCTION) impacts on a parent's dental anxiety, oral health-related quality of life and attitude to their dental care & that of their children.

To investigate this research question we would like to find out more about parents' feelings and attitudes to taking part with research that involves their children. A questionnaire for you to complete would be given to you at the beginning of the project and then after 18 months. The researcher (Heather Coventry) may also ask to have a chat with you to discuss your general thoughts about taking part in research.

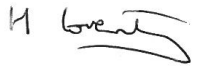
By not participating in IMPACT, you and your child's involvement in the FiCTION trial would not be affected in any way. You, and your child, do not need to be participating in the FiCTION Trial to take part in the IMPACT study.

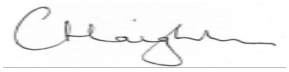
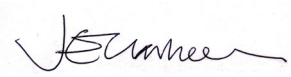
If you would like to take part in IMPACT please complete the consent form on the next page and return it in the pre-paid self-addressed envelope to the chief investigator (Heather Coventry).

If you would like to discuss the study in greater detail first, or have any questions these can be addressed by your own dentist or by a member of the study team (details below). If you would not like to take part in this study please could you record this on the consent form on the next page and return it in the pre-paid self-addressed envelope to the chief investigator (Heather Coventry).

With many thanks

Yours sincerely.



Heather Coventry | Professor Anne Maguire | Dr Katie Haighton | Professor Jan Clarkson

- Heather Coventry, Clinical Fellow in Paediatric Dentistry, Newcastle University, heather.coventry@ncl.ac.uk, Tel: 0191 208 7829
- Professor Anne Maguire, Professor of Preventive Dentistry, School of Dental Sciences, Newcastle University.
- Dr Katie Haighton, Lecturer in Public Health Research (Evaluation of Complex Interventions), Institute of Health & Society, Newcastle University.
- Professor Jan Clarkson, Director of the Effective Dental Practice Programme, Dental Health Services Research Unit, University of Dundee.

Consent form for parents living in Scotland for IMPACT (Investigating Parental Attitudes to Randomised Controlled Trials in Primary Dental Care)

Scottish Dental PBRN

Newcastle University

School of Dental Sciences
Newcastle University
Framlington Place
Newcastle upon Tyne
NE2 4BW United Kingdom

Patient identification number:
□□□□□□□□

Version 3.0

		Please put your initials in the boxes if you agree:
1	I have read and understood the parent's information sheet and have had the opportunity to ask questions	
2	I understand that I do not have to take part in this project. I also understand that I can opt out at any time, without giving a reason and this will not affect either my or my child's dental care or legal rights.	
3	I understand that by opting out at any time, without giving a reason will not affect my child's involvement in the FiCTION trial (if applicable) in any way.	
4	I understand that the study team may want to talk to me once they have looked at the questionnaire results & I agree to being contacted.	
5	I agree to being included in this study.	

Name of parent (Please PRINT name and give title e.g. Mr/Mrs/Ms/Miss)	
Address of parent (Please include postcode if known)	
Telephone number of parent (Please include if known)	
Your child's Date of Birth	

Parent information sheet

Scottish Dental PBRN

Newcastle University

School of Dental Sciences
Newcastle University
Framlington Place
Newcastle upon Tyne
NE2 4BW United Kingdom

Version 4.0

We are inviting you to participate in a research study which we think is really important. However, before you decide whether or not you wish to take part, we need to be sure that you understand firstly why we are doing it, and secondly what it would involve if you agreed. We are therefore providing you with the following information. Please read it carefully and be sure to ask any questions you have, and if you want to, discuss it with others. We will do our best to explain and to provide any further information you may ask for now or later. You do not have to make an immediate decision.

What is this study about?

This study, called IMPACT, is running alongside a larger project (the FiCTION Trial) looking at the best way of looking after children's teeth. IMPACT is being undertaken by Heather Coventry in part-fulfilment of an educational qualification (PhD). IMPACT plans to collect information from a number of parents to see if taking part in research affects your quality of life, and how you feel about your dental health and that of your children. We would also like to find out more about parents feelings and attitudes to taking part in research that involves their children.

IMPACT will be asking parents to take part if their children's teeth are decayed or healthy.

Why have I been contacted?

Because your child has been invited to participate in the FiCTION Trial which randomly assigns eligible children with dental decay in their baby teeth to one of three treatment groups;

- Conventional with prevention (using dental drills and local anaesthetic injections to cut away decay, then filling the cavity
- Biological with prevention (sealing decay into teeth with filling materials, generally without using dental drills or injections)
- Prevention alone, 'no fillings'.

Even if your child is not participating in the FiCTION Trial, you may still be eligible for the IMPACT Study.

Do I have to take part?
No, it is up to you to decide whether or not to take part and your child will continue to get the best possible care no matter what you decide to do. Dentists are not being paid to include parents into IMPACT. By not taking part in this study, your involvement within the FiCTION study will not be affected in any way.

If you decide to take part you will be asked to sign a consent form and return it in the pre-paid envelope to the researcher (Heather Coventry). If you change your mind later and you don't want to take part anymore, no one will mind and your dentist will still look after your child's teeth in the best way they can. By withdrawing, this will have no impact in either you or your child's involvement within the FiCTION study.

What will happen if I agree that I will take part?
Before you agree to take part, you should ask the study team (details enclosed in this letter) or your dentist any questions you might have. They will be pleased to answer any questions. After you post the consent form back to Heather Coventry (the PhD student running this project) in the pre-paid self-addressed envelope, she will then write to you to let you know if you have been selected to be included in the IMPACT study.

Heather (the PhD student running this project) would like to recruit a similar number of parents of children participating in the FiCTION Trial and parents of children not participating in the FiCTION Trial living in Scotland and in north-east England.

If you have been selected to be included in the IMPACT study, you will be given a short questionnaire to fill in and post back to Heather. If you receive a questionnaire at the beginning of the study, she will post you another questionnaire 18 months later which should also be completed and returned. Heather will send you a letter prior to the beginning of the study thanking you for your interest in IMPACT.

Heather may also ask if she can have a chat with you to gain more information than is being captured by the questionnaires. This is so we get a fuller picture of your thoughts and experiences of being involved in research.

Are there any risks to taking part?
It will take you a short period of time for you to complete the 2 questionnaires; one now, at the beginning of the study and one after 18 months. If Heather arranges a chat with you to discuss your general thoughts about your teeth/mouth this will obviously take up some of your time.

Are there any possible benefits to taking part?
We cannot promise that IMPACT will help you or your child but by taking part you will be helping to answer an important research question.
What if new information becomes available?
Sometimes during the course of a research study we may get new information. If this happens, we will tell you about it and discuss how it may affect you or your child's care.

What happens to the results of this project?
All study data are anonymised– this means that your personal details and those of your child do not appear. The results from IMPACT may be put online or printed in dental journals which are read by dentists and their staff. The findings may also be presented at conferences where they can be shared with other dentists, healthcare professionals and researchers.

Will anyone else know I am in this study?
We will keep your details and study information confidential. Only key people who have a need or a right to know will know you are in this project.

Who has reviewed this project?
NRES Committee North East – Newcastle & North Tyneside 1, which has responsibilities for scrutinising proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that the records of children in this research, together with any relevant medical records may be made available for scrutiny by monitors from Dundee University, Newcastle University and NHS Regulatory Authorities, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

What if something goes wrong?
The National Health Service complaints mechanism will be available to participants. In the unlikely event that something does go wrong, you have the right to pursue a complaint and seek any resulting compensation through Newcastle University.

What if I have any more questions?
If you have any more questions you can ask your dentist when you see them or you can contact any of the team (see below).

Heather Coventry, Newcastle University.	0191 208 7829 heather.coventry@ncl.ac.uk
Professor Anne Maguire, Newcastle University.	anne.maguire@ncl.ac.uk
Dr Katie Haighton, Newcastle University.	katie.haighton@newcastle.ac.uk
Professor Jan Clarkson, University of Dundee	j.e.clarkson@dundee.ac.uk

Appendix D: Covering letter for baseline parent questionnaire

Scottish Dental PBRN

Newcastle University

School of Dental Sciences
Newcastle University
Framlington Place
Newcastle upon Tyne
NE2 4BW United Kingdom

Version 4.0

Title, Initial, Surname,
Dental Practice,
Address
Date

Dear Parent

Re: Study nested alongside the NIHR-HTA FiCTION Trial

Title – IMPACT (Investigating Parental Attitudes to Randomised Controlled Trials in Primary Dental Care)

I am writing to thank you for thank you for agreeing to participate in the IMPACT study. Unfortunately, we have already recruited from your area and are unable to accept you into the IMPACT study. We would like to take this opportunity to thank you for your interest. If you would like to receive the final results from the IMPACT study (in approximately 2 years' time) please do not hesitate to contact the researcher (Heather Coventry) using the contact details given below. If you have any further questions these can be addressed by your own dentist or by a member of the study team (details below).

With many thanks

Yours sincerely.

Heather Coventry Professor Anne Maguire Dr Katie Haighton Professor Jan Clarkson

- Heather Coventry, Clinical Fellow in Paediatric Dentistry, Newcastle University, heather.coventry@ncl.ac.uk, Tel: 0191 208 7829
- Professor Anne Maguire, Professor of Preventive Dentistry, School of Dental Sciences, Newcastle University.
- Dr Katie Haighton, Lecturer in Public Health Research (Evaluation of Complex Interventions), Institute of Health & Society, Newcastle University.
- Professor Jan Clarkson, Director of the Effective Dental Practice Programme, Dental Health Services Research Unit, University of Dundee.

Appendix E: Number of missing items per scale at baseline

MDAS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.00	243	93.1	93.1	93.1
	1.00	7	2.7	2.7	95.8
	4.00	2	.8	.8	96.6
	5.00	9	3.4	3.4	100.0
	Total	261	100.0	100.0	

OHIP-14

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.00	241	92.3	92.3	92.3
	1.00	2	.8	.8	93.1
	4.00	1	.4	.4	93.5
	5.00	1	.4	.4	93.9
	6.00	3	1.1	1.1	95.0
	8.00	13	5.0	5.0	100.0
	Total	261	100.0	100.0	

Total Dental Health Beliefs

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.00	251	96.2	96.2	96.2
	1.00	10	3.8	3.8	100.0
	Total	261	100.0	100.0	

Total SOC-13

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.00	248	95.0	95.0	95.0
	1.00	8	3.1	3.1	98.1
	8.00	3	1.1	1.1	99.2
	12.00	1	.4	.4	99.6
	13.00	1	.4	.4	100.0
	Total	261	100.0	100.0	

Total SOC-13 Comprehensibility

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.00	252	96.6	96.6	96.6
	1.00	4	1.5	1.5	98.1
	4.00	3	1.1	1.1	99.2
	5.00	2	.8	.8	100.0
	Total	261	100.0	100.0	

Total SOC-13 Manageability

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.00	254	97.3	97.3	97.3
	1.00	2	.8	.8	98.1
	2.00	3	1.1	1.1	99.2
	4.00	2	.8	.8	100.0
	Total	261	100.0	100.0	

Total SOC-13 Meaningfulness

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.00	254	97.3	97.3	97.3
	1.00	2	.8	.8	98.1
	2.00	3	1.1	1.1	99.2
	3.00	1	.4	.4	99.6
	4.00	1	.4	.4	100.0
	Total	261	100.0	100.0	

Appendix F: Qualitative Interview Topic Guide

Start recording

I. Opening

(Establish Rapport) [shake hands] My name is Heather and as a dentist and PhD student who has had some involvement with FiCTION, I thought it would be a good idea to interview you, so that I can better inform further dental research.

(Purpose) I would like to ask some questions about some dental experiences you've had and how much you understand about the FiCTION Trial & my PhD Study (IMPACT) n order to learn more about you and share this information with the rest of the dental team.

(Motivation) I hope to use this information to help dental research easier and the patient journey more enjoyable/

(Time Line) The interview should take about 60 minutes. Are you available to respond to some questions at this time?

(**Transition:** Let me begin by asking you some questions about your dental health)

II. Body

A. <u>General thoughts</u>

1. (Tell me) What do you understand having good oral health or good dental health to mean?
2. What do you envisage somebody with good oral health to have in terms of teeth or gums?
3. What do you think enables someone to have good dental health?
4. What problems do you think that someone with poor oral health or poor dental health might have?
5. How important is having good dental health to you? Other people? Why do you think it's important?

B. <u>Previous dental history</u>

6. How often did you go to the dentist when you were a child?
7. Did you have many problems with your teeth as a child?
8. Do you remember going to the dentist as a child as being a good or bad experience?
9. Did you always see the same dentist when you were younger?
    - Were they particularly influential over you at that time?
    - Do you remember them teaching you how to brush your teeth and things?
    - Or was it more to just go and the teeth fixed?

C. <u>Current dental history</u>

10. How often do you go to the dentist now?
11. How important do you think regular visits to the dentist are?
12. What do you do to keep your teeth clean?
13. Where do you think the knowledge to do that came from?

14. Do you go to the same dentist as your child(ren)? If different, why?

D. Research – general thoughts
15. What do you understand by the term research?
16. (Explain research if necessary). Have you take part in any research before? If yes, were there any benefits you felt in taking part?
17. Why do you think dental practices are getting involved in research?
18. There is a big push for the general public to be involved in research now. This would involve primary care settings (e.g. routine doctors, dentists, opticians). Do you think the majority of people would be interested in this? Are there any groups that you don't think would be willing to take part it in?
19. Would you choose to go to a dental practice that is involved in research or one that wasn't? Why?
20. How do you feel about children taking part in research?

E. Research – opinions specific to IMPACT/FiCTION
21. How did you feel about being invited to take part in IMPACT? Were you happy to be invited via post, or would you have preferred another option/alternative?
22. What made you decide to take part in IMPACT?
23. Was there anything that worried you about taking part in IMPACT? Has this worry been founded?
24. What did you think about the written information for IMPACT?
25. Did you discuss IMPACT with anybody else before making your decision to take part?
26. IMPACT is a small study that ties in with the FiCTION trial. What did you understand the FiCTION trial is looking at?
27. The FiCTION trial is a randomised controlled trial. Do you know what this means?
28. (Explain randomisation if necessary). How do you feel about a computer picking a treatment arm for your child rather than your dentist/therapist/etc?
29. What do you think your options would be if your child was selected a trial arm that you that you later weren't happy with? How would you feel about that?
30. Have you found any positives in taking part in IMPACT? What about negatives?
31. Have you found any positives in taking part in FiCTION? What about negatives?
32. Would you participate to take part in another dental study if asked now? Why?

(**Transition:** Well, it has been a pleasure finding out more about you. Let me briefly summarize the information that I have recorded during our interview).

III Closing

A. (Summarize). You are very involved in____. You thought_____

B. (Maintain Rapport) I appreciate the time you took for this interview. IS there anything else you think would be helpful for me to know?
C. (Action to be taken) I should have all the information I need. Would it be alright to call you if I have any more questions? Thanks again.

End recording.

Appendix G: Covering letter explaining the IMPACT Qualitative Study to parents, parent information sheet and consent form

a. Child participating in the FiCTION Trial

Covering letter

Scottish Dental PBRN

Newcastle University

School of Dental Sciences
Newcastle University
Framlington Place
Newcastle upon Tyne
NE2 4BW United Kingdom

Version 4.0

Dear Parent

Re: Qualitative Study nested within the IMPACT (Investigating Parental Attitudes to Randomised Controlled Trials in Primary Dental Care) Study

You have kindly participated in IMPACTs questionnaire survey and with this in mind we are now writing to ask if you might be interested in taking part in an additional aspect of IMPACT. You did previously indicate that you might be interested in taking part in this aspect of the study which is why we are writing to you. We want to understand your thoughts and feelings about going to the dentist as well as your general thoughts about taking part in research and we would do this by asking you some questions.

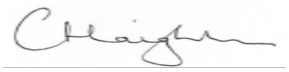
This can be done in your own home or at a convenient venue and time that would be suitable for you. We would like to record what you say so that we can write down your comments and responses and compare them with those of other parents taking part in this part of the IMPACT study. By not participating in this study, you and your child's involvement in the FiCTION trial will not be affected.

We have attached the parent information leaflet and the consent form for your information. I will telephone in two weeks to discuss the study with you and enquire if you would like to take part.

If you would like to discuss the qualitative study in greater detail first or have any questions a member of the study team would be happy to do this (details on next page).

Best wishes.
Yours sincerely.






Heather Coventry Professor Anne Maguire Dr Katie Haighton Professor Jan Clarkson

- Heather Coventry, Clinical Fellow in Paediatric Dentistry, Newcastle University, heather.coventry@ncl.ac.uk, Tel: 0191 208 7829
- Professor Anne Maguire, Professor of Preventive Dentistry, School of Dental Sciences, Newcastle University.
- Dr Katie Haighton, Lecturer in Public Health Research (Evaluation of Complex Interventions), Institute of Health & Society, Newcastle University.
- Professor Jan Clarkson, Director of the Effective Dental Practice Programme, Dental Health Services Research Unit, University of Dundee.

Parent information sheet

Scottish Dental PBRN

Newcastle University

School of Dental Sciences
Newcastle University
Framlington Place
Newcastle upon Tyne
NE2 4BW United Kingdom

Version 5.0

We are inviting you to participate in an additional IMPACT research study (Qualitative study) which we think is really important. However, before you decide whether or not you wish to take part, we need to be sure that you understand firstly why we are doing it, and secondly what it would involve if you agreed. We are therefore providing you with the following information. Please read it carefully and be sure to ask any questions you have, and if you want to, discuss it with others. We will do our best to explain and to provide any further information you may ask for now or later. You do not have to make an immediate decision.

What is this study about?
This study involves talking to parents to gain more information than is being captured by the questionnaire study. This is so we can get a fuller picture of your thoughts and experiences of being involved in research and how you feel about your dental health and that of your children.

Do I have to take part?
No, it is up to you to decide whether or not to take part and your child will continue to get the best possible care no matter what you decide to do. Dentists are not being paid to include parents into IMPACT. By not taking part in this study, your involvement within the FiCTION study or the rest of the IMPACT study will not be affected in any way.

If you change your mind later and you don't want to take part anymore, no one will mind and your dentist will still look after your child's teeth in the best way they can.

What will happen if I agree that I will take part?
Before you agree to take part, you should ask the study team (details enclosed in this letter) any questions you might have. They will be pleased to answer any questions. Heather plans to telephone you in two weeks to discuss the study with you and enquire if you would like to take part.

If you agree to take part, Heather will carry out this study at a convenient place and time for you (preferably your home or a public place). She anticipates it will take up to 60 minutes.

Are there any risks to taking part?
This will take up an additional amount of your time.

Are there any possible benefits to taking part?
We cannot promise that IMPACT will help you or your child but by taking part you will be helping to answer an important research question.

What if new information becomes available?
Sometimes during the course of a research study we may get new information. If this happens, we will tell you about it and discuss how it may affect you or your child's care.

What happens to the results of this project?
All study data are anonymised– this means that your personal details and those of your child do not appear. The results from IMPACT may be put online or printed in dental journals which are read by dentists and their staff. The findings may also be presented at conferences where they can be shared with other dentists, healthcare professionals and researchers.

Will anyone else know I am in this study?
We will keep your details and study information confidential. Only key people who have a need or a right to know will know you are in this project.

Who has reviewed this project?
NRES Committee North East – Newcastle & North Tyneside 1, which has responsibilities for scrutinising proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that the records of children in this research, together with any relevant medical records may be made available for scrutiny by monitors from Dundee University, Newcastle University and NHS Regulatory Authorities, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

What if something goes wrong?
The National Health Service complaints mechanism will be available to participants. In the unlikely event that something does go wrong, you have the right to pursue a complaint and seek any resulting compensation through Newcastle University.

What if I have any more questions?
If you have any more questions you can ask your dentist when you see them or you can contact any of the team (see below).

Heather Coventry, Newcastle University.	0191 208 7829 heather.coventry@ncl.ac.uk
Professor Anne Maguire, Newcastle University.	anne.maguire@ncl.ac.uk
Dr Katie Haighton, Newcastle University.	katie.haighton@newcastle.ac.uk
Professor Jan Clarkson, University of Dundee	j.e.clarkson@dundee.ac.uk

Consent form

Newcastle University

Scottish Dental PBRN

School of Dental Sciences
Newcastle University
Framlington Place
Newcastle upon Tyne
NE2 4BW United Kingdom

Patient identification number:

□□□□□□□□

Version number 2.0

	IMPACT Qualitative Study (Investigating Parental Attitudes to Randomised Controlled Trials in Primary Dental Care)	**Please put your initials in the boxes if you agree:**
1	I have read and understood the parents information sheet and have had the opportunity to ask questions	
2	I understand that I do not have to take part in this project. I also understand that I can opt out at any time, without giving a reason and this will not affect either my or my child's dental care or legal rights.	
3	I understand that by opting out at any time, without giving a reason will not affect my child's involvement in the FiCTION trial.	
4	I understand that the anonymised data collected during the study, may be looked at by the responsible individuals from the study team. I give permission for these individuals to have access to these data.	
5	I agree to being included in this study.	

_____	_____	_____
Name of parent (Please PRINT name and give title e.g. Mr/Mrs/Ms/Miss)	Date	Signature
_____	_____	_____
Name of person taking consent	Date	Signature

b. Child not participating in the FiCTION Trial Study

Covering letter

Newcastle University

School of Dental Sciences

Newcastle University
Framlington Place
Newcastle upon Tyne
NE2 4BW United Kingdom

Scottish Dental PBRN

Version 4.0
Date

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Re: Qualitative Study nested within the IMPACT (Investigating Parental Attitudes to Randomised Controlled Trials in Primary Dental Care) Study

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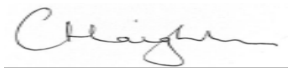
This can be done in your own home or at a convenient venue and time that would be suitable for you. We would like to record what you say so that we can write down your comments and responses and compare these anonymously with those of other parents taking part in this part of the IMPACT study.

We have attached the parent information leaflet and the consent form for your information. I will telephone in two weeks to discuss the study with you and enquire if you would like to take part.

If you would like to discuss the qualitative study in greater detail first or have any questions a member of the study team would be happy to do this (details on next page).
Best wishes.

Yours sincerely.



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Parent information letter

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Consent form

Scottish Dental PBRN

Newcastle University

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