An investigation of the predictors, barriers and facilitators to recruitment and retention of children and families to oral health trials

Thesis submitted in accordance with the requirements of the University of Liverpool for the degree of Doctor in Philosophy by Louise Robinson

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Abbreviations

ECC	Early Childhood Caries
FA	Framework Analysis
GPs	General Practitioners
HTA	Health Technology Assessment
IMD	Index of Multiple Deprivation
NIHR	National Institute for Health Research
NIH	National Institute for Health
NHS	National Health Service
OHBQ	Oral Health Behaviours Questionnaire
PIL	Patient Information Leaflet
R&D	Research and Development
RCT	Randomised Controlled Trial
SES	Socioeconomic Status

Abstract

This thesis presents a detailed investigation into the predictors, barriers and facilitators to recruitment and retention of children and families in oral health trials. Study 1 is a systematic review of the predictors of recruitment and retention to RCTs involving children and families with no specific health focus. This study concludes that younger, those with low socioeconomic backgrounds, less well-educated and ethnic minority parents are less likely to be recruited and retained on RCTs; although there was disagreement between studies. Study 2 has an oral health focus and investigates study design predictors of recruitment and retention to trials involving children and families. The study findings were that trials over a year in length, set in community based settings with healthy participants were most likely to experience problems with recruitment and retention. Study 3 is a qualitative interview and focus group study with participants who continued and/or withdrew from the Salford Bright Smiles Baby Study (a community based early childhood caries trial with children ages 1-3 and their parents). Parents were motivated to take part in the study through wanting to be a better parent and wanting good oral health for their child. Facilitators to participation were flexibility in how the study was designed and delivered, e.g. nursery and home appointments and multiple forms of contact. Amongst the barriers to taking part were fear of being judged by others and the burden of participation. Finally study 4 is a quantitative analysis of the sociodemographic and oral health belief predictors of retention of participants on the Salford Bright Smiles Baby Study. This found that younger, unemployed lesser educated parents were less likely to remain on the trial to the end of the study.

The thesis also provides insight into the quality of reporting of recruitment and retention in oral health trials. Whilst study two found that use of the CONSORT guidelines has increased over time, oral health trials still have a lower use of the guidelines than other research areas.

To date very few studies have investigated predictors of recruitment and retention with children and families, even fewer in the field of oral health. This thesis presents a unique investigation into the actual barriers and facilitators to participation and provides findings that can be applied to future research with children and families. Specifically, recommendations to increase participation in longitudinal, community based oral health trials are presented.

Chapter 1
Introduction

1.1 Introduction

This thesis reports a mixed methods investigation into recruitment and retention of children and families to randomised controlled trials (RCTs), with a specific focus on oral health trials. The Cochrane Oral Health Group definition of oral health will be utilised throughout:

"Oral health is broadly conceived to include the prevention, treatment, and rehabilitation of oral, dental, and craniofacial diseases and disorders" (Cochrane Oral Health, 2017).

Existing research into RCT recruitment and retention is extensive. Common research questions focus on strategies to improve recruitment (Treweek et al., 2013a, Watson and Torgerson, 2006, Caldwell et al., 2010) and retention (Robinson et al., 2007, Brueton et al., 2011, Booker et al., 2011), clinicians views of recruitment to RCTs (Fletcher et al., 2012, Rendell et al., 2007) and how the informed consent process impacts a patients decision to take part (Flory and Emanuel, 2004, Nishimura et al., 2013). In the UK, several funder specific reviews of recruitment have been undertaken in recent years (Walters et al., 2017, McDonald et al., 2006, Sully et al., 2013, Campbell et al., 2007). Yet despite the breadth of research, the incidence of type II errors due to poor recruitment and retention, remains a continuing, significant threat to RCTs (Adamson et al., 2015).

Across the world, 60-90% of school children have experience of tooth decay (WHO, 2012). The majority of oral disease is preventable, however, it remains one of the most common global health burdens (Gussy et al., 2006). RCTs in oral health therefore have the potential for widespread impact due to the global significance of the problem. Additionally, inequalities in oral health exist, with a close correlation between deprivation and poor childhood oral health (Thomson, 2012). Research into improving recruitment and retention of children and families to oral health RCTs therefore has the potential to address global health inequalities.

This thesis outlines the gaps in current literature, firstly identifying trials with children and families, then more specifically, oral health trials, as areas for further investigation. Barriers to research in these areas are also considered and reported, including multiple, conflicting definitions of the key terms in retention research, and the quality of reporting, specifically CONSORT guidelines use in oral health trial reporting.

1.2 Overview of chapters in this thesis

This chapter provides an overview for the thesis as a whole and justifies the use of a mixed methods design. Context for studies 3 and 4 of the thesis is also provided with a description of the Salford Bright Smiles Baby Study, the trial from which data for the final two studies was drawn.

Chapters 2 and 3 present a narrative review of the literature relevant to the studies in this thesis. Chapter 2 begins with an overview of literature on recruitment and retention of children and families. Chapter 3 focusses more specifically on oral health trials.

Chapter 4 presents study 1, a broad systematic review of predictors of recruitment and retention of children and families as participants to RCTs. Informed by the findings and limitations of study 1, chapter 5 (study 2) is a quantitative investigation of study design predictors of recruitment and retention success in oral health trials.

Data for studies 3 and 4 (chapters 6 and 7) were obtained from the 'Salford Bright Smiles Baby Study', a community based early childhood caries (ECC) trial. Chapter 6 presents a qualitative focus group and interview study exploring the reasons for parents choosing to take part or drop out of the trial. Chapter 7 examines whether parents' sociodemographic profiles, oral health beliefs and behaviours predicted retention on the trial.

Finally, chapter 8 presents a discussion of the combined findings of the studies in this thesis, with conclusions and recommendations for future oral health trials involving children and families.

1.3 Justification for mixed methods

There are multiple descriptions of mixed methods research offered across the literature; Creswell (2015) provides the definition:

> *"An approach to research in the social, behavioural, and health sciences in which the investigator gathers both quantitative (closed-ended) and qualitative (open-ended) data, integrates the two, and then draws interpretations based on the combined strengths of both sets of data to understand research problems" (pg. 2).*

However Doyle et al. (2009) argue that because of the ongoing growth in this area of research, a fixed definition is not possible. The literature generally agrees that mixed methods originated in the 1990s (Creswell, 2015, Bryman, 2012). Fielding (2010) attributes the rise of mixed methods in the UK and USA to an increase in evaluation research, favoured by the US and UK Governments in the late 1990s. A threefold increase in the number of journal articles featuring mixed methods between 1994 and 2003 and the establishment of wholly mixed method academic journals is further evidence of its increase in use over the past 25 years (Bryman, 2012, Bryman, 2006, Feilzer, 2010).

Despite the increased acceptance and use of mixed methods research, debate still remains about the divide between qualitative and quantitative research. Arguments traditionally focus around the epistemological and ontological beliefs of the two paradigms, with purist researchers arguing that the two cannot be combined (Bryman, 2012). However, many researchers assert that mixed methods is now more widely accepted, and there is less of a divide between the paradigms; or that 'paradigm war' has been replaced with 'paradigm peace' (Bryman, 2006, Doyle et al., 2009).

Onwuegbuzie and Leech (2005) highlight that traditional arguments from purists have focussed on the difference between positivist (quantitative) and constructivist (qualitative) paradigms, overlooking the similarities. They argue that there are more similarities than differences between the two paradigms, drawing on parallels such as both approaches using observations to answer research questions as well as both using safeguards, data verification and analytical techniques. They lay a case for research being seen as a continuum rather than a dichotomy of two paradigms (Onwuegbuzie and Leech, 2005).

Another argument is for a third paradigm labelled 'pragmatism' (Doyle et al., 2009, Johnson and Onwuegbuzie, 2004, Feilzer, 2010). As an alternative to positivism and constructivism, pragmatism is an approach to research that puts the result, rather than the research question, at the forefront when making a decision about which method to use (Doyle et al., 2009). Pragmatism has been described as a theoretical and philosophical middle ground which allows researchers to select a mix of methodologies in order to get the best answer to the research question (Johnson and Onwuegbuzie, 2004). Rather than being tied to specific qualitative or quantitative research design, pragmatic mixed methods researchers are able

to choose the most appropriate method(s), often mixing qualitative with quantitative within the same study, to carry out the investigation most effectively. In an interview study Bryman (2006) found that the majority of mixed methods researchers adopted their methods for pragmatic reasons. Most of those interviewed acknowledged differences between the two paradigms but felt it was more important to fully answer the research question than limiting the research by adhering to methods traditionally belonging to one paradigm over the other (Bryman, 2006).

Researchers have also sought to differentiate between 'mixed methods' and 'multi method' designs. Morse (2003) outlines the difference between mixed and multi being that the latter uses multiple techniques in isolated projects to triangulate, rather than combine data, unlike mixed methods where data is merged and methods are incorporated. Research examining how mixed methods are used highlighted the interchangeable use of the two terms by 'leaders in mixed-methods'(Johnson et al., 2007). Despite this interchangeable use by many, this thesis recognises the conceptual differences between the two. As the results of studies three and four are combined to provide a deeper, more comprehensive understanding of the issues surrounding retention in the Bright Smiles Trial, the term 'mixed methods' will be used to describe this thesis as a whole, whilst also recognising elements of 'multi method' design due to the use of different approaches between the four studies.

A mixed methods approach was adopted in this thesis to provide fullness and completeness of the answer to the research questions. Behind this is a belief that combining the two research paradigms will enable a fuller and more holistic understanding of the barriers and facilitators to families taking part in research, than could be gained by taking a fully qualitative or quantitative approach. Any combination of findings from the two methods will be done sensitively, and in awareness of the different ideological and theoretical assumptions underpinning qualitative and quantitative research design, as well as the pitfalls of combining methods.

1.4 Context for chapters 6 and 7 – The Salford Bright Smiles Baby Study

The Salford Bright Smiles Baby Study was a three-year, community-based randomised controlled trial, funded by the National Institute for Health Research, Research for Patient

Benefit Programme (NIHR RfPB). The study aims were to compare the effectiveness of three interventions to reduce early childhood caries (ECC).

Participants were children aged 1-3 years and their families, living in Salford and two neighbouring boroughs of Manchester. This is an urbanised area of the North West of England. The population of Salford is 233,900 (Salford City Council, 2015). Data from the 2007 IMD survey classified Salford as the 7th most deprived district in the UK (IMD, 2007). Young children in Salford have some of the highest rates of tooth decay in the UK. In 2012, 47% of children aged 5 in Salford had experience of tooth decay (Public Health England, 2012).

Parents of children aged birth to 13 months were identified through NHS birth records and sent a participant information leaflet in the post. Parents were asked to contact the study team if they were interested in being involved. Parents were also given the option to return a consent form by post (informed consent was retaken from these parents at the first visit). Parents were also approached at community locations across Salford and Manchester e.g. public libraries, health centres, shopping centres, community centres and child care settings. The majority of recruitment was conducted face to face at Sure Start Children's Centres. These are Local Authority established venues situated in the most disadvantaged areas of the UK (National Audit Office, 2006). The centres are used for Well baby clinics run by health visitors, and groups and classes aimed at parents and babies (e.g. baby massage, 'Stay and Play', weaning groups, breast feeding support etc.). Many parents visit these centres when their children are under one year, to attend the Well-baby clinics.

Once enrolled onto the trial families were randomised into one of three groups:

1) Usual care (Control) – children continued with their dental care arrangements as usual
2) Test group 1 (Behavioural Intervention) – parents of children attended four sessions about child oral health over two years
3) Test group 2 (Fluoride Varnish) – children had fluoride varnish applied to their teeth every six months for two years

Parents of all children were asked to complete a questionnaire at baseline (enrolment), at age 2 and 3 years. Children in all groups were also invited to attend a dental examination at

age 2 and 3 years. Intervention and data collection appointments were offered in group sessions held at Sure Start Centres or local Gateway Community Centres. Gateway Centres are community venues offering local residents health and council services in one location; they often include libraries alongside primary and secondary health care and are used as satellite venues for children centres. If families were unable to attend group sessions one-to-one home or nursery appointments were offered as an alternative.

The recruitment phase of the Salford Bright Smiles Baby Study was extended by six months to achieve the desired sample size. Retention of participants was challenging and the protocol was amended to include retention techniques such as one-to-one intervention appointments and home visits for the final dental examinations (Pine et al., 2014). Figure 1.1 presents the flow of participants on the Salford Bright Smiles Baby Study.

Figure 1.1 - Bright Smiles Baby Study Flow Diagram of Participants

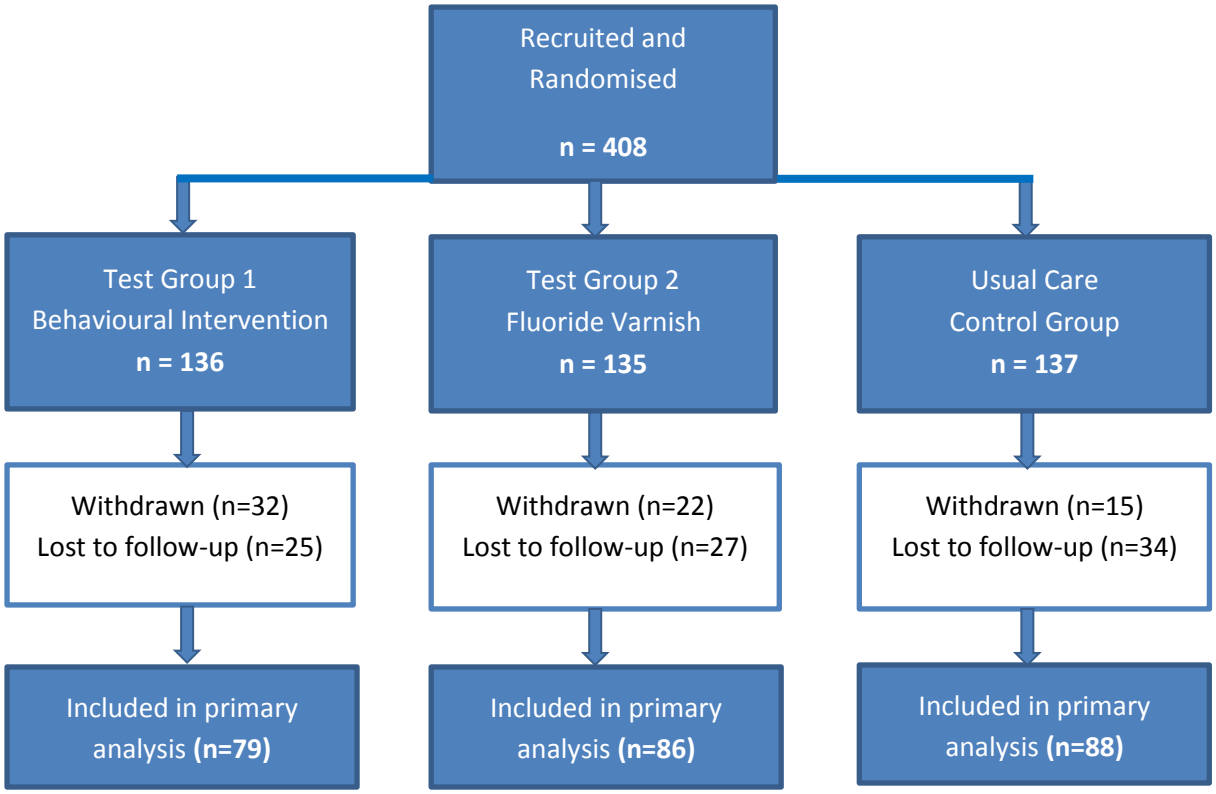


Figure 1.1 illustrates the problem which this thesis sets out to explore. Of the 408 children recruited and randomised, 253 had a final dental examination at three years old. In total 69 participants withdrew from the trial and a further 89 were lost to follow up. When questioned at the time of withdrawal from the trial, the most common reasons for drop out given by parents were moving away from the area and lack of time due to returning to work (Pine et al., 2014). At age 3 years, the trial did not show a significant difference between groups i.e. control and fluoride varnish or control and behavioural support.

1.5 Chapter summary

In summary, recruitment and retention of children and families to RCTs is problematic and threatens the internal and external validity of trial findings. Despite this, relatively little research has been conducted with this population in comparison to trials with adults.

This thesis aims to contribute to existing research into recruitment and retention by using a mixed methods design to examine a relatively unexplored area of research - oral health

RCTs with children and families. RCTs in oral health are of global significance and can potentially address global health inequalities.

Four studies will be presented within this thesis. A recent trial - the Salford Bright Smiles Baby Study, will be used as a case-study for studies 3 and 4. The trial experienced significant issues with recruitment and retention at various stages and allows detailed exploration and insight into the population of interest within this thesis.

Unique evidence is presented throughout the four studies in this thesis. The findings and recommendations can be used by researchers designing and conducting oral health RCTs with young children and their families.

Chapter 2
Literature review – Recruitment and retention of children and families

2.1 Overview

The following chapter provides a narrative review of the literature concerning recruitment and retention studies in children and families. The focus is particularly concerned with studies that predict recruitment and retention by investigating participant characteristics and trial design. Literature on barriers to research in this field will be considered. A review of qualitative studies with parents, investigating reasons for taking part in trials is also covered. Finally a critical summary of research into recruitment and retention strategies is presented.

2.2 Recruitment and retention to randomised controlled trials

Randomised controlled trials (RCTs) are generally considered to be the gold standard in evaluating healthcare interventions, primarily because their use of random assignment reduces the potential for bias (Odgaard-Jensen et al., 2011, Treweek et al., 2013a). However, the reliability of results can be compromised when non-random subsets of participants who enrol or maintain on a study are significantly different from those who choose not to take part or subsequently drop out (Karlson and Rapoff, 2009, Aylward, 1985).

Difficulties surrounding the recruitment and retention of participants to RCTs are well documented (McDonald et al., 2006). Many clinical trials are stopped or extended due to issues surrounding recruitment and retention (Tooher et al., 2008). A review of RCTs on recruitment methods carried out in 2006, reported that almost 60% of RCTs either fail to meet their recruitment targets or request extensions due to recruitment (Watson and Torgerson, 2006). Similarly, reviews of UK based trials have found that less than 31% of publicly funded trials in the UK achieved their original recruitment target between 1994 – 2002 (McDonald et al., 2006). Attrition rates have been reported as high as 70% for some intervention studies (Karlson and Rapoff, 2009).

The problems surrounding recruitment of participants are well reported. Delays in recruitment can increase the costs of a trial and reduce the chances of future investment by funders, as well as reducing the significance of results due to small sample sizes. In additional, ethical concerns can be raised around delays in the exposure of populations to potentially effective drugs (Treweek et al., 2013a), or over-exposure of participants to a dangerous treatment (Watson and Torgerson, 2006). For studies extending recruitment

periods in order to meet targets, it is also possible that clinical practice can change in the meantime, making the results of the trial of little importance anyway (Tooher et al., 2008).

Retention of participants is as critical to the success of RCTs as recruitment; especially in studies with long-term follow up (Booker et al., 2011). Some argue that retention is of more concern than recruitment due to the risk of bias if attrition differs between the groups (Adamson et al., 2015). The impacts of significant attrition of a sample are congruent with issues surrounding recruitment; loss of subjects can reduce the statistical power of results thus limiting the internal and external validity of findings (Moser et al., 2000). Attrition can also result in unnecessary use of resources such as drugs and researcher/clinician time (Moser et al., 2000). In the findings from a systematic review of paediatric chronic conditions, Karlson and Rapoff (2009), recommend enrolling 30% more participants than is deemed necessary to allow for significant power, as attrition is likely to occur in most studies; however, given their report of up to 70% dropout in previous studies, their estimate could be construed as conservative.

2.3 Trials with children and families

It is now widely acknowledged that children should not be treated as 'mini adults' due to their unique physiology and development (Stephenson, 2006). As a result, RCTs in children are now considered best practice to ensure that the therapies and interventions in use for this age group are appropriate and not simply based on extrapolations from adult research (World Health Organization, 2017). Recent changes in legislation have led to an increase in child research; in 1998 the US National Institute for Health (NIH) issued a policy requiring all human research funded or supported by the NIH to include children unless there were ethical reasons to do otherwise (Caldwell et al., 2003). In 2006 the European parliament regulation (EC) 1901/2006 mandated the inclusion of children in clinical trials in Europe.

The consequences of un-trialled use of drugs in children are well publicised, perhaps most famously thalidomide, used for morning sickness in pregnancy and resulting in thousands of children being born with birth defects (Curran, 1971). Fortunately, the success of RCTs in children is now demonstrated through advances in healthcare in the eradication of polio and increases in childhood cancer survival rates (Joseph et al., 2015). However, Caldwell et

al. (2004) argue that despite backing and evidence to support the need for trials, there remains a limited body of research available from paediatric trials.

2.4 Recruitment and retention research with children and families

Recruitment and retention of children and their caregivers poses specific challenges to RCTs that may not be as significant in adult populations. Research into the reasons for participation and non-participation in child focussed RCTs therefore warrants investigation separate to adult populations (Shilling et al., 2011b). Despite this, the majority of studies into recruitment and retention in RCTs are focussed on adult populations (Eiser et al., 2005, Shilling et al., 2011b).

Whilst participation in RCTs in adult populations is influenced by the characteristics and beliefs of the participant and their families; in child focussed studies where the child is old enough to assent to their participation, parent, family and child characteristics can be significant in determining whether the family choose to participate, thus adding further complexity to reasons for participation and non-participation (Driscoll et al., 2009). Furthermore, studies have indicated that parents find it is more difficult making the decision on behalf of their children, than it would be making it for themselves (Caldwell et al., 2003). Shilling and Young (2009) describe this decision as "serious and possibly overwhelming" in comparison to an adult making the decision for themselves. For sick children, the parents may just have received their child's diagnosis and be in a state of shock or extreme distress, these parents may be vulnerable (Shilling and Young, 2009). It may be tempting to exclude parents and children who are at times of stress, however this would exclude many groups of sick children from potentially beneficial research (Macrae, 2009). Other studies have highlighted worry or regret about making the wrong decision on behalf of their child, and some indicate that parents of these children often do not remember giving consent when questioned at a later date (Rodriguez et al., 2006). The factors influencing parents decision is explored further in section 2.8 of this chapter.

2.5 Predicting recruitment and retention – participant predictors

Whilst attrition and delays in recruitment appear inevitable in the majority of RCTs, it is possible to identify certain characteristics of the participants who are more likely to drop out or refuse randomisation onto a clinical trial. Being able to predict which participants are

at most risk of non-participation could allow researchers to focus their attention on developing recruitment and retention strategies sensitive to the sample population and retaining contact with these participants throughout the course of the study (Janus and Goldberg, 1997). Findings from studies that successfully predict which participants are less likely to participate could be used to develop screening tools enabling researchers to provide additional support to target populations (Driscoll et al., 2009).

In adult populations it is commonly accepted that ethnic minority, lower socioeconomic status (SES), low income or poorly educated groups are less likely to take part in research and are therefore traditionally underrepresented (Gul and Ali, 2010, Cox and McGarry, 2003, Patel et al., 2003, Davis et al., 2002). These assumptions appear to be based on common findings from the analysis of single trial datasets. The literature suggests that whilst many individual studies have analysed data on participants who chose to participate against those who did not from within their own sample, very few studies have synthesised data from a range of trial datasets.

A previous systematic review of predictors to participation in cancer clinical trials, found that older age, lower SES and ethnic minority status most commonly predicted non-participation in the 65 studies included (Ford et al., 2008). This review included 4 articles on adolescents or children; all finding that parental influence was an important factor. There is however a lack of evidence synthesis in this area regarding a wider range of types of clinical trials.

2.6 Participant predictors of recruitment and retention in trials with children

Studies investigating factors that predict recruitment and retention of participants to RCTs involving children are less common than in adult populations (Janus and Goldberg, 1997). Nonetheless, parallel to predictor studies in adult populations, recruitment and retention of children and families to research studies is commonly studied in relation to socioeconomic status, age, gender and ethnicity of caregiver (Karlson and Rapoff, 2009, Spoth et al., 1999).

For reasons identified above, parent characteristics and family conflict or cohesion are also often found to be important factors (Driscoll et al., 2009, Coatsworth, 2006). Equally, recent studies have demonstrated that parent personality traits can be particularly important in

longitudinal participation programs where parents are the focus of the intervention (Bloomquist et al., 2011).

The majority of studies investigate determinants of participation within their specific health topic. However, in their study of predictors of participation in healthy and non-healthy samples Janus and Goldberg (1997) found that severity of illness as well as sociodemographic factors predicted participation to their research study. Despite this finding, studies examining clinical and non-clinical factors are scarce (Vermaire et al., 2011).

Few reviews have synthesised evidence on predictors of recruitment and retention of children and their caregivers to RCTs. Existing reviews are adult focussed, in a specific disease (Ford et al., 2005) or non-systematic in their design and specifically focussed on babies under 1 year old (Tooher et al., 2008, Ford et al., 2008). There is very little evidence on how severity of disease impacts predictors of participation. A questionnaire based study investigating motivations of mothers to enrol their children in clinical research highlighted that most studies focus on sick children and there is little known about why mothers of healthy children would decide to participate (Maayan-Metzger et al., 2008). One small study (n=209) conducted with three groups of children with differing severities of illness showed that healthy populations are more likely to drop out of research and patients who already attend hospital on a frequent/regular basis are more likely to remain in a study. All groups showed age and level of education of the main caregiver predicted participation (Janus and Goldberg, 1997).

2.7 Predicting recruitment and retention – trial design predictors

Recruitment and retention have been examined in relation to trial design in several reviews; yet, as with investigation of sociodemographic profiles their predominance is within adult populations. In a trial with pregnant women, a defined, supportive research trial structure was found to increase recruitment at sites (Levett et al., 2014). Similarly, McDonald et al. (2006) found evidence to suggest that trials with a dedicated trial manager as well as offering new drugs only available within the trial and being for cancer are more likely to result in recruitment success. However the validity of results from this review were questioned within the discussion and firm conclusions could not be drawn. The study included RCTs from 10 clinical areas as well as 18 studies labelled ‘other’, and it is therefore

possible that heterogeneity and an insufficient sample size led to the lack of significant findings. As participant characteristics and demographics were not reported it is not possible to apply these findings to specific population groups or understand whether trials involving children were included within the analysis.

In a review of UK funded Health Technology Assessment (HTA) trials published between 2004 and 2016, a relationship was found between trial setting and monthly recruitment rate and percentage retained. Target sample sizes (original and final) were also shown to be correlated to recruitment and retention rates (Walters et al., 2017). Whilst the authors present evidence of a statistical association with the aforementioned variables there were no clear patterns and further investigation on the impact of these variables would be warranted. Furthermore, as this review only included HTA funded trials the generalisability of results is questionable.

Other reviews have provided evidence to suggest that the study design and origin of funding can impact recruitment and retention of participants. In a review investigating the reporting of participant recruitment and retention, analysis of study characteristics suggested that two arm trials were more likely to achieve target outcome assessment than trials with three or more arms (Toerien et al., 2009). This review also found that surgery trials were more likely to assess higher proportions of outcomes than other treatment approaches and industry funded trials were more successful than government or charity funded studies (Toerien et al., 2009). The number of studies included in the review was considerable in comparison to the review reported by McDonald et al (2006), however, the broad range of studies and narrow date range in the search strategy could again limit the generalisability to specific populations or clinical areas. As with the McDonald et al. (2006) review it not clear from the article what age participants the trials were aimed at and it is therefore not possible to understand whether the results are applicable to RCTs involving children and families.

In addition to the lack of child focussed studies it has also been acknowledged that there is actually little research into recruitment and retention barriers within any one population group or any single intervention type (Davis et al., 2002). It has been suggested that research conducted within specific settings, interventions or age groups are worthwhile as

they could help investigators planning similar trials to overcome specific barriers to recruitment and retention (Wakim et al., 2011).

Some study level variables have been found to be significant predictors of recruitment and retention in condition specific reviews of trials. In a review of obesity treatment trials it was found that a lead-in time (during which, a placebo was administered for 2-5 weeks before the true intervention started) led to reduced attrition, but number of study visits did not impact retention of participants (Fabricatore et al., 2009). However, the significance of a lead-in time could be questioned, as the majority of trials that utilised this design required participants to adhere to treatment during this 3-5 week placebo before they could continue onto the full trial, thus selecting participants who were more motivated to take part. In a later review of recruitment and retention techniques in obesity trials involving 2-17 year olds, study characteristics were found to impact retention (Cui et al., 2015). Studies over a year in length, in community based settings were less likely to retain participants than shorter studies in school settings. The intervention focus and outcome measure also appeared to predict retention whereas age of the children, number of sessions and sample size had no impact on retention of participants (Cui et al., 2015).

In a drug abuse focussed study, Wakim et al. (2011) analysed trial characteristics for 24 trials registered on the USA based, National Drug Abuse Treatment Clinical Trial Network. This study aimed to investigate the impact of trial characteristics on recruitment and retention rates. The study characteristics tested were intervention type, full trial and treatment duration, number of treatment sessions and follow up visits, number and timing of primary assessments, number of case report forms at baseline and in the entire trial. Randomisation was measured by number of recruits per week as well as ratio of actual to planned recruitment rate. Retention was measured by availability of the planned outcome measures, treatment exposure and attendance at follow up visits. The results implied that study characteristics had little correlation with recruitment and retention, yet there was some evidence to suggest that a greater number of treatment sessions leads to a lower ratio of actual to planned recruitment; whilst lower retention appeared to be correlated to group therapy and non-psychosocial intervention types (Wakim et al., 2011).

There were several limitations to the aforementioned drug abuse study. Unfortunately, the number of studies included in the analysis was low and as the trials were described as 'multi-site complex' trials it is possible that variables not included in the analysis could have confounded results. In response to these limitations, the recommendations for further research included a need for investigation into the location of participating sites, as well as analysis of the impact of incentives. Six percent of the participants included in the review were identified as under 17 years old, however, there was no separate analysis by age. This lack of analysis by age makes it difficult to draw conclusions on whether the recommendations are applicable in trials with children. This is further confounded by the clinical area being drug abuse, which is relatively non-transferable, especially to infant populations.

A final gap in the literature is around the effect of setting on recruitment and retention. Authors reported clustering effects in schools (Machiulskiene et al., 2002), and others have suggested that the difficulties associated with community based study recruitment outweighing those based in secondary care due to compliance of patients, ease for follow up and resources (Chadwick and Treasure, 2005). Despite this, very little literature on the impact of setting currently exists.

2.8 Obstacles to predictor studies in children and families

Several researchers have identified inconsistent definitions of attrition as a significant obstacle to research on attrition (Marcellus, 2004, Zebracki et al., 2003, Yancey et al., 2006). Zebracki et al. (2003) highlighted varying definitions including participants who 'chose not to participate', dropout at baseline or dropout only during follow up phases. Marcellus (2004) added disparities ranging from participants that have missed just one appointment to those who have not completed the protocol. In a systematic review of reporting of participation rates in adult populations, lack of clarity about whether dropout rates referred to the whole study or particular intervention groups impeded results, additional confusion was present over numbers screened and referred versus numbers recruited (Sohanpal et al., 2012). A systematic review of reporting of participant adherence to the CONSORT guidelines for reporting participant flow, found that whilst the majority of papers included a flow chart there was great variability over the definition of "lost to follow up" (Toerien et al., 2009).

Several predictor studies have refined and operationalised definitions of attrition and loss to follow up as a consequence of variance between studies (Driscoll et al., 2009, Garvey et al., 2006, Zebracki et al., 2003), however, a consensus has not been reached and there has been no analysis on how lack of clarity of reporting of non-participation could have affected common findings between predictor studies to date.

2.9 Understanding reasons for participation in trials - qualitative studies with parents

It is common for qualitative studies to be undertaken within RCTs. In a review of registered controlled trials in the UK, 12% were found to conduct some qualitative research together with the RCT. Eleven (3% of the 296 studies that embedded qualitative research) were focussed on recruitment and retention (O'Cathain et al., 2014). As with most research into trial participation, the majority of qualitative studies into recruitment and retention have been conducted in adult populations (Shilling et al., 2011b). The focus has been on clinicians' views of recruitment and retention (Donovan et al., 2014a, Donovan et al., 2014b) and similar work with minority populations (Corbie-Smith et al., 1999, Hussain-Gambles et al., 2004).

Fisher et al. (2011) conducted a literature review of qualitative studies involving parents of children asked to enrol on research studies, investigating reasons for acceptance and decline. The review included 16 studies across a range of conditions; two thirds of the studies were in life threatening or life limiting illnesses. Five themes were identified in their narrative synthesis, these were 'considering the child'; 'access to free or unobtainable healthcare'; 'innovation versus tried and tested'; 'choice, benefit and risk' and 'being a good citizen'. Severity of illness and risk were common influencing factors across all studies, with parents of more severely ill children considering risk to be less of an issue and were more likely to enrol than parents with less severely ill children. Risk was measured by the type of hypothetical study that parents showed willingness to join; as measured by Likert scales on questionnaires. This study highlighted the differences between healthy populations and sick children, indicating that different factors influence the decision of parents of the two groups of children. The authors identified a lack of research around healthy children and preventive or therapeutic interventions. The recommendations made were targeted at studies involving severely ill children, with little attention given to less severe illnesses and the

generalisability to non-paediatric trials is therefore questionable. The concept of risk would also warrant further investigation, as the proxy rating was devised by the study authors rather than developed by the parents' own views.

A concentration of research in this area is focussed on oncology and neonatology (Shilling et al., 2011b). A large proportion of this is around the decision making process (Hayman et al., 2001) and parents' recall of information given to them at the recruitment phase. When approached to consent to a study, parents of very sick children may feel overwhelmed and make snap decisions with very little understanding of the research. Studies have suggested that in such stressful situations parents can prefer the clinician to make the decision on their behalf (Chappuy et al., 2006, Shilling et al., 2011a), and this may heavily influence a parent's decision to take part. Shilling and Young (2009) report that recruitment to cancer and neonatal trials is generally high which could indicate that parents feel threatened and are looking for hope when in these circumstances. Despite the stress of the situation, research suggests that parents of neonates primarily display altruistic reasons for participation (Zupancic et al., 1997, Mason and Allmark, 2000, Rodriguez et al., 2006). Personal benefit, risk, perception of harm, views on experimentation and time and pressure have also been cited as reasons for participation or non-participation in sick neonates (Rodriguez et al., 2006).

As with adults, the majority of research into recruitment and retention of neonates focusses on sick children, with little exploration on why parents choose to take part with healthy new-borns. The research above would suggest that the stress of a life threatening illness or critically ill child would have a significant impact on a parent's decision to take part in a trial. It is therefore possible that parents of less sick children will have longer to consider their decision and may have different motivations for taking part. However, in a study inviting parents to take part in hypothetical trials for healthy new-borns Maayan-Metzger et al. (2008) found that risk to the child, benefit, altruism and attitudes toward medicine were all important to mothers of the children, indicating there may be no difference in motivations between parents of healthy and sick children. They report that contrary to sick neonates, parents of healthy neonates rated risk as the most important factor in their decision, thereby agreeing with the theory of Fisher et al. (2011), that the risk involved in taking part in a trial is of greater significance to parents of healthy children than unhealthy children.

It is difficult to explore differences in reasons for recruitment and retention between families of sick and 'healthy' children in the existing literature. There are relatively few studies with parents of 'healthy', or less severely sick children. The reason for this is unclear, but may reflect the general trend of higher numbers of RCTs in neonatology and oncology than in other areas (Shilling et al., 2011a). It is also possible that access to non-participants on healthy population trials is more difficult since these are often conducted outside of a clinical setting. In this regard, one study compared interview responses from paediatric patient's parents and parents of healthy school children (Caldwell et al., 2003). Unfortunately it was not possible to differentiate the views of parents of healthy and sick children in the resulting report. Their study however offers general insights into how their child's severity of illness may impact a parent's decision. Parents felt that the health status of their child influenced the decision as to whether to take part in a trial. Some of the interviewed parents felt that parents of sick children may be traumatised by the ordeal and less likely to take part, whilst others felt that parents of healthy children may see trial participation as an unnecessary inconvenience (Caldwell et al., 2003). Whilst some of the interviewed parents had children who were already enrolled onto trials it appears that other parents were being asked about hypothetical trials testing drugs or interventions for sick children. The generalisability of these results to healthy populations is therefore questionable.

Insight into healthy populations could potentially be gained from vaccine research. A qualitative interview study with parents invited to enrol their children onto two community-based UK vaccine trials for pre-school children, found that parents were predominantly motivated to take part in vaccines research due to altruism (Chantler et al., 2007). The authors hypothesised that parents of healthy children are less likely to be motivated by advantages to the health of their child because healthy volunteers have a lack of distress due to the absence of current health problems. Their findings also indicated that parents who were familiar with science or medicine due to their professional careers or education, were more motivated to participate and more confident in their decision making capability. Parents who chose not to take part blamed discomfort, vaccination-related concerns or their child's existing ill health or side effects. Whilst the community setting, and presence of otherwise 'healthy' participants make it unusual amongst the literature the generalisability

of the findings of this vaccines research study to other areas of health are questionable due to the media coverage and controversy in the UK surrounding vaccines (Chantler et al., 2007). Further investigation in community based settings with healthy participants would therefore be warranted.

Perceived seriousness of the child's condition may also be an important factor in a parent's decision making, particularly for parents of healthy or less-sick children. A trial of a healthy lifestyle intervention with children identified from childhood obesity records offered access to parents who refused to take part in the trial (Barratt et al., 2013). Time and priorities were common reasons for refusal, with other commitments such as work being more of a priority than the research. Parents were put off by paperwork and the risk of their child having a negative view of themselves because of the stigma surrounding an obesity trial. The authors identified that parents did not see obesity as a serious problem, but as something that was transient and of little concern to their General Practitioners (GPs) (Barratt et al., 2013). Whilst the study had a small sample size, and acknowledges that the issues surrounding negative effects on their child due to the sensitivity of obesity are unique to this population, it nevertheless offers an interesting insight into non-clinical populations, areas of which could be investigated with other families of healthy or less-sick children.

2.10 Strategies to improve recruitment and retention of participants

Whist not a key aim of this thesis, recruitment and retention strategies will be referred to throughout the thesis. A large amount of literature on recruitment and retention is concerned with strategies to improve recruitment and retention. However, as with the majority of literature presented in this chapter, studies investigating recruitment and retention strategies are predominantly based on studies with adults.

Strategies to improve recruitment has been the focus of several systematic reviews, including two Cochrane reviews (Treweek et al., 2013a, Mapstone et al., 2007). A summary of the reviews and their findings are presented in table 2.1. Collectively they report that failure to recruit to the desired sample size and within the specified time is common despite the various strategies developed to improve recruitment to RCTs. Telephone reminders, opt-out procedures, open designs, questionnaires and education about the health problem being studied were all identified as effective recruitment strategies (Treweek et al., 2013a,

Mapstone et al., 2007, Watson and Torgerson, 2006, Caldwell et al., 2010, McDonald et al., 2006).

Table 2.1 – Systematic review of strategies to improve recruitment to RCTs

Author	Title	Year	Findings
Treweek, et, al.	Methods to improve recruitment to randomised controlled trials: Cochrane systematic review and meta-analysis	2013	Telephone reminders, opt-out procedures and open designs increase recruitment
Caldwell, et, al.	Strategies for Increasing Recruitment to Randomised Controlled Trials: Systematic Review	2010	Strategies that target patients awareness of the health problem being investigated, its impact on health and engagement in the learning process increased recruitment
Mapstone, et, al.	Strategies to improve recruitment to research studies	2007	Because of heterogeneity between trials and within strategies it was not possible to synthesise the results
Watson & Torgerson	Increasing recruitment to randomised trials: a review of randomised controlled trials	2006	Telephone reminders; questionnaire inclusion; monetary incentives; using an 'open' rather than placebo design; and making trial materials culturally sensitive increased recruitment
McDonald, et, al.	What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies	2006	It was not possible to assess the impact of recruitment strategies

These reviews are not without limitations. Treweek et al. (2013a) included 28 studies in their Cochrane review, however 19 of these were hypothetical trials and the application of findings to real-life situations are questionable. Two reviews were unable to draw conclusions on the effectiveness of strategies due to heterogeneity between studies

(McDonald et al., 2006, Mapstone et al., 2007) and a further study was unable to perform a meta-analysis for similar reasons (Caldwell et al., 2010). Watson and Torgerson (2006) based their conclusions on a small number of studies, and the external validity of findings could therefore be challenged. In summary, the evidence make it difficult to choose the most effective recruitment methods, and further, robust randomised trials of strategies are warranted.

Studies on the impact of participant retention and strategies to maintain samples once enrolled onto RCTs are less common than recruitment studies (Booker et al., 2011, Robinson et al., 2007). Despite this, three systematic reviews have investigated retention strategies, suggesting that a combination of retention strategies is the most effective method of increasing retention in studies (table 2.2).

Table 2.2 – Systematic review of strategies to improve retention to RCTs

Author	Title	Year	Findings
Robinson, et al.	Updated systematic review identifies substantial number of retention strategies: Using more strategies retains more study participants	2015	A combination of retention strategies is most effective
Brueton, et al	Strategies to improve retention in randomised trials: a Cochrane systematic review and meta-analysis	2014	The following increased questionnaire response: monetary incentives, recorded delivery, using multiple postal communication strategies and open trial designs
Booker, et al.	A systematic review of the effect of retention methods in population-based cohort studies.	2011	Incentives, reminder letters, telephone calls, repeat questionnaires and face to face contact all increased retention

As with recruitment studies, the evidence base for effective retention strategies is restrained by the small number of studies included in each review. Furthermore, the

heterogeneity between studies make recommendations for specific health fields and ages difficult.

2.11 Chapter summary

In summary, it has been evidenced that children and families warrant separate research into recruitment and retention to adult populations. Despite this, the majority of studies are focussed in adults.

There is a lack of synthesised evidence on the participant predictors of recruitment and retention, particularly with children and families. Similarly, the current literature indicates a gap surrounding research into whether study level characteristics can be used to predict recruitment and retention to trials specifically involving children and families. Studies with this age group appear to be limited to obesity trials. Predictor studies are hindered by lack of consistent definitions of recruitment and retention.

Whilst there are multiple qualitative studies with parents, existing studies are predominantly concerning trials involving adults, in healthcare settings and with patients rather than healthy participants. Studies in children have focussed on parent recall of information at recruitment or motivations for enrolment. As demonstrated in the literature reviewed here (where the majority of qualitative studies are focussed on recruitment), there is little evidence of investigation on reasons for retention or drop out from studies. In addition it can be summarised that the majority of studies are concerned with trials involving severely ill children or neonates and research into healthy children is limited and predominantly based in healthcare settings. There is limited qualitative research into the factors affecting recruitment and retention of children and families to community based trials or trials with a non-clinical focus

Finally, whilst there are several reviews summarising evidence on the effectiveness of recruitment and retention strategies, these have all been conducted in adults. It is not possible to make specific recommendations for health fields and specific age ranges.

Chapter 3
Literature review – recruitment and retention of children and families to oral health trials

3.1 Overview

As identified in chapter 2 of this thesis there are relatively few studies investigating the recruitment and retention of children and families to RCTs in comparison to adult focussed studies. Even fewer have been conducted in the field of dentistry and oral health. The following chapter provides a narrative review of the literature concerning recruitment and retention of children and families to oral health trials.

An overview of the global significance of oral health research is initially presented. Focus then moves to the significant areas of research around recruitment and retention in the field of oral health. Firstly, studies investigating predictors of recruitment and retention to oral health trials with children are critically summarised. Qualitative studies with parents investigating reasons for participation in oral health and dentistry trials are then presented. Finally, recruitment and retention strategies evolving from recent health disparities research are then presented along with findings from other community based oral health trials with children.

3.2 The global significance of oral health research

Oral diseases are a global issue, with dental caries being the most prevalent chronic disease in children across the world (Gussy et al., 2006). Despite being largely preventable, it is reported that between 60% and 90% of children in industrialised countries are affected by dental caries (WHO, 2012).

Dental caries can cause pain, and if untreated can lead to further, more serious complications such as sepsis (Pine et al., 2006). Untreated caries can impact on a child's weight and growth as well as general health and wellbeing (Sheiham, 2005, Ramos-Jorge et al., 2014). More specifically, children with early childhood caries (ECC) may experience pain and consequently have difficulty chewing, sleeping and concentrating at school. They may be reluctant to smile or laugh and their speech development may be impacted as a consequence (Martins-Júnior et al., 2013). This can lead to issues with behaviour, self-esteem, depression and irritability (Gussy et al., 2006). Furthermore, children with discoloured or missing teeth may be viewed negatively by others and experience stigma or negativity because of this (Exley, 2009). ECC is consequently a global public health priority.

The significance of oral health is wider reaching than just dental caries. Oral health is linked to a person's overall general health and wellbeing. Research has suggested that there are links between periodontal health and coronary disease (Seymour and Steele, 1998), diabetes (Soskolne and Klinger, 2001) and pneumonia and pulmonary disease (Scannapieco et al., 2003). There is evidence to suggest that the oral health behaviours developed in childhood, are linked to oral health in adulthood (Nunn, 2006). Therefore interventions with children have the possibility to impact adult health later in life. In the case of ECC, most children have developed caries by the age of 5, therefore pre-school ECC interventions are important for prevention (Chadwick and Treasure, 2005); however, studies with school aged children appear to be favoured as children are easier to involve and more receptive when in the school environment (Gussy et al., 2008).

A World Health Organization report on the global burden of disease highlighted variations in oral health according to a country's development status (Petersen et al., 2005). In the past, low-income 'developing' countries, traditionally had lower levels of dental caries; however, over recent decades prevalence of decay has increased due to increased sugar consumption and low levels of fluoride exposure. Similarly, increased intervention in high-income 'developing' countries has led to a decrease in decay prevalence. However, despite advances in oral health promotion, self-care and exposure to fluoride, poor oral health remains a prevalent health concern in all countries worldwide and is therefore a global public health problem requiring attention (Petersen et al., 2005, Pitts et al., 2011).

On a global and local scale, the burden of oral health is most profound in poorer and socially disadvantaged populations (Pitts et al., 2011, Petersen et al., 2005). Therefore oral health research and RCTs have a valuable role to play in reduction of global health inequalities.

3.3 The national and local significance of oral health research

In the UK there is a clear correlation between socioeconomic status (SES), deprivation and oral health. The 2015 epidemiological survey of five year old children identified that children with the highest levels of dental decay were living in the most deprived parts of the country (Public Health England, 2016). Across the country an average of 24.7% of children had experienced decay, however this rate was much lower (20.1%) in the South East of England than children in the North West (33.4%). The report presented a correlation between dental

decay and index of multiple deprivation (IMD) (a measure of deprivation calculated through indicators e.g. income, education and employment (IMD, 2007)) (Public Health England, 2016).

3.4 Predictors of recruitment and retention to dental and oral health RCTs

In a pre-school randomised controlled trial of preventive techniques to reduce the prevalence of ECC in Manchester, UK; Davies et al. (2007) analysed the characteristics of participants (parents who received interventions on the trial) versus non-participants (parents who did not attend the health checks at which the interventions were delivered). They found a higher prevalence of caries in children who did not participate than those who continued their participation. They concluded that participation bias in their sample questions the validity of population based interventions to reduce ECC. Whilst some sociodemographic measures were collected at baseline and were compared between the two groups (intervention and control), they were not presented in relation to retention in this study and it is therefore not possible to determine whether parent characteristics were an influencing factor.

In a second pre-school ECC prevention trial Ramos-Gomez et al. (2008) investigated the sociodemographic factors, dental knowledge and reported dental health of mothers of children aged 4 months in relation to both recruitment and retention. Their trial, based on the US-Mexico border, identified that Hispanic mothers were more likely to be randomised and retained than mothers from other ethnic heritage. Several other variables predicted recruitment. Mothers with better household income, dental knowledge and a higher self-reported dental health were more likely to be recruited on the trial, however these variables were reported to have no impact upon retention of the recruited participants. The unique population, setting, and intensive culturally sensitive retention techniques adopted on this trial make the generalisability of results to other studies questionable.

In a similar oral health promotion and fluoride varnish trial in Navajo Nation, US minority parent and child (mean age 3.6 years) dyads were recruited to a trial. Parent and child characteristics were tested to determine predictors of drop out. Males and children whose parents reported their child's oral health status to be 'good' were more likely to be retained on the school component of the trial. Parent oral health promotion classes were poorly

attended. Drop out was associated with parents from larger households and a lower locus of external control (a belief that their child's oral health is the responsibility of the dentist) (Bryant et al., 2016). Again, the nature of the minority population being studied in this trial make the external validity of results questionable.

Two studies with primary school aged children analysed differences between recruitment 'responders' and 'non-responders' to investigate the external validity of their trial results. Splieth et al. (2005) found that non-responding children in their school based trial with 6-11 year olds were older, had higher caries and plaque levels, had fewer preventive measures and parents were less likely to complete a baseline questionnaire than responders. They concluded that the significant clinical variables indicated that children whose parents did not respond were in greater need of the caries prevention programme than responders. The authors likened their findings to a smoking prevention trial, where children most at risk of smoking were less likely to get parental consent to take part than those that were low risk (Severson and Biglan, 1989).

Vermaire et al. (2011) also hypothesised that parents who agreed for their child to participate in a practice based caries prevention trial were those least in need. They found that non-participation was more likely in parents who did not have 3 regular meals a day, were less likely to brush twice a day or use interdental brushes and had a lower level of dental knowledge. Contrary to Davies et al. (2007) and (Splieth et al., 2005), they found no difference in level of caries between participants and non-participants and therefore concluded that the external validity of their findings was not at risk due to participation bias.

3.5 Qualitative work on recruitment and retention in oral health and dentistry trials

There is little evidence of qualitative work on recruitment or retention of participants in dental RCTs. This is despite oral health being a global health problem. One study (Marshman et al., 2012) conducted interviews with parents involved in a pilot study prior to an RCT, to explore their views on involvement in the pilot study. Researchers generally found parents to be positive, as long as the trial had minimum impact on their child and would lead to improved treatment in the future (Marshman et al., 2012). In another study Carvalho and Costa (2013) interviewed mothers who had recently given informed consent for their child to be randomised to a dental trial of behaviour management techniques for paediatric

dental rehabilitation. As with many other qualitative studies in this area, the focus of the exploration was on understanding of the consent process and randomisation. Carvalho and Costa (2013) observed little parental understanding of the different techniques that their child could be randomised to, or comprehension of the randomisation process. The study did not investigate reasons for acceptance or refusal, but the authors hypothesised that mothers were so disturbed by their young child (under 3 years) requiring treatment for caries, that they felt powerless and were motivated to engage with the trial because this promised access to care and a benefit to the child. This finding draws into question the validity of consent and ethics of the trial itself, given that participants admitted to being under such stress. Despite being interviewed immediately after consent and randomisation, little knowledge on either process was apparent. There is currently no evidence of studies conducted on dental or oral health trials with heathy or non-patient participants.

3.6 Recruitment and retention techniques in oral health trials

In recent years, funding by the US National Institutes of Health has led to an increase in the number of studies targeting oral health disparities, particularly community based caries prevention trials with minority populations (Garcia et al., 2016). This has led to investigations into recruitment and retention strategies with populations who are most at risk of oral health disparity.

In a study of three of the NIH funded research centres in the US, the authors concluded that community based participatory research (research involving the community members in the design and conduct of the study) is required for successful recruitment of ethnic and racial minority communities to ECC oral health trials (Tiwari, 2014). A later study of the aforementioned research centres, Garcia et al. (2016) reported that involving the community in intervention design and delivery was also critical to RCT success with minority populations. They also advise using a variety community sensitive methods to assist with retention of participants, including promotion through local media, building rapport and trust between the research team and participants, extensive contact, home visits and family friendly appointment clinics (Garcia et al., 2016). However, the external validity of the two studies could be limited. The trials from which the results were gathered were all with specific minority groups across America. Furthermore, the trials were not designed to

evaluate retention strategies, findings were observational and it is therefore not possible to determine the effects of individual strategies.

In a similar study, based in Australia, a similar participatory approach was used to recruit and retain ethnic minority families with children aged 1-4 years to an oral health promotion trial. Contrary to the previous two studies retention remained an issue in this trial. Despite employing cultural partners and an intensive tracking system, 47% of participants were lost to follow up. The authors concluded that research interventions need to align with existing social and cultural groups (Gibbs et al., 2015).

Similar studies with minority populations or groups at risk of health inequalities have been conducted in the UK. Extensive recruitment and retention efforts were required in a community based, pre-school (18-30 months) trial in Wales, UK (Chadwick and Treasure, 2005). Despite referrals by enthusiastic health visitors 55.5% of participants failed to attend the recruitment appointment. Once recruited only 11.6% of participants dropped out of the trial, however they report extensive efforts to retain participants including up to 15 home visits for one child to have an assessment. In total 1,056 home visits were required to see 449 children for follow up appointments. The authors did not speak to the participants but speculated that problems were due to the age of the sample, involving pre-school children, who don't usually attend the dentist at this age unless there is a problem. They also speculated that parents were not interested in research, healthcare or dental issues (Chadwick and Treasure, 2005).

Aside from the community based research with minority groups discussed above, evidence for effective recruitment and retention strategies for dental trials, particularly within health care settings appear limited. Previous studies have also identified this lack of dental specific advice around recruitment and retention (Keightley et al., 2014, Weintraub and Breland, 2015). Weintraub and Breland (2015) reviewed dental literature to develop recommendations on recruitment strategies in paediatric dental research. Their search of the top 10 cited articles in a paediatric dentistry journal and targeted literature review in PubMed returned very little evidence. Instead they took recommendations from non-dental studies identified from grey literature to produce guidance on how to improve recruitment to paediatric dental studies; this included building trust with the participant population,

through using venues such as schools and community hubs. Whilst this study was of limited quality, due to the non-systematic approach to their searches (it is likely that literature was overlooked) the study does demonstrate the dearth of recruitment studies in the oral health and dentistry field.

Retention strategies in oral health and dental trials are also under-researched. Martin-Kerry et al. (2015) looked at the challenges of conducting trials in primary care dentistry. Recommendations around recruitment were suggestions for clinicians to find enough time and delegate appropriate staff, however the authors did provide practical recommendations to improve retention in that participant burden should be reduced, specifically length of appointments and convenient appointment times for participants (Martin-Kerry et al., 2015).

3.7 Chapter summary

In summary, oral health is a global health problem, particularly in childhood. Research conducted with children has the possibility to have impact on general health and wellbeing with lasting effects into adulthood. Research into recruitment and retention of children and their families to oral health and dentistry trials is therefore warranted. Despite this, research into this area is scarce.

The literature investigating predictors of recruitment and retention in oral health trials with children is limited, with the majority focussed on recruitment rather than retention of participants. Most studies that have investigated characteristics of participants have focussed on clinical variables (decay prevalence) due to a concern for the generalisability of results. There is limited evidence from studies investigating sociodemographic factors, oral health beliefs of parents, or parental self-efficacy in relation to oral health behaviours, however there is some evidence to suggest that the children enrolled on trials are those in least need of the intervention.

Similarly, only a small number of qualitative studies have investigated reasons for parents choosing to take part in oral health trials with their children, only two studies were found, investigating recruitment. It is not currently possible to understand the reason for parents enrolling their children on oral health trials or continuing with participation past enrolment.

Finally, recommendations for recruitment and retention techniques in oral health and dental trials are very limited. Evidence is based on specific communities involved in health disparities research, this is mainly based in the US. There is very little advice on successfully recruiting and retaining participants on trials in health care settings.

Addressing these gaps in the literature, this thesis uses mixed methods to investigate predictors and explore the barriers and facilitators to recruitment and retention of children and families to oral health trials. To achieve this aim a number of objectives were set out across four individual studies:

Study	Objective
1	1. What factors have been identified as significant participant predictors of recruitment and retention to RCTs involving children? 2. Are there any differences in predicting factors between community based and non-community based RCTs? 3. Are there any differences in predicting factors between 'healthy' and 'patient' (non-healthy) populations? 4. How do studies define participant drop-out?
2	1. Are study-level variables associated with recruitment and retention of children and families to oral health trials? 2. Do oral health trials involving children utilise the CONSORT guidelines for reporting of participant flow?
3	1. What motivated parents to enrol onto the Salford Bright Smiles Baby study? 2. What factors made it easier for the enrolled participants to continue on the trial to the end? 3. What factors made it difficult for the enrolled participants to continue on the trial to the end? 4. What do interviewed parents perceive to be barriers to recruitment for families that chose not to enrol on the trial?
4	1. Did sociodemographic variables predict which participants were more likely to be retained on the SBS? 2. Did oral health beliefs and behaviours predict which participants were more likely to be retained on the SBS?

Chapter 4

Identifying the participant characteristics that predict recruitment and retention of participants to RCTs involving children: A systematic review - 'Study 1'

4.1 Overview

This chapter begins by outlining the rationale for study 1. A systematic review of participant predictors of recruitment and retention in trials involving children and their families is then presented. The search strategy and data extraction and analysis methods are described. The results are presented with a discussion of how the findings relate to existing literature. Limitations of the study will be discussed along with recommendations for future research and reporting of RCTs.

4.2 Rationale for study 1

As identified in the thesis literature review in chapter 2, very few reviews have synthesised evidence on predictors of recruitment and retention of children and their caregivers to RCTs (Chapter2, section 2.6). Existing reviews are in a specific disease (Ford et al., 2005, Ford et al., 2008) or non-systematic specifically on babies under 1 year old (Tooher et al., 2008).

Furthermore, the literature provides very little evidence on how severity of disease impacts predictors of participation (chapter 2, section 2.6). A questionnaire based study investigating motivations of mothers to enrol their children to clinical research highlighted that most studies focus on sick children and there is little know about why mothers of healthy children would decide to participate (Maayan-Metzger et al., 2008). One small study (n=209) conducted with three groups of children with differing severities of illness showed that healthy populations are more likely to drop out of research and patients who already attend hospital on a frequent/regular basis are more likely to remain in a study. All groups showed age and level of education of the main caregiver predicted participation (Janus and Goldberg, 1997).

A further gap is apparent for the effect of setting on prediction of participation (chapter 2, section 2.7), despite authors reporting clustering effects in schools (Machiulskiene et al., 2002), and the difficulties associated with community based study recruitment outweighing those based in secondary care due to compliance of patients, ease for follow up and resources (Chadwick and Treasure, 2005).

The literature review also identified inconsistent use of definitions of attrition (chapter 2, section 2.8) as a significant hindrance to retention research (Marcellus, 2004, Zebracki et al.,

2003, Yancey et al., 2006). This review will therefore also investigate the definitions of attrition used in the included studies and comment on the impact of this in reporting.

4.3 Study aim

The main aim of this systematic review was to identify the predictors of recruitment and retention in a range of types of RCTs involving children.

4.4 Study objectives

What participant factors predict recruitment and retention to RCTs for children and their families?

1) What factors have been identified as significant participant predictors of recruitment and retention to RCTs involving children?
2) Are there any differences in predicting factors between community based and non-community based RCTs?
3) Are there any differences in predicting factors between 'healthy' and 'patient' (non-healthy) populations?
4) How do studies define participant drop-out/ attrition?

4.5 Methods

4.5.1 Design and justification of methods

Study 1 is a systematic review of studies investigating participant predictors of recruitment and retention to RCTs involving children and families. An overview of systematic reviews and the methods' strengths and weaknesses will be discussed briefly hereon.

4.5.1.1 Systematic reviews

A systematic review is a method of summarising literature, using procedures that are reproducible and transparent. Systematic reviews may or may not include a meta-analysis (statistical analysis of combined data), depending on whether studies are similar enough so that combining results would be meaningful (Gopalakrishnan and Ganeshkumar, 2013). Systematic reviews are commonly used for keeping clinicians abreast of the best evidence base, developing clinical guidelines and justifying the need for further research (Moher et

al., 2009). They can also be used to identify where evidence is absent or insufficient (Gopalakrishnan and Ganeshkumar, 2013).

4.5.1.2 Strengths of systematic reviews

Systematic reviews aim to identify and synthesise results for studies in a given area. As part of the process studies are evaluated for their quality and risk of bias. By combining studies, bias is reduced and the effectiveness of an intervention is decided in a more precise and reliable way than relying on single studies alone (Centre for Reviews and Dissemination, 2009).

Systematic reviews and meta-analysis of RCTs are placed at the top of the hierarchy of evidence (Evans, 2003). This position indicates that the results of a systematic review are the most reliable form of evidence from which researchers and clinicians can base decisions upon.

4.5.1.3 Limitations of systematic reviews

Whilst systematic reviews limit the bias due to heterogeneity between studies it can never be eliminated and it has therefore been suggested by some that the 'pyramid' of hierarchies of evidence be modified (Murad et al., 2016). Furthermore, the concept of a hierarchy of evidence has been criticised, as a study lower in the hierarchy (e.g. an observational study), may in fact be of better quality than a study higher in the hierarchy (e.g. an RCT) due to the methodology and rigour used (Petrisor and Bhandari, 2007). Further areas for criticism of systematic reviews are how the studies were selected, heterogeneity between studies and inappropriate analysis (Gopalakrishnan and Ganeshkumar, 2013). In summary, it can be generalised that the results of a systematic review are only as reliable as the review itself.

Reporting guidelines can assist in the transparency and appraisal of systematic reviews. Guidelines lay out a minimum set of items required to ensure complete and transparent reporting, thus making it easier for the reader to evaluate the reliability of results (Simera et al., 2010). Several guidelines exist including the QUOROM statement for reporting of meta-analysis (Moher et al., 2000) and the PRISMA guidelines for reporting systematic reviews and meta-analysis (Moher et al., 2009). The latter will be adopted for reporting of this review.

4.5.2 Eligibility criteria

The following criteria were applied to the search

- **Types of studies:** Studies based on data from randomised controlled trials (including randomised cross over trials, cluster randomised trials)
- **Types of participant:** Children, or parents/ legal guardians of children aged birth – 12 years (study intervention finishes before child's 13th birthday).
- **Types of outcome measure:** Significance of a factor to predict recruitment and/ or retention of participants to a trial (see section 4.5.2 for definitions of recruitment and retention).
- **Language:** English language papers only.

There were no date restrictions applied to the search, included papers were published in peer reviewed journals

4.5.3 Definitions of recruitment and retention

For the purposed of this study **recruitment** is defined as being randomised onto a study and therefore the participant has enrolled. Papers comparing participants who were randomised with those who chose not to be randomised were eligible for inclusion in the review.

Retention was defined as a measure of whether participants remained in the study for final outcome assessment. Papers were eligible for inclusion if they had a clear definition of participants who withdrew (e.g. were withdrawn due to protocol non-compliance or chose to withdraw) and compared the characteristics of these participants to participants who remained in the study (did not withdraw or were not withdrawn from the study due to protocol non-compliance).

4.5.4 Exclusion criteria

- Studies that do not analyse participant data to predict recruitment and retention of participants in studies.
- Studies that do not specify whether a participant entered or left the study (i.e. definition of recruitment and or dropout is not clear).

- Papers that only discuss participation/ engagement (i.e. involvement in an intervention) and not entry and exit from a study were excluded.
- Studies not testing participant factors for significance of prediction ability of recruitment and/ or retention to clinical trials.
- Studies not based on data derived from RCTs.
- Studies not investigating children aged 0-12 (or study finishes after child's 13th birthday).
- Studies that are not based on measurements within real settings (hypothetical trials) were excluded.

4.5.5 Search strategy and data extraction

An electronic search was carried out in MEDLINE, PSychINFO, CINAHL and the Cochrane Library (see table 4.1). Citation searching of all 'included' and 'unclear' papers put forward after the title and abstract screening phase was conducted using the Web of Knowledge. In addition the reference section of each of the aforementioned papers was searched for further papers to include in the review. One reviewer (LR) screened titles and abstracts of all retrieved articles against the inclusion and exclusion criteria using the 'initial screening tool' (appendix 1). Articles that were classified as 'include' or 'unclear' were carried forward to the next stage of screening where full text papers were obtained. If it was evident that papers did not meet the inclusion criteria they were classified as 'exclude' and full text articles were not obtained. Any uncertainties were classified as 'unclear' to avoid bias due to one author screening at this stage. Full text screening was conducted by LR against the inclusion and exclusion criteria using a pre-developed screening tool (appendix 2). 'Unclear' papers were independently reviewed by another researcher after the full text screening phase. Data extraction was undertaken independently by two reviewers.

Table 4.1 – Search terms and strategy

Medline	
1	((Predict$ or influenc$ or motivat$ or measur$ or determin$ or estimate$ or differenti$ or compar$) adj5 (Recruit$ or participat$ or consent$ or Retention or attrition or Loss to follow-up or Dropout$ or withdraw or non-participation))
2	(child$ or baby or infant or pediatric$ or paediatric$)
3	(exp Patient Dropouts or exp Patient Participation or exp Prospective Studies)
4	1 AND 2 AND 3

PsychInfo	
1	((Predict* or influenc* or motivat* or measur* or determin* or estimate* or differenti* or compar*) adj5 (Recruit* or participat* or consent* or Retention or attrition or Loss to follow-up or Dropout* or withdraw or non-participation))
2	(child* or baby or infant or pediatric* or paediatric*)
3	(exp Treatment Dropouts or exp Experimental Attrition or exp Experimental Subjects)
4	1 AND 2 AND 3

Cinahl	
1	((Predict* or influenc* or motivat* or measur* or determin* or estimate* or differenti* or compar*) N5 (Recruit* or participat* or consent* or Retention or attrition or Loss to follow-up or Dropout* or withdraw or non-participation))
2	(child* or baby or infant or pediatric* or paediatric*)
3	(exp Research Subject recruitment or exp Research Dropouts or exp Prospective Study OR Patient Selection)
4	1 AND 2 AND 3

Cochrane	
1	((Predict* or influenc* or motivat* or measur* or determin* or estimate* or differenti* or compar*) NEAR (Recruit* or participat* or consent* or Retention or attrition or Loss to follow-up or Dropout* or withdraw or non-participation))
2	(child* or baby or infant or pediatric* or paediatric*)
3	(exp Patient dropouts or exp Patient Selection or exp Patient Compliance OR Follow Up Studies)
4	1 AND 2 AND 3

4.5.6 Data extraction

Data was extracted from all included papers by LR using a structured data extraction tool developed specifically for the purpose of the study. Information on study length and design, disease type, setting and factors reported as significant and insignificant for predicting the recruitment and/ or retention was collected and is summarised in table 4.2. Where necessary supplementary papers were searched for additional data (e.g. original trial

protocol or results papers were consulted for clarification on study design and details of the intervention as full details of the original study are not always included in a secondary analysis paper). If information was still not attainable it was recorded as 'not available'.

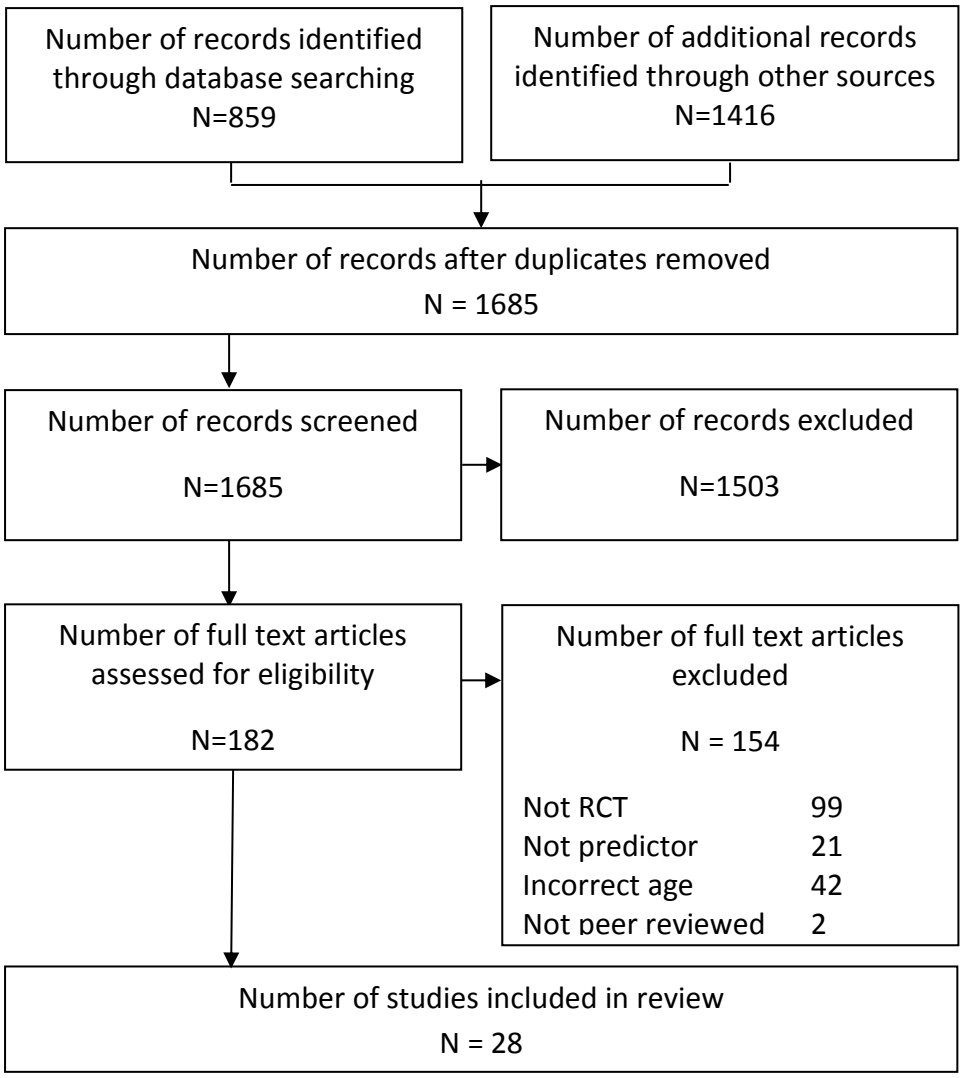
4.5.7 Quality assessment and risk of bias

Due to the diversity of studies and outcomes included in the articles within this review, a traditional quality assessment tool was difficult to adapt to the assessment of studies; therefore, a tool was specifically developed for this review (appendix 3), adapted from two existing checklists - STROBE (Von Elm et al., 2007) and 'checklist for the evaluation of research articles' (Durant, 1994). Each item on the 14 point checklist was scored 0 – 2 (0 = inadequate description, 1 = fair description, 2 = adequate description). Each paper was then given a percentage quality score (based on points attained out of total points available). The use of a 3 point rating scale was based on methods used in similar studies (Ford et al., 2008, Thomas et al., 2004).

4.5.8 Method of analysis and synthesis

The most frequently reported variables across the included studies were considered for meta-analysis, using adjusted odds ratios of recruitment and/or retention as the outcome variables. Unfortunately, due to the heterogeneity in scales and measures it was not possible to conduct a meta-analysis on any of the sociodemographic variables identified in this review.

Figure 4.1 - Flow diagram of phases of systematic review



4.6 Results

A flow diagram of the screening process is presented in Figure 4.1. The database search, full paper reference and citation searches of included papers resulted in 2,275 papers, 590 of which were duplicates. 1,503 papers were excluded through screening of titles and abstracts, full paper articles were obtained for the 75 'include' and 105 'unclear' for full paper screening. The most frequent reason for exclusion after full text screening was the study design not being an RCT and/or the intervention did not focus on children aged 0-12 years.

4.6.1 Description of included studies

Twenty-eight studies met the inclusion criteria (Aylward, 1985, Baker et al., 2011, Boggs et al., 2004, Byrnes et al., 2012, Constantine et al., 1993, Cunningham et al., 1995, Cunningham

et al., 2000, Damashek et al., 2011, Daniels et al., 2012, Eisner and Meidert, 2011, Fernandez and Eyberg, 2009, Firestone and Witt, 1982, Gross et al., 2001, Heinrichs et al., 2005, Ireys et al., 2001, Katz et al., 2001, Medical Research Council Multicentre Otitis Media Study Group, 2001, Mihrshahi et al., 2002, Miller and Prinz, 2003, Ramos-Gomez et al., 2008, Roggman et al., 2008, Van Den Akker et al., 2003, Wagner et al., 2003, Werba et al., 2006, Winslow et al., 2009, Zebracki et al., 2003, Moser et al., 2000). This gave a total of 12,504 participants being assessed for factors predictive of their participation across the 28 RCTs. Eleven studies were specifically concerned with prediction of recruitment of participants to RCTs. Eleven studies focussed on retention of participants and six studies examined predictors of both recruitment and retention to an RCT.

Of the 28 included studies, 23 RCTs were randomised at an individual level (including one crossover trial) and the remaining five studies were cluster trials. The articles reported on recruitment and retention in numerous settings including home visits, university clinics, hospitals and schools. Twelve of the studies were community-based, 11 were located in a health setting and three were carried out between community and health-care settings (with information on setting unavailable for two studies).

The majority of articles were conducted in the US and published in 2000 or later, only four studies were published prior to this. The RCTs covered a wide range of medical conditions differing in severity from children with cystic fibrosis (Ireys et al., 2001) to a nutrition focussed prevention programme for first time mothers (Daniels et al., 2012). Twelve studies were classified as medical in their focus, whilst the remaining 16 fell into the non-medical category. The study characteristics are summarised in table 4.2.

Table 4.2 - Summary of study characteristics

Author	Year	Intervention	Study Length	Study Design	Focus	Country	Sample Size	Setting	Disease Type	Medical or non medical intervention	Target Population
Aylward, G.P., Hatcher, R.P., Stripp, B., Gustafson, N.F. and Leavitt, L., A. (1985)	1985	Dexamethasone administration	Repeated visits	RCT individual	Retention	USA	645	Health setting - university centres	Prevention of respiratory distress syndrome	Medical	Babies - surviving infants
Baker, C. N., Arnold, D. H. and Meagher, S. (2011)	2011	Parenting intervention	8 weeks	RCT cluster	Recruitment	USA	106	Community - childcare centres	Parent training for preventing conduct problems	Non medical	Families of preschoolers mean age of child 4.6 years (intervention group only)
Boggs, S.R., Eyberg, S.M., Edwards, D.L., Rayfield, A., Jacobs, J., Bagner, D. and Hood, K.K. (2004)	2004	Parent child interaction therapy (PCIT)	Longitudinal - time unlimited, mean treatment length 13 weekly sessions	RCT individual	Retention	USA	46/ 61 enrolled	Unclear	Existing disruptive behaviour	Medical	Children with disruptive behaviour disorders
Byearnes, H. F., Miller, B. A., Aalborg, A. E. and Keagy, C. D. (2012)	2012	Parenting intervention	Longitudinal but this looks at enrolment	RCT individual	Recruitment	USA	351/ 744 eligible	Health setting - medical centres	Substance use prevention	Non medical	Families with an 11-12 year old

Author	Year	Intervention	Study Length	Study Design	Focus	Country	Sample Size	Setting	Disease Type	Medical or non medical intervention	Target Population
Constantine, W.L., Haynes, C.W., Spiker, D., Kendall-Tackett, K. and Constantine, N.A. (1993)	1993	3 year home visits, parent support groups and education program v normal care	3 years	RCT individual	Retention	USA	885/1302 eligible	Mixed - large urban tertiary care centres and satellite clinics for hard to reach	Low birth weight premature infants reducing health and development problems	Non medical	Babies born before 37 weeks
Cunningham, C. E., Boyle, M., Offord, D., Racine, Y., Hundert, J., Secord, M. and McDonald, J. (2000)	2000	Parenting intervention	Enrolment	RCT cluster	Recruitment (retention not clear)	Canada	1498	Community - schools	Children at risk of disruptive behaviour disorder - parent training	Non medical	5-8 year olds with high parent reported externalising problems
Cunningham, C. E., Bremner, R. and Boyle, M. (1995)	1995	Parenting intervention	Longitudinal	RCT individual	Retention	Canada	150	Community - community-based neighbourhood schools and community centres	Children at risk of disruptive behaviour disorder - parent training	Non medical	Junior kindergarten school children with problems at home
Damashek, A., Doughty, D. Ware, L. and Silovsky, J. (2011)	2011	Parenting intervention	Longitudinal	RCT individual	Recruitment	USA	398	Community - home	Child maltreatment prevention	Non medical	Female caregivers with a child 1-5 years in home

Author	Year	Intervention	Study Length	Study Design	Focus	Country	Sample Size	Setting	Disease Type	Medical or non medical intervention	Target Population
Daniels, L, A; Wilson, J, L; Mallan, K, M; Mihrshahi, S; Perry, R; Nicholson, J, M; Magarey, A	2012	Parenting intervention	Longitudinal	RCT individual	Recruitment and retention	Australia	698	Community - community child health clinics	Nutrition – prevention	Non medical	1st time mothers of healthy infants
Eisner, M and Meidert, U. (2011)	2011	Parenting intervention	Longitudinal but this looks at enrolment	RCT cluster	Recruitment (retention not clear)	Switzerland	821 test group only	Community - public primary schools	Parent training (triple P)	Non medical	Children in primary school
Fernandez, M.A. and Eyberg, S.M. (2009)	2009	PCIT	2 year follow up	RCT individual	Retention	USA	99	Health setting - PCIT Lab	Existing disruptive behaviour	Medical	3-6 year olds with Disruptive Behaviour Disorder
Firestone, P. and Witt, J. E. (1982)	1982	Parenting intervention	4 month programme	RCT crossover	Retention	Canada	83 families (test group only)	Health setting - psychology department hospital	Hyperactive children	Medical	Families of hyperactive children 5-9 years of age
Gross,D., Julion, W. and Fogg, L. (2001)	2001	Parenting intervention	1 year - 15 months	RCT cluster	Recruitment and retention	USA	155 test group only	Community - childcare centres (community bases)	Parent training	Non medical	2-3 year olds attending day care centres, serving low income families

Author	Year	Intervention	Study Length	Study Design	Focus	Country	Sample Size	Setting	Disease Type	Medical or non medical intervention	Target Population
Heinrichs, N., Bertram, H., Kuschel, A. and Hahlweg, K. (2005)	2005	Parenting intervention	Enrolment	RCT cluster	Recruitment	Germany	186/ 282 enrolled, test group only	Community - schools	Prevention of emotional and behaviour problems, parent training	Non medical	3-6 year olds
Ireys, H. T., DeVet, K. A., and Chernoff, R. (2001)	2001	Parenting intervention	15 months	RCT individual	Recruitment	USA	161	Mixed - pediatric practices and home visits	Children at risk of mental health problems because of serious ongoing physical health conditions	Medical	Mothers with children aged 7-10 months with diabetes sickle cell disease, cystic fibrosis or asthma
Katz, K.S., El-Mohandes, P.A., Johnson, D.M., Jarrett, P.M., Rose, A. and Cober, M. (2001)	2001	Parenting intervention	12 months	RCT individual	Recruitment and retention	USA	286	Community - Home visits	Parenting intervention to increase use of healthcare and to increase skills in providing safe and structured child rearing	Non medical	Mothers of babies, low income

Author	Year	Intervention	Study Length	Study Design	Focus	Country	Sample Size	Setting	Disease Type	Medical or non medical intervention	Target Population
Mihrshahi, S;Vukasin, N; Forbes, S; Wainwright, C; Krause, W; Ampon, R; Mellis, C; Marks, G; Peat, J	2002	Parenting intervention	5 years	RCT individual	Recruitment	Australia	616	Community - home visits	Asthma – prevention	Medical	Pregnant women with asthma or father has asthma
Miller, G. E. and Prinz, R. J. (2003)	2003	Parenting intervention	Longitudinal	RCT individual	Retention	USA	147	Health setting - children and family centre affiliated with a university	Serious childhood aggression and conduct problems	Medical	Families with 5-9 year old boys
Moser, D.K., Dracup, K. and Doering, J.V. (2000)	2000	3 methods of cardiopulmonary resuscitation training v control	Longitudinal	RCT individual	Retention	USA	578	Unclear	Cardiac/ respiratory arrest	Medical	Parents and caregivers of high risk neonates at risk of cardiac/ respiratory arrest
Multicentre Otitis Media Study Group (2001)	2001	Bilateral intervention tubes with and without adenoidectomy against non-surgical management	12 weeks from 1st visit to randomisation	RCT individual	Recruitment	UK	1315	Health setting - 3 UK Centres - Hospitals	Otologica (hearing) Glue Ear	Medical	3y3m - 9y9m referred for otological problems (OME)

Author	Year	Intervention	Study Length	Study Design	Focus	Country	Sample Size	Setting	Disease Type	Medical or non medical intervention	Target Population
Ramos-Gomez, F; Chung, LH; Beristain, RG; Santo, W; Jue, B; Weintraub, J; Gansky, S (2008)	2008	Dental disease management	Longitudinal	RCT individual	Recruitment and retention	USA	361	Health setting - health centres	Childhood caries	Non medical	Pregnant women attending community health centres, mostly Hispanic
Roggman, L.A., Cook, G. A., Peterson, C. A. and Raikes, H.H. (2008)	2008	Parenting intervention	Longitudinal	RCT individual	Retention	USA	564 test group only	Community - interviews by phone and home visits	Home visits for early childhood development	Non medical	Children up to age 3
Van den Akker, E. H., Rovers, M. M., Van Staaij, B. K., Hoes, A. W. and Schilder, A. G. M. (2003)	2003	Adenotonsillectomy	Enrolment	RCT individual	Recruitment	Netherlands	First 270 randomised children	Health setting - hospital	Adenotonsille-ctomy	Medical	2-8 years old
Vermaire, J.H., van Loveren, C. and Hoogstraten, J. (2011)	2011	Caries prevention strategies - detail unknown	6 years	RCT individual	Recruitment	Netherlands	286	Health setting - dental practices	Caries	Non medical	6 year old in dental clinics

Author	Year	Intervention	Study Length	Study Design	Focus	Country	Sample Size	Setting	Disease Type	Medical or non medical intervention	Target Population
Wagner, M. ; Spiker, D., Inman Linn, M. and Hernandez, F. (2003)	2003	Parenting intervention	Monthly home visits, look at sample up to child's first birthday	RCT individual	Retention	Canada	238	Community - home based	Behaviour	Non medical	Low income families, up to 8 months old (home visitation group only - not control)
Werba, B.E., Eyberg, S.M., Boggs, S.R. and Algina, J. (2006)	2006	PCIT	Longitudinal	RCT individual	Retention	USA	99	Health setting - psychology clinic in health sciences centre	Existing disruptive behaviour disorder – PCIT	Medical	Families of 3-6 year olds
Winslow, EB; Bonds, D; Wolchik, S; Sandler, I; Braver, S (2009)	2009	Parenting intervention	11 weeks	RCT individual	Recruitment and retention	USA	325	Mixed - home and sessions on University campus	Parenting programs for divorced mothers	Non medical	Divorced mothers with a child aged 9-12
Zebracki, K., Drotar, D., Kirchner, H., Schluchter, M., Redline, S., Kercsmar, C. and Walders, N. (2003)	2003	Control v session of problem solving therapy for family asthma management skills	Longitudinal	RCT individual	Recruitment and retention	USA	327	Health setting - teaching hospital	Asthma	Medical	4-12 year olds

4.6.2 Predictor variables

A total of 155 participant factors were analysed across the 28 papers; there was considerable variation between articles in the variables that were tested for their significance to predict recruitment and retention. Most papers included an analysis of sociodemographic variables (e.g. ethnicity, age, income etc.) alongside treatment/condition specific variables. Whilst the majority of studies included condition specific (e.g. asthma severity (Zebracki et al., 2003), parent stress (Boggs et al., 2004), predictors of participation in their analysis, the variation in measures used was considerable, even for studies within the same field. Heterogeneity therefore precluded any meta-analysis.

Participant factors were classified into four categories: a) parent characteristics, b) child characteristics, c) family characteristics and d) neighbourhood characteristics. Of the 155 variables reported, 45 parent, 19 child, 4 family and 2 neighbourhood variables were found to be significant predictors of recruitment and retention to RCTs involving children and families in at least one study. Nine parent, two child, two family and two neighbourhood characteristics were recurrent across the included papers and were analysed. The 15 recurrent predictors are presented in tables 4.3 (recruitment focussed studies) and 4.4 (retention focussed studies) and will be discussed hereon.

Table 4.3 – Recruitment studies – summary of predictors

Key: x = not significant ✔ = significant				**Parent**									**Child**		**Family**		**Neighbourhood**	
Author	**Predicting**	**Setting**	**Medical or non medical intervention**	**Ethnicity**	**Education**	**Parent Age**	**Income**	**SES**	**Parent depression**	**Single Parenthood**	**Marital status**	**Employment**	**Child gender**	**Child age**	**Number of family members**	**Number of children**	**N'hood high school drop out**	**Density of n'hood networks**
Baker et al., 2011	recruitment	Community	non medical	✔				✔	X	X								
Byrnes et al., 2012	recruitment	Health	non medical	✔	✔	✔							X				✔	
Constantine et al., 1993	recruitment	Mixed	non medical	✔														
Cunningham et al., 2000	recruitment	Community	non medical		✔		X		X	✔			✔	X				
Damashek et al., 2011	recruitment	Community	non medical	X	X	X	X		✔									
Daniels et al., 2012	recruitment	Community	non medical	X	✔	✔					✔							
Eisner and Meidert, 2011	recruitment	Community	non medical	✔			✔	✔		X								✔
Heinrichs et al., 2005	recruitment	Community	non medical			X		✔		✔					X			
Ireys et al., 2001	recruitment	Mixed	medical	✔					✔				X					

Key: x = not significant ✔ = significant

				Parent									Child		Family		Neighbourhood	
Author	**Predicting**	**Setting**	**Medical or non medical intervention**	**Ethnicity**	**Education**	**Parent Age**	**Income**	**SES**	**Parent depression**	**Single Parenthood**	**Marital status**	**Employment**	**Child gender**	**Child age**	**Number of family members**	**Number of children**	**N'hood high school drop out**	**Density of n'hood networks**
Mihrshahi et al., 2002	recruitment	Community	medical	X	✔	X						X						
Multicentre Otitis Media Study Group, 2001	recruitment	Health	medical	X				X					X	X		X		
Van den Akker, et al.,2003	recruitment	Health	medical										X	X				
Vermaire et al., 2011	recruitment	Health	non medical	✔				✔		X	X		X					
Winslow et al., 2009	recruitment	Mixed	non medical	X	X		✔											
Zebracki et. Al., 2003	recruitment	Health	medical	X	X	✔	X				X	X			X			
			Total	12	7	6	5	5	4	5	3	2	6	3	2	1	1	1
			Significant	6	4	3	2	4	2	2	1	0	1	0	0	0	1	1
			Non-significant	6	3	3	3	1	2	3	2	2	5	3	2	1	0	0

Table 4.4 – Retention studies – summary of predictors

Key: x = not significant ✔ = significant				**Parent**									**Child**		**Family**		**N'hood**	
Author	**Predicting**	**Setting**	**Medical or non medical intervention**	**Ethnicity**	**Education**	**Parent Age**	**Income**	**SES**	**Parent depression**	**Single Parenthood**	**Marital status**	**Employment**	**Child gender**	**Child age**	**Number of family members**	**Number of children**	**N'hood high school drop out**	**Density of n'hood networks**
Aylward et al., 1985	retention	Health	medical					✔										
Boggs et al., 2004	retention	Unclear	medical	X		X		X					X	X				
Constantine et al., 1993	retention	Mixed	non medical		✔	X												
Cunningham et al.,1995	retention	Community	non medical		X				X									
Daniels et al., 2012	retention	Community	non medical	X	✔	✔					X							
Fernandez and Eyberg, 2009	retention	Health	medical					✔										
Firestone and Witt 1982	retention	Health	medical		✔	✔	✔						✔	✔		X		
Gross et al., 2001	retention	Community	non medical	X	X	X	X		X		✔	X	X					
Katz et al., 2001	retention	Community	non medical	X	X	X					X	X				✔		

Key: x = not significant ✔ = significant

Author	Predicting	Setting	Medical or non medical intervention	Parent: Ethnicity	Parent: Education	Parent: Parent Age	Parent: Income	Parent: SES	Parent: Parent depression	Parent: Single Parenthood	Parent: Marital status	Parent: Employment	Child: Child gender	Child: Child age	Family: Number of family members	Family: Number of children	N'hood: N'hood high school drop out	N'hood: Density of n'hood networks
Miller and Prinz 2003	retention	Health	medical		X													
Moser et al., 2000	retention	Unclear	medical	X	X	X	X		✔		X				X			
Ramos-Gomez et al., 2008	retention	Health	non medical	✔	X	X	✔			X								
Roggman et al., 2008	retention	Community	non medical		X	X			X	✔		X	✔	✔	X			
Wagner et al., 2003	retention	Community	non medical		✔	✔	✔											
Werba et al., 2006	retention	Health	medical			✔		X	✔	X				X				
Winslow et al., 2009	retention	Mixed	non medical	✔	✔		X											
Zebracki et. Al., 2003	retention	Health	medical	X	✔	✔	X				X	X			X			
			Total	8	13	12	7	4	5	3	5	4	4	4	3	2	1	1
			Significant	2	6	5	3	2	2	1	1	0	2	2	0	1	1	1
			Non-significant	**6**	**7**	**7**	**4**	**2**	**3**	**2**	**4**	**4**	**2**	**2**	**3**	**1**	**0**	**0**

4.6.2.1 Parent characteristics

Parent characteristics were the most common factors assessed for significance to predict recruitment and retention in RCTs; 88 parent related predictors were included in the analyses. Nine parent characteristics were frequently assessed across the 28 studies, these were ethnicity (n = 17 studies), parent education (n = 16 studies), parent age (n = 16 studies), income (n = 10 studies), SES and parent depression (n = 9 studies), single parent status (n = 8 studies), marital status (n = 6 studies) and employment (n = 5 studies).

Ethnicity

Ethnicity was found to be a significant predictor of recruitment in six of the 12 studies where this variable was included. Ethnic minorities were less likely to enrol in five of the six studies that found it to be a significant predictor (Baker et al., 2011, Byrnes et al., 2012, Eisner and Meidert, 2011, Ireys et al., 2001, Vermaire et al., 2011). Constantine et al. (1993) reported that 'Blacks and Hispanics' were more likely to enrol than 'Whites and Others' in their home visits for a low birth weight children trial based in the USA. This finding however, appears to represent confound due to the offer of free, long term medical follow-up in a population that were less likely to have guaranteed care (Constantine et al., 1993). Six studies analysed ethnicity but did not find it to be a significant predictor. The majority of recruitment studies that found ethnicity to be a significant predictor were non-medical, only one of the six studies was in a medical intervention. Two of the studies were community-based, two were in a health-care setting and two were delivered across both settings.

Ethnicity was analysed in eight retention studies; for example in one of the included studies Winslow et al. (2009) reported that ethnic minorities were more likely to remain in their mixed setting (health and community based) parenting intervention for divorced mothers and Ramos-Gomez et al. (2008) reported that Mexican Americans were more likely to remain on their practice based dental prevention trial than other Hispanic or non-Hispanic populations. Six other studies found that ethnicity was not a significant predictor of retention in their samples.

Education

A measure of parent/caregiver education was included in seven of the recruitment trials and was found to be a significant predictor in four of these studies. Whilst the studies measured different levels of education including college (Byrnes et al., 2012), high school (Cunningham et al., 2000), university (Daniels et al., 2012), and tertiary education (Mihrshahi et al., 2002) all four articles report that recruitment was predicted by higher educational attainment of parents. Two of the four studies were community-based non-medical interventions; the other two were a community-based medical and a health setting based non-medical intervention, respectively.

Education was the most frequently examined variable in relation to retention, however, retention was only reported to be significantly impacted by higher levels of education in 6 of the 13 retention articles (Constantine et al., 1993, Firestone and Witt, 1982, Wagner et al., 2003, Winslow et al., 2009, Zebracki et al., 2003, Daniels et al., 2012). Studies that found education to be a significant predictor of retention showed no preference for setting, however, four of the studies were non-medical interventions and two were medical.

Socioeconomic Status (SES)

Indicators of SES varied, with no common measure being used between studies. Lower SES predicted non-participation of families in four of the five recruitment studies (Baker et al., 2011, Eisner and Meidert, 2011, Heinrichs et al., 2005, Vermaire et al., 2011), all of these were non-medical intervention RCTs, one being based in a health setting. Only one trial did not find SES to be a significant predictor of recruitment, this was of a medical intervention tested in a healthcare setting.

Two studies (Aylward, 1985, Fernandez and Eyberg, 2009) both found that low SES predicted drop out from their studies, two other studies found SES to be a non-significant predictor of retention. All four studies that reported SES were medical intervention studies, three were conducted in a health care setting and one setting was unclear.

Income

Some studies reported parent's 'income' in the place of SES, one study (Eisner and Meidert, 2011) reported both as separate variables. Eisner and Meidert (2011) found that children from dual earner families were less likely to enrol to their trial; whereas mother's income was positively correlated with enrolment in Winslow et al. (2009) parenting intervention for divorced families. Both studies were non-medical interventions, the former was based in a health care setting with the latter being split between a health settings and the participant's home. Three trials found that income had no impact on enrolment.

Similarly three retention studies that investigated parent income found that higher household income parents were more likely to remain participants on their RCTs , however, a further four studies found that this was not a significant predictor of retention. There appeared to be no relationship between significance of income and setting or intervention type.

Age

Six studies analysed the impact of parent age on recruitment, three of the studies found that older parents were more likely to enrol. Three studies (all community-based) concluded that parent age had no impact on recruitment.

Twelve studies investigated parent age in relation to retention of participants; the majority found this to be a non-significant predictor of drop out, however in the five studies that reported age as significant predictor, older parents were more likely to remain on the trial, these studies showed no predilection to setting or health status.

Other parent characteristics

Parent depression was investigated in relation to recruitment in four studies, with two finding that higher levels of depression correlated with an increased likelihood of enrolment; whereas two studies found that depression had no impact on recruitment rates. Five studies analysed parental depression in relation to retention, Moser et al. (2000) concluded that parents with higher levels of depression were more likely to drop out of their trial with infants at risk of cardiopulmonary arrest; similarly parents who showed

higher levels of depression were more likely to withdraw from a trial delivering parent child interaction therapy (Werba et al., 2006). However a further three studies found no relationship between depression and retention.

The impact of being a single parent was investigated in relation to recruitment in two parent training intervention trials, whilst Cunningham et al. (2000) found that single parents were less likely to enrol, Heinrichs et al. (2005) reported that it increased the likelihood of enrolment. Three studies found no impact on recruitment. Only one (Roggman et al., 2008) of the three studies that measured retention of participants found that single mothers were more likely to drop out of the research.

One study into recruitment found that mothers who were married were more likely to enrol in a community-based, infant feeding intervention trial, but that marital status had no impact on retention of their participants (Daniels et al., 2012). Similarly, one retention focussed study found that parents in partnered relationships were significantly more likely to drop out of the prevention programme trial than parents who were married, single or foster parents (Gross et al., 2001). Conversely two non-community-based recruitment studies and three retention studies found marital status to have no impact on retention.

The final predictor commonly tested across studies was parent employment. Employment status was examined in two recruitment and four retention studies but was not found to be a significant predictor on the recruitment or retention of the RCT participants.

4.6.2.2 Child characteristics

Child characteristics were less frequently reported for significance than their parents'; 56 variables were analysed across the studies however the majority of these variables were condition specific and therefore found only in a small number of studies. The two most frequently tested variables were child age (n = 7 studies) and child gender (n = 10 studies).

Child age

Age of the child was examined in three recruitment studies but found to have no impact on rates of enrolment. Younger children were significantly more likely to drop out of the sample of 5-9 year old children enrolled onto a behavioural parent-training programme

(Firestone and Witt, 1982), the same was true in a sample of children and parents enrolled onto a home visit programme (Roggman et al., 2008). However, child age had no impact on retention of participants in two other studies in the review.

Child gender

Parents of boys were more likely to enrol onto parenting courses in one study (Cunningham et al., 2000) but had no impact on recruitment in the other studies that analysed the variable. Firestone and Witt (1982) found that females were more likely to withdraw from their hospital based trial with hyperactive children, whereas Roggman et al. (2008) found that males were more likely to drop out of their home visit programme early. Two trials found that child gender had no impact on retention of participants.

4.6.2.3 Family characteristics

Analysis of family variables was also less common; the two commonly assessed factors were number of children in the family/ home (n = 3 studies) and number of people in the family (n = 4 studies). Only one study that investigated characteristics of the family found an impact, Katz et al. (2001) found that mothers with more children were more likely to drop out than mothers with fewer children.

4.6.2.4 Neighbourhood characteristics

Whilst identified as a separate category, neighbourhood factors were only investigated in two of the included studies. Eisner and Meidert (2011) found that a greater density of neighbourhood networks predicted recruitment, however they were the only study to investigate this variable. Similarly neighbourhood high school drop-out was a significant predictor of recruitment in the one study that analysed it.

4.6.3 Definitions of participant attrition

Of the 28 included papers, 17 included a definition of retention/attrition which met the study inclusion criteria (appendix 4). Whilst some articles used missing data at the endpoint as a marker (Fernandez and Eyberg, 2009, Zebracki et al., 2003, Constantine et al., 1993, Daniels et al., 2012), other studies classed people as withdrawals if they missed follow up appointments (Cunningham et al., 1995, Miller and Prinz, 2003), or based their cut off point

on the number of sessions attended (Gross et al., 2001, Werba et al., 2006). Only two studies reported participants who could not be contacted in their definition as attrition (Katz et al., 2001, Miller and Prinz, 2003). A number of studies identified different levels of attrition at various stages of the study, providing a more comprehensive understanding of the types and timing of attrition (Miller and Prinz, 2003, Werba et al., 2006, Zebracki et al., 2003).

4.6.4 Assessment of quality of included studies

Results of the quality assessment of the 28 studies are presented in Table 4.4. The quality of papers ranged from 89% to 46%. Whilst the majority of papers gave a detailed background and scientific rationale, fewer papers outlined clear objectives and hypotheses for the research (n=11 included a hypothesis).

Most papers gave sufficient detail on the trial from which data originated to understand the study design, populations and settings, however two of the studies (Wagner et al., 2003, Werba et al., 2006) did not include sufficient detail for the reader to understand the nature of the trial. Similarly three of the 26 studies did not detail the intervention, including length of exposure to the intervention. All of the studies were judged to have provided an objective account, with sufficient detail and explanation of the method of analysis and results for the reader to have a sound understanding and judge the results for themselves. None of the included studies raised concern regarding the internal consistency of the findings. It was felt that three of the included studies (Ireys et al., 2001, Baker et al., 2011, Heinrichs et al., 2005) did not present findings in clear tables. Heinrichs et al. (2005) conducted logistic regression including a number of sociodemographic variables and parent/family characteristics but did not present the results. Similarly, Baker et al. (2011) conducted statistical analysis including chi-square tests, t-tests and logistic regression analysis, however results of tests are only reported in free text and are difficult to comprehend as a consequence. In some instances it was difficult to extract results including one (Constantine et al., 1993) that only reported significant predictors and did not present results for non-significant predictors; similarly Aylward (1985) did not report results of the statistical analysis for the full range of predictors. This made it difficult to compile results during data extraction as it was not clear whether predictors not reported were not

statistically significant or were not included in the testing. In six of the 26 studies the authors provided no detail on whether it was necessary to control for confounding variables during analysis, in such cases, studies were scored ‘0’. Only seven of the studies gave detailed recommendations for future research, whilst only six of the 28 included studies discussed the external validity of their findings.

	Table 4.5: Quality Assessment of Included Papers	Aylward, et, al. (1985)	Baker, et, al. (2011)	Boggs, et,al. (2004)	Byrnes, et, al. (2012)	Constantine, et, al. (1993)	Cunningham, et, al. (2000)	Cunningham, et, al. (1995)
Intro	Does the paper explain the scientific background and rationale for the investigation being reported?	2	2	2	2	2	2	2
	Are specific objectives stated, including any pre-specified hypotheses?	1	2	2	2	1	1	1
Methods	Are key elements of study design and original trial explained in enough detail?	1	2	2	1	2	1	1
	Are setting, locations, and the study sample described clearly in terms of sample size and characteristics?	1	1	2	1	2	1	1
	Are lengths of exposure/ intervention provided for applicable groups i.e. control and intervention or just intervention if only measuring this group?	0	2	1	2	1	2	2
	Is the study size large enough to test the hypotheses?	2	1	1	1	2	1	1
	If a longitudinal retention study are details given of the efforts to maintain the sample? i.e. payments, contacts made etc?	1	1	2	N/a	2	N/a	1
Results	Are the findings presented clearly, objectively and in sufficient detail to enable the reader to judge the results for himself/ herself?	2	1	2	2	1	1	1
	Are the findings internally consistent, i.e. do the numbers add up properly, can the different tables be reconciled etc?	2	1	2	2	2	1	1
	Were appropriate variables or factors controlled for or blocked during the analysis?	2	1	0	1	1	1	1
	Do the investigators present sufficient data in tables and in the text to adequately evaluate the results?	2	0	2	2	1	1	1
Discussion	Are limitations of the study discussed, taking into account sources of potential bias or imprecision?	0	2	2	2	0	0	2
	Do the authors discuss the generalisability (external validity) of the study results?	0	0	0	0	2	0	0
	Are recommendations for future research made?	0	2	1	2	0	0	0
	Percent (points attained out of total points available)	57%	64%	75%	77%	68%	46%	57%

		Damashek, et,al. (2011)	Daniels et, al. (2011)	Eisner and Meidert (2011)	Fernandez, and Eyberg, (2009)	Firestone and Witt, (1982)	Gross,D., et, al. (2001)	Heinrichs, et, al. (2005)
Intro	Does the paper explain the scientific background and rationale for the investigation being reported?	2	2	1	2	1	2	2
	Are specific objectives stated, including any pre-specified hypotheses?	2	1	0	2	1	1	2
Methods	Are key elements of study design and original trial explained in enough detail?	1	2	1	2	2	2	2
	Are setting, locations, and the study sample described clearly in terms of sample size and characteristics?	1	2	1	1	1	2	1
	Are lengths of exposure/ intervention provided for applicable groups i.e. control and intervention or just intervention if only measuring this group?	1	1	1	1	1	1	2
	Is the study size large enough to test the hypotheses?	1	1	2	1	1	2	1
	If a longitudinal retention study are details given of the efforts to maintain the sample? i.e. payments, contacts made etc?	0	2	1	1	1	2	N/a
Results	Are the findings presented clearly, objectively and in sufficient detail to enable the reader to judge the results for himself/ herself?	2	2	2	1	1	1	1
	Are the findings internally consistent, i.e. do the numbers add up properly, can the different tables be reconciled etc?	2	2	2	1	2	2	1
	Were appropriate variables or factors controlled for or blocked during the analysis?	2	1	0	2	1	0	1
	Do the investigators present sufficient data in tables and in the text to adequately evaluate the results?	2	2	1	1	1	2	0
Discussion	Are limitations of the study discussed, taking into account sources of potential bias or imprecision?	2	2	2	1	2	2	1
	Do the authors discuss the generalisability (external validity) of the study results?	0	1	1	0	0	0	2
	Are recommendations for future research made?	0	1	0	1	1	1	1
	Percent (points attained out of total points available)	69%	76%	64%	61%	57%	71%	65%

		Ireys, et, al. (2001)	Katz, et, al. (2001)	Mihrshahi et, al. (2002)	Miller and Prinz, (2003)	Moser, et, al. (2000)	Multicentre Otitis Media Study Group (2001)	Ramos-Gomez, et, al (2008)
Intro	Does the paper explain the scientific background and rationale for the investigation being reported?	2	2	2	2	2	2	2
	Are specific objectives stated, including any pre-specified hypotheses?	2	1	0	2	1	1	1
Methods	Are key elements of study design and original trial explained in enough detail?	2	1	1	2	2	2	2
	Are setting, locations, and the study sample described clearly in terms of sample size and characteristics?	1	2	2	2	1	2	2
	Are lengths of exposure/ intervention provided for applicable groups i.e. control and intervention or just intervention if only measuring this group?	1	2	2	2	1	1	1
	Is the study size large enough to test the hypotheses?	1	1	1	1	2	2	2
	If a longitudinal retention study are details given of the efforts to maintain the sample? i.e. payments, contacts made etc?	N/a	1	0	1	2	N/a	2
Results	Are the findings presented clearly, objectively and in sufficient detail to enable the reader to judge the results for himself/ herself?	2	2	1	1	2	1	2
	Are the findings internally consistent, i.e. do the numbers add up properly, can the different tables be reconciled etc?	2	1	1	1	2	2	2
	Were appropriate variables or factors controlled for or blocked during the analysis?	1	2	0	1	1	0	1
	Do the investigators present sufficient data in tables and in the text to adequately evaluate the results?	0	0	1	1	1	2	2
Discussion	Are limitations of the study discussed, taking into account sources of potential bias or imprecision?	1	1	0	0	0	1	2
	Do the authors discuss the generalisability (external validity) of the study results?	1	0	0	0	0	2	2
	Are recommendations for future research made?	0	0	0	2	0	0	1
	Percent (points attained out of total points available)	62%	54%	42%	64%	61%	69%	86%

		Roggman, et, al. (2008)	Van den Akker, et, al (2003)	Vermaire, et, al. (2011)	Wagner, et, al. (2003)	Werba, et, al. (2006)	Winslow, et, al. (2009)	Zebracki, et, al. (2003)
Intro	Does the paper explain the scientific background and rationale for the investigation being reported?	2	1	2	2	2	2	2
	Are specific objectives stated, including any pre-specified hypotheses?	1	1	1	1	2	2	2
Methods	Are key elements of study design and original trial explained in enough detail?	1	1	1	0	0	2	2
	Are setting, locations, and the study sample described clearly in terms of sample size and characteristics?	1	1	1	2	2	1	2
	Are lengths of exposure/ intervention provided for applicable groups i.e. control and intervention or just intervention if only measuring this group?	0	1	0	1	2	2	2
	Is the study size large enough to test the hypotheses?	2	2	2	1	1	1	1
	If a longitudinal retention study are details given of the efforts to maintain the sample? i.e. payments, contacts made etc?	0	N/a	N/a	1	1	N/a	2
Results	Are the findings presented clearly, objectively and in sufficient detail to enable the reader to judge the results for himself/ herself?	1	1	2	1	2	2	2
	Are the findings internally consistent, i.e. do the numbers add up properly, can the different tables be reconciled etc?	1	2	2	2	2	2	2
	Were appropriate variables or factors controlled for or blocked during the analysis?	1	0	2	1	1	2	1
	Do the investigators present sufficient data in tables and in the text to adequately evaluate the results?	2	1	2	2	2	2	1
Discussion	Are limitations of the study discussed, taking into account sources of potential bias or imprecision?	0	1	0	2	2	2	2
	Do the authors discuss the generalisability (external validity) of the study results?	0	1	1	2	0	0	2
	Are recommendations for future research made?	2	0	1	2	1	2	2
	Percent (points attained out of total points available)	50%	50%	65%	71%	71%	85%	89%

4.7 Discussion

This systematic review of 28 RCTs has identified several significant predictors of recruitment and retention for children and their families. A wide range of parent, child, family and neighbourhood factors have been identified to predict recruitment and retention; of the 154 variables included in analyses, 66 were found to be significant in at least one study. Parent characteristics were the most commonly assessed characteristics. Given their involvement in the decision making and informed consent process in this age group, this finding was to be expected.

Parental ethnicity was a commonly reported predictor of recruitment and retention in the RCTs, and supports findings from a previous review focused on adult RCT recruitment and retention where ethnic minority groups were found to be less likely to agree to participate in trials (Ford et al., 2008). The literature reports specific reasons for ethnic minorities being excluded from research as mistrust due to events in history (Janson et al., 2001, Corbie-Smith et al., 1999, Hussain-Gambles et al., 2004), language needs or discrimination (Baker et al., 2011), suspicion of intervention providers and perceived racism and stigmatisation (Winslow et al., 2009). Efforts to address the inclusion of minority groups in RCTs is evident in US policy, where, since the introduction of the National Institute of Health Revitalization Act in 1993, increased efforts have been employed to involve minorities in research including ethnic minority populations (Baquet et al., 2006, Ford et al., 2008). These measures prevent unequal distributions of the risks and benefits of trial participation, whilst also ensuring that findings are relevant to underrepresented populations (Ford et al., 2008). The findings of this review could indicate that such measures are still required for research involving families and children as ethnic minorities appear to be less likely to enrol on RCTs than non-minority ethnic groups. However, whilst ethnicity was a significant predictor in six recruitment studies, a further seven investigated ethnicity but did not find an association and it is therefore not possible to generalise this finding to all RCTs.

The relationship between socioeconomic status and ethnicity, within both adult and child populations, is widely accepted to be closely correlated; with arguments put forward that they should no longer be seen as categorical variables because ethnicity interacts with and is confounded by social class or socioeconomic status (Committee on Pediatric Research,

2000). Most of the studies included in this review acknowledge the difficulties in separating SES and ethnicity. Whilst some identified the confounding effect of the two variables, not all studies evidenced that this was controlled for during analysis, and it is therefore possible that there is shared variance in the predictive value of the interaction between two factors in the same study. The context of the study should also be considered when interpreting the results on the impact of ethnicity and SES on recruitment and retention. Ethnicity represents a complex issue relating to a range of particular cultural values and perspectives which will be confounded by the country in which the RCT was conducted. Further research to identify particular groups at risk of non-participation within specific contexts would therefore be warranted.

Within this review four of the five recruitment studies and two of the four retention studies that investigated SES as a variable, identified lower SES as a significant predictor of participation in RCTs. Many authors outside of this review have suggested why having a low SES status predicts non-participation in research studies. Explanations focus on the demands placed on families in lower SES categories and having less time to devote to research given that they are struggling with immediate problems such as childcare and insufficient financial support (Garvey et al., 2006), lack of time or family commitments (Baker et al., 2011), and fewer resources for childcare and transport (Janson et al., 2001). Parents facing these challenges may have different priorities to families with fewer challenges and may be deterred from participating as a result. Families with higher levels of stress due to factors such as access to childcare, low income and single parent status are more at risk of lack of regular routine, interfering with participation of regular trial appointments, as was observed in the Roggman et al. (2008) home visit programme. Non-participation of these groups could lead to non-representative results and recommendations for family interventions that are unsuitable for low SES groups, and strategies to facilitate participation are therefore required.

Parent income was analysed in ten studies within this review, however, only one of these also had a separate measure of SES (Eisner and Meidert, 2011). SES is commonly a combined measure of income, education and occupation (Winkleby et al., 1992) and the results for income and SES are therefore likely to be linked. In this review, higher income seemed to predict participation in some studies and therefore fits with the SES trend

discussed above. The studies hypothesised that low income families are more likely to face the problems linked to SES i.e. problems with childcare, lack of transportation, less regular work schedules (Winslow et al., 2009) and more challenges than affluent families (Wagner et al., 2003). In contrast, employment, commonly used in SES calculation, showed no impact on recruitment or retention in any of the five studies that analysed it.

Higher level of parental education was also found to be positively correlated with increased recruitment and retention in eleven studies. Explanations for this finding from within this review suggest that parents with less education may have a lack of interest due to a lack of comprehension of the goals and how research is conducted (Mihrshahi et al., 2002). Other researchers (Winslow et al., 2009) argue that higher educated parents may value education and research more, and their occupations may allow greater flexibility and control over their work schedules to attend appointments than employed parents with lower educational attainment. Similarly, a qualitative vaccine research study found that parent's decision making was impacted by how much experience a parent has in science and medicine, and therefore those with experience of research through education would be more likely to take part (Chantler et al., 2007). Studies have also suggested that less educated parents may not fully understand the altruistic value of research (Sullivan, 2004) and are therefore less likely to take part if they do not perceive it to be relevant to them.

Evidence from the trials included in this review suggests that older parents are more likely to enrol and remain on trials with their children. The specific reason for age being a predictor of participation is less well documented that the other variables and would therefore warrant further investigation in future studies. The impact of being a younger parent was investigated in one study that suggested that the older parents in a behaviour study may have tried everything else and therefore saw more value in remaining in the research or were 'desperate' for help (Firestone and Witt, 1982). The other three retention studies finding this predictor significant provided little explanation for the result, however reasons could be linked to different priorities between younger and older parents or that being younger, with lower income or being a single parent is indicative of higher levels of stress and differing priorities because of this (Roggman et al., 2008).

The findings on parent depression were less conclusive, with conflicting results between studies. Similarly the impact of marital status and single parenthood were difficult to interpret due to contradictory effects and non-significant results. Despite the relative lack of involvement from children in the decision making process at this age, child characteristics were also frequently tested for their ability to predict recruitment and retention. The majority of child variables were condition specific clinical variables, however age and gender were common across a range of studies and allowed some comparison. The relatively small number of studies and disagreement between studies also made it difficult to draw conclusions on the impact of these variables.

An original objective of this review was to investigate the impact of study setting and child health-status. The relatively low number of studies that analysed each variable, and presence of non-significant findings made it difficult to draw firm conclusions on these study level variables and would warrant further investigation in future research.

4.7.1 Definitions of recruitment and retention

An initial aim of the review was to investigate how studies define recruitment and retention, in particular the varying definitions of drop out. During the initial stages of this review it became apparent that a clear definition of recruitment and retention was required to support the inclusion and exclusion criteria due to the plethora of definitions in use. The definitions chosen were selected to be as inclusive as possible, but confined enough to ensure that poor attendance at sessions did not get mistaken with drop-out from a study. As a result, 16 papers were excluded at the full paper review stage due to unclear definitions.

In support of the work of previous authors (Zebracki et al., 2003, Fernandez and Eyberg, 2009, Driscoll et al., 2009) a recommendation from this study would be for reporting guidelines to adopt unequivocal definitions of recruitment and retention, eradicating the interchangeable use of widely adopted terms such as loss to follow up, drop out, engagement, non-participation etc. Further to Karlson and Rapoff (2009) identification of lack of clarity in reporting and additional guidelines to accompany the Consort diagram, the findings of this study would support recommendations for further guidelines on definitions

of attrition to support the consort flow diagram; this addition would standardise reporting and ease comparison between RCTs.

4.7.2 Reporting

Whilst not an initial aim of the review, this study has provided insight into the differing standards of reporting of studies that predict recruitment and retention of participants to RCTs. The quality assessment of the studies highlighted differing varies of quality ranging from 46 – 89% (table 4.8). As discussed in previous sections, due to the wide range of factors analysed for prediction ability it was difficult to compare studies. Whilst there have been very few reviews of predictor studies to draw recommendations from, one suggestion from this review would be for future studies assessing factors for prediction to focus on common predictors, correlated within their field to allow ease of comparison between studies. Similarly, how results were reported differed across studies, with some studies excluding insignificant predictors from their results and other ambiguous exclusions making results difficult to draw conclusions upon. The impact of poor reporting on this review's findings is further addressed under limitations of the study.

Finally it was noticed that some studies omit incentives and recruitment and/or retention strategies from their reporting. When understanding the participant flow within a trial it is necessary to know what incentives were offered to the participants and how intensively they were followed up and tracked. Without this information it is difficult to ascertain what impact the predictor had and how much of it was down to the incentive offered (Gross et al., 2001).

4.8 Limitations of the review

One limitation is the wide range of studies compared. Whilst also being a strength of the review, the broad number of health topics, settings and intervention types could limit the validity of findings due to the range of possible confounding factors. Whilst effort was made to compare commonly used predictors across the studies to ensure consistency and comparability, there was variation within these due to the measures, data collection methods and analysis not being consistent across the 28 included papers. Most notably indicators and analysis of SES varied, with some studies using parent income as an indicator of SES whilst other studies treated this as a discrete variable. As addressed previously, whilst

SES was controlled as a confounding variable in some analyses, this was not true in all papers. It is acknowledged that SES may be confounded by other variables, for example parent's education and income, but a discussion of the impact is outside the scope of this thesis.

The method used for quality assessments of the included studies is not standardised due to the lack of suitable tool availability. The STROBE checklist from which part of the tool was adapted (Von Elm et al., 2007) is not recommended for use as a quality assessment tool but was deemed suitable due to the lack of an alternative.

A further drawback, which highlights a wider issue within this field (Glickman et al., 2009) is the origin of studies, predominantly based in the US, Canada and Europe. Whilst geographical setting was not an exclusion criteria, this review did not identify any studies from lower income countries. The validity of findings to non-Caucasian dominated populations is therefore confined by this limitation.

4.9 Recommendations for further research

The findings of this review highlight a need for consistency and strengthening of reporting in studies investigating predictors of recruitment and retention. Clearer definitions of recruitment and retention would make comparisons of results between studies more tangible, as would analysis of common predictors both within heath topics and across all studies.

Whilst SES and ethnicity were identified as common predictors it is difficult to draw firm recommendations for future studies. Further research into recruitment and retention strategies for infant ethnic minority populations is required, as this is not currently available. A randomised controlled trial of different strategies within ethnic minority populations and SES categories would identify the most effective methods to overcome the obvious barriers; the impact of free childcare was highlighted as an under-explored potential incentive for low SES groups.

Thirdly further investigation of the importance of clinical variables in predicting recruitment and retention to RCTs would be of value. This was highlighted as an important area for

future research by Vermaire et al. (2011), but was unfortunately not able to be addressed within this review due to the large range of studies.

4.10 Conclusions

This review found that the commonly assessed predictors of recruitment and retention can be categorised into parent characteristics, child characteristics, family characteristics and neighbourhood characteristics. The most commonly assessed variables were related to the parent. It would appear that younger, less educated parents from ethnic minorities and low SES groups are least likely to participate in RCTs; however these variables were also found to be non-significant predictors in multiple studies in this review. There is no conclusive evidence to suggest any one parent, child, family or neighbourhood characteristic can be used to predict recruitment or retention of children and their families to all RCTs. The predictors should therefore be treated with caution.

Similarly, the review has identified some predictors that are more commonly significant in different settings and health statuses, however the presence of similar non-significant findings prevent clear conclusions from being drawn.

The common variables discussed within this review are difficult for the researcher to influence, and there is little in the way of understanding on how recruitment and retention strategies can be applied to the groups most at risk of non-participation, particularly as the majority of work in this field has been conducted in adults and the applicability of strategies with children and families is under explored. Further research into the actual barriers and processes would therefore be beneficial alongside investigation into what recruitment and retention strategies are most effective in this population. Qualitative methods could be utilised for an in-depth exploration of the barriers and facilitators with existing trial populations. Further investigation into study level variables would provide further insight into the impact of study setting and health status/ intervention type on the predictors of recruitment and retention.

Reporting of studies in this field would benefit from greater clarity as well as agreed definitions of what is meant by retention.

Chapter 5
Does study design impact participant recruitment and retention success in child oral health and dentistry Randomised Controlled Trials (RCTs)? – 'Study 2'

5.1 Overview

Study 2 was a quantitative analysis of the impact of study level variables on recruitment and retention success in oral health trials. This study aimed to expand on the findings of study 1 by identifying study level variables that impact recruitment and retention of participants in one area - oral health trials.

This chapter begins by outlining the rationale for study 2. A critical justification for the chosen method is presented. The methods for identification of trials and data extraction techniques are described along with data analysis techniques. The results are presented with a discussion of how the findings relate to existing literature and add to the knowledge obtained in study 1. Limitations of the study will be discussed along with recommendations for future research and reporting of oral health RCTs.

5.2 Rationale for study 2

Many studies, predominantly outside the field of oral health, have investigated participant sociodemographic and clinical variables in relation to rates of recruitment and retention. In adult trials older, lower income, non-white male participants with low education levels are traditionally less likely to participate (Davis et al., 2002). Fewer participant predictor studies have been conducted on child and family RCTs (Janus and Goldberg, 1997). In study 1 of this thesis, several parent and child characteristics were identified as predictors of recruitment and randomisation to studies involving children and families, these variables were analogous with adult RCTs. However, the lack of agreement between studies made drawing firm conclusions on their actual influence difficult.

An original aim of study 1 was to investigate the impact of study setting and health status on recruitment and retention of participants. However the relatively small number of studies prevented a sub-group analysis based on trial setting and health status. Further investigation into the impact of study level variables was therefore recommended.

A further limitation of study 1 was the inclusion of trials across all health topics. Further research into specific health areas was recommended to reduce bias resulting from heterogeneity of the population studied (Robinson et al., 2016). Oral health was identified as an area of focus for this study. It has been suggested that there is a lack of studies

investigating recruitment and retention difficulties in trials within the field of oral health, despite problems with recruitment and retention being commonly reported (Davies et al., 2007, Harrison et al., 2010, Marshman et al., 2012, Chadwick et al., 2005). Given the lack of studies into recruitment and retention in oral health trials and the global scale of poor oral health and its link to general health and quality of life (Gul and Ali, 2010), research in this area is warranted.

In response to gaps and recommendations within the existing literature, this study aims to examine the impact of study level variables on recruitment and retention of children and families to oral health RCTs.

Within dentistry it has been recognised that the current quality of reporting of randomised controlled trials is poor (Froud et al., 2012, Cioffi and Farella, 2011, Needleman et al., 2008). Whilst the introduction of CONSORT reporting guidelines has led to better reporting of participant flow through trials, the extent of its use has been criticised (Toerien et al., 2009). This study will therefore also explore the application and usefulness of the CONSORT flow diagram for participant flow in oral health trials.

5.3 Study aim

This study aims to synthesise recruitment and retention data from existing childhood oral health and dentistry trials, to explore how study characteristics impact the recruitment and retention of participants.

5.4 Study objectives

5) Are study-level variables associated with recruitment and retention of children and families to oral health trials?
6) Do oral health trials involving children utilise the CONSORT guidelines for reporting of participant flow?

5.5 Methods

5.5.1 Design and justification of methods

A quantitative analysis of recruitment and retention data from child focussed oral health and dentistry trials was undertaken. A dataset of oral health trials were identified and data on study design, recruitment and retention were extracted and analysed for predictors of recruitment and retention.

Unlike study 1 of this thesis, study 2 is not a 'systematic review' (Higgins and Green, 2009). However, aspects of systematic review methodology were adopted for the data collection and extraction process. This methodological decision allowed a systematic method for identifying and including trials within the study. Methods adopted:

1) Identification of studies for inclusion: Trials included in the analysis were identified through the Cochrane Database using 'inclusion' and 'exclusion criteria'. This method was utilised due to the transparency and reproducibility of the search. The strengths and limitations of this design will be discussed further in section 5.8 of this chapter.
2) Data extraction: Data from each of the RCTs were extracted systematically using a pre-designed template and recorded in a data extraction table.
3) Quality review: Each study was given a quality assessment score, based on the risk of bias tool used in the Cochrane review from which the trial originated. This will be explored further in section 5.5.11.

Due to the parallels between this study and traditional systematic review methodology, the chapter hereon will be reported in line with the PRISMA guidelines for reporting of systematic reviews (Moher et al., 2009). The benefits of utilising reporting guidelines was discussed previously in chapter4 (section 4.5.1.3)

5.5.2 Types of studies

RCTs were limited to those involving dental or oral health interventions where randomisation occurred at the level of the individual. Cluster trials were excluded as recruitment and retention issues are often different to individual level trials (Booker et al., 2011, Marshman et al., 2012).

5.5.3 Types of participant

Children aged 16 years or less at the start of treatment, randomised to a 'dentistry and oral health trial'.

5.5.4 Types of outcome measure

Recruitment; calculated by:

- Recruitment success (was the sample size achieved)
- Recruitment (number of eligible participants v. number enrolled)

Retention; calculated by:

- Availability of primary outcome measures at endpoint (total number of participants providing final primary outcome endpoint date v. recruited number of participants)
- Retention success (retention of at least 80% of original sample).

It is recognised that previous studies have also investigated engagement or attendance at follow up visits (Wakim et al., 2011) as a measure of retention; however engagement was not analysed in this study due to the variation in use of the term engagement and lack of clear definitions in reporting (Staudt, 2007).

5.5.5 Language

English language, peer reviewed published papers only.

5.5.6 Inclusion criteria

- RCTs included in 'child health and 'dentistry and oral health' Cochrane reviews.
- RCTs randomised at an individual level.
- RCTs aimed at children 16 years or under at the start of the intervention.
- Studies published post CONSORT (1997 onwards).
- English language, peer reviewed articles.

5.5.7 Exclusion criteria

- Cluster randomised trials.

- RCTs that included adults within the trial participants (studies were excluded if the sample population included any participants over the age of 16 at time of recruitment). This reflects the legal age that children are able to give consent to trial participation in the UK (Medical Research Council, 2017).
- Studies published before 1997.
- Non English language articles.
- Non peer-reviewed articles.

5.5.8 Identification of studies

Studies were identified from 'included titles' in existing Cochrane Collaboration systematic reviews. Reviews were identified from the Cochrane Database of Systematic Reviews under the topic 'Child Health' and 'Dentistry and Oral Health'. The search was run in March 2014 and was updated in April 2015.

All 'included' studies within the systematic reviews categorised under the subcategories 'child health' and 'dentistry and oral health' were screened against the inclusion and exclusion criteria. 'Excluded titles' i.e. those that did not meet the inclusion criteria for the Cochrane review from which they originated, were not included in this review.

5.5.9 Study selection

Cochrane review 'characteristics of included studies' tables were screened by LR against the inclusion and exclusion criteria. 'Include' and 'unclear' papers were carried forward to phase two of selection (full screening of papers). LR conducted phase two of study selection, all uncertainties were discussed with a second researcher.

5.5.10 Data extraction

One researcher (LR) extracted data from included papers, managing data in an Excel database. Information extracted included number of trial arms, number of sites, country, intervention type, age of participants, study setting, length of study, a priori sample size calculation, number of participants enrolled, number of participants analysed in final outcome data, type of participants (i.e. patients or healthy participants) and presence of a CONSORT flow diagram.

Any uncertainties were discussed with a second researcher.

5.5.11 Quality assessment

Quality assessment data for each trial was extracted from the risk of bias results reported within the Cochrane review that the study originated from. The Cochrane risk of bias tool is used to assess specific features of studies, giving each feature a rating of low, high or unclear risk of bias (Higgins and Green, 2009). Categories assessed for potential risk of bias include sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessor, intention to treat, selective outcome reporting, incomplete outcome data and 'other' (Higgins and Green, 2009). Studies were then classified into 'high' or 'low' risk of bias. Studies were allocated to the 'high' category if they had been given a high risk of bias rating in one or more of the categories in the original Cochrane review. Studies that did not have a high risk of bias in the Cochrane review were classified as 'low' risk of bias.

5.5.12 Data analysis

Data was entered into SPSS version 22 (IBM Corp, Released 2013) and each entered case was double checked with the source data to control for data entry errors. Descriptive statistics, including frequencies for nominal or ordinal data and means for continuous data were generated to check for outliers. Where outliers were found, the source data was checked against the database.

Recruitment success was quantified by percentage of original sample size achieved (continuous variable) and the categorical variable 'recruitment success' categorised as 'success' (sample size achieved) and 'fail' (sample size not achieved). A continuous variable 'eligible enrolled' was also computed based on percentage of eligible participants that chose to enrol.

Retention was classified as the categorical variable 'success' or 'fail'. Studies were deemed to be a success if they retained 80% or more of their original number recruited, and fail if less than 80% of the original participants were retained. The cut off points were determined by the levels used in evidence based medicine 'levels of evidence', where 80% of retained participants is classed as a high quality RCT and trials retaining less than 80% of the original

sample are classified as low quality trials (Fewtrell et al., 2008). Analysis was also conducted on the continuous variable 'percentage of participants retained'.

Histograms for continuous data were examined, where continuous variables indicated skew data were transformed to categorical variables. Data was analysed using single-predictor logistic regression (for categorical measures of recruitment and retention) and linear regression (for continuous measures of recruitment and retention) to test association with trial design characteristics.

Multicollinearity tests were conducted, highly correlated variables were excluded from further tests. Variables with a p value of <0.2 in single predictor analysis were included in multiple linear and logistic regression models. Multiple linear regression analysis was conducted to determine whether study level variables predict percentage of participants retained (continuous variable). Second, logistic regression was run to predict retention success (categorical variable).

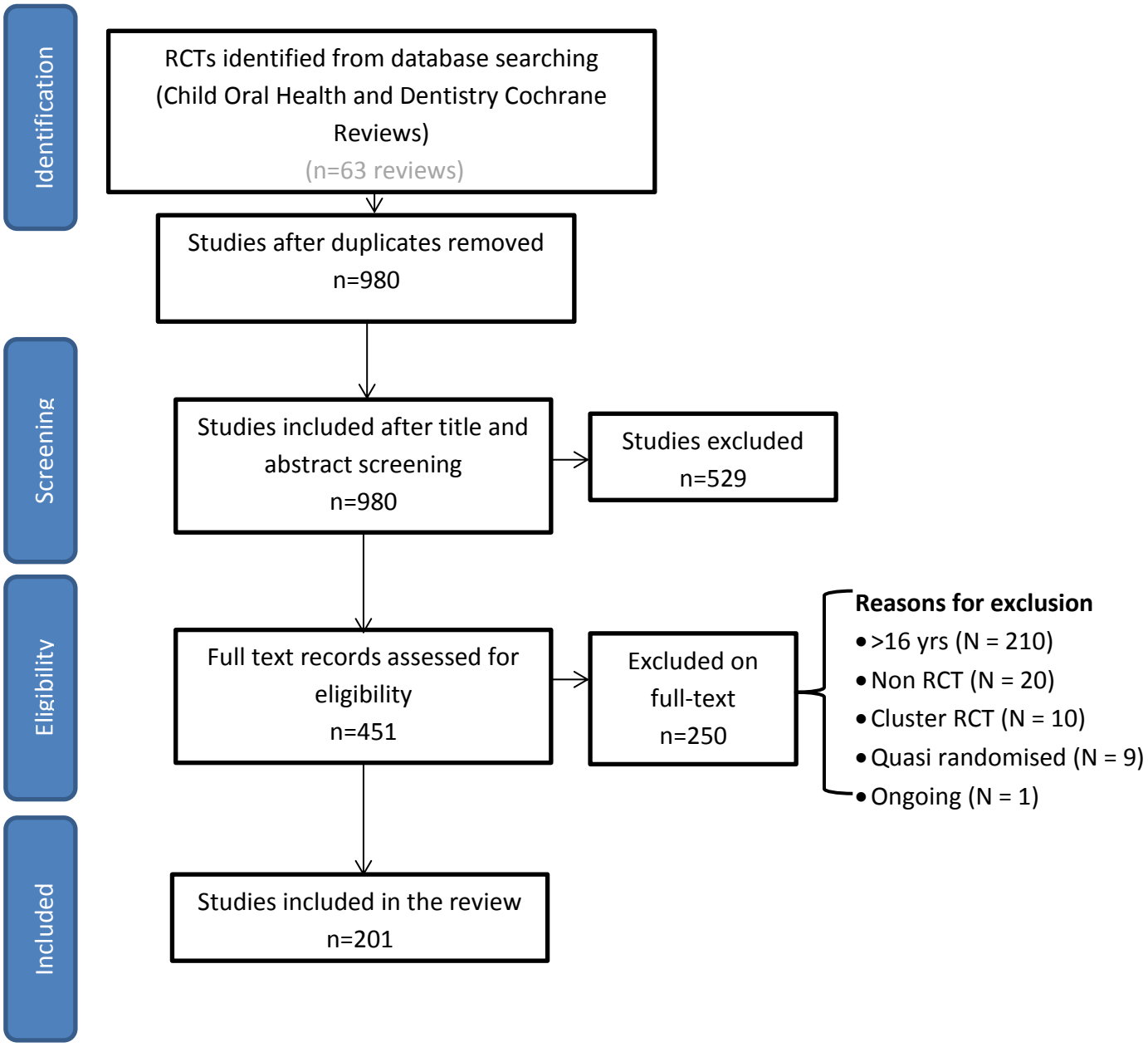
A significance level of $\alpha = 0.05$ was adopted for all statistical analyses reported.

5.6 Results

5.6.1 Study selection

A flow diagram of the screening process is presented in figure 5.1. The Cochrane database search for 'Child Health', 'Oral Health and Dentistry' returned 63 Cochrane reviews. The 63 reviews reported on 985 'included' studies. Screening of the studies against the inclusion and exclusion criteria (and full papers where necessary) led to the exclusion of 784 studies. The most common reason for exclusion was publication prior to 1997 (when the CONSORT guidelines were implemented). 210 RCTs were excluded because their sample population included children and adults over age 16. Five duplicate papers were found and excluded, the full list of reasons for exclusion are detailed in figure 5.1. In total, 201 studies were included in the final sample (appendix 6).

Figure 5.1 - Flow diagram of study selection



5.6.2 Study characteristics

The majority of studies (85.6%) were based in health care settings, with primary school aged children (5-11 years old) (65.7%). The sample sizes ranged between 7 and 3,731 participants and number of sites between 1 and 28. Eighty percent of studies recruited 'patients' as their participants, only 19.4% were aimed at healthy participants. The host countries for the RCTs varied, these were classified according to their World Bank Index (WBI) (The World Bank, 2015); the majority fell into the 'High' (56.2%) or 'Upper Middle' categories (30.3%). Only

one study fell into the 'Low' category. Table 5.1 shows the distribution of study variables across the 201 RCTs. The full data extraction table is attached in appendix 5.

Table 5.1 – Study characteristics

				Not reported
Intervention length (days)	Median (IQR)	2	(1 , 1825)	6
Study length (days)	Median (IQR)	365	(1 , 3650)	5
Number of appointments over trial	Median (IQR)	4	(1 , 63)	4
Number of study arms	Median (IQR)	2	(2 , 6)	0
Number of sites	Median (IQR)	1	(1 , 28)	33
Sample size	Median (IQR)	64	(20 , 3750)	146
Number eligible	Median (IQR)	168	(27 , 11500)	162
Number participants randomised	Median (IQR)	60	(8 , 6781)	1
Number participants analysed	Median (IQR)	52	(7 , 3731)	12
Number of drop outs	Median (IQR)	0	(0 , 2110)	13
Number participants excluded	Median (IQR)	0	(0 , 90)	12
Child age	<5	33	(16.4%)	1
	5-11	132	(65.7%)	
	12-18	35	(17.4%)	
Participant type	Healthy	40	(19.4%)	1
	Patient	160	(79.6%)	
Recruitment setting	Health	172	(85.6%)	1
	Community	28	(13.9%)	
Intervention setting	Health	154	(76.6%)	1
	Health & Home	17	(8.5%)	
	Home	11	(5.5%)	
	School	15	(7.5%)	
	School & Home	3	(1.5%)	
World Bank Index (WBI)	High	114	(56.7%)	2
	Upper Middle	61	(30.3%)	
	Lower Middle	23	(11.4%)	
	Low	1	(0.5%)	
Blinding of participants	Yes	56	(27.9%)	3
	No	18	(9.0%)	
	Unclear	124	(61.7%)	
Risk of bias	Yes	98	(48.8%)	1
	No	102	(50.7%)	
CONSORT diagram	Yes	49	(24.4%)	1
	No	151	(75.1%)	
Sample size calculation reported	Yes	55	(27.4%)	0
	No	146	(72.6%)	

5.6.3 Recruitment

5.6.3.1 Percentage of eligible enrolled

Only 39 studies reported the number of eligible participants (19%). Percentages ranged from 12 to 100% of eligible participants enrolled on to the trial (M = 78.8%). Simple linear regression was performed to predict percentage of eligible participants enrolled based on 9 study characteristics (child age, participant type, recruitment setting, intervention setting, number of arms, number of sites, intervention length, total study length, and number of appointments). Four variables were found to be significant predictors of percentage of eligible enrolled: participant type, intervention setting, total study length and intervention length. The models indicated that studies with patients, in healthcare settings that were shorter than a year in length (both in total and intervention length) converted a greater percentage of eligible participants to enrolled than trials involving participants, in community settings and over a year in length. The results are presented in table 5.2.

Table 5.2 – Univariable linear regression results - percentage of eligible enrolled

							95% C.I. for B	
	N	df	R^2	F	P	B	Lower	Upper
Age	37	1	0.073	2.898	0.097	-10.423	-22.828	1.982
Participant type	39	1	0.164	7.266	0.011*			
Healthy	11					Ref		
Patient	28					23.888	5.932	41.844
Recruitment setting	39	1	0.044	1.684	0.202			
Healthcare	30					Ref		
Community	9					-13.139	33.655	7.376
Intervention setting	39	1	0.101	4.164	0.048*			
Healthcare	30					Ref		
Community	9					-20.028	-39.196	-0.410
No. sites	38	1	0.000	0.000	1.000			
Single-site	22					Ref		
Multi-site	16					0.001	-18.278	18.280
No. arms	39	1	0.054	2.094	0.156			
2 arms	28					Ref		
> 2 arms	11					-13.645	-32.752	5.462
Total length	38	1	0.166	7.158	0.011*			
< 1 year	12					Ref		
1 year +	26					-23.526	-41.359	-5.693
Intervention length	37	1	0.269	12.907	0.001*			
< 1 year	18					Ref		
1 year +	19					-28.059	-43.915	-12.203
No. appointments	37	1	0.022	0.824	0.370	-2.215	-7.159	2.730

*p <0.05

A multiple regression was conducted to predict percentage of eligible participants that enrolled based on the variables with a p-value <0.2 in univariable analysis (age, participant type, number of arms and intervention). Despite intervention setting and total length being identified as significant predictors in the previous step they were excluded from this model due to collinearity between participant type and intervention length respectively. The model, containing 32 studies was significant as a whole (p=0.016), however the individual predictors were not significant. The results are presented in table 5.3.

Table 5.3 – Multiple regression results - percentage of eligible enrolled

				95% C.I. for B	
	P	**B**	**SE**	**Lower**	**Upper**
Age	0.251	-7.566	6.465	-20.735	5.603
Participant type	0.441				
Healthy			Ref		
Patient		8.821	11.311	-14.218	31.859
Arms	0.589				
2			Ref		
>2		-5.438	9.995	-25.715	14.840
Intervention length	0.123				
< 1 year			Ref		
1 year +		-18.059	11.414	-41.309	5.191

$R^2 = 0.310$, $F = 3.591$, $p = 0.016$

5.6.3.2 Achievement of sample size

A relatively low number of studies reported a sample size calculation (n=55, 27%). Only six studies did not achieve their sample size. Studies were categorised according to whether they achieved their original sample size calculation and coded into fail = 0, success = 1. Single predictor logistic regression was conducted for nine variables (child age, participant type, recruitment setting, intervention setting, number of arms, number of sites, intervention length, total study length and number of appointments). No significant relationships between recruitment success and study characteristics were found, however two variables (participant type and intervention length) were predictors of recruitment success at $p < 0.2$ (table 5.4). When included in a multiple regression model, neither the model itself or the two variables (participant type and intervention length) were significant (table 5.5).

Table 5.4 – Single predictor logistic regression results – achievement of sample size

							95% C.I. for OR	
	N	df	B	Wald	p	OR	Lower	Upper
Age	55	1	0.426	0.499	0.480	1.588	0.440	5.723
Participant type	54							
Healthy	10					Ref		
Patient	44	1	1.768	3.747	0.053	5.857	0.978	35.075
Recruitment setting	55							
Community	44					Ref		
Healthcare	11	1	-0.799	0.720	0.396	0.450	0.071	2.848
Intervention setting	55							
Healthcare	45					Ref		
Community	10	1	-0.941	0.984	0.321	0.390	0.061	2.504
No. arms	56							
2	41					Ref		
>2	15	1	-0.433	0.218	0.641	0.649	0.150	3.995
No. sites	51							
Single-site	33					Ref		
Multi-site	18	1	-1.131	1.373	0.241	0.323	0.049	2.140
Intervention length	54							
< 1 year	32					Ref		
1 year +	22	1	-1.204	1.728	0.189	0.300	0.050	1.806
Total study length	55							
< 1 year	22					Ref		
1 year +	33	1	-0.322	0.124	0.725	0.725	0.121	4.344
No. appointments	54	1	0.148	0.380	0.538	0.159	0.724	1.855

Table 5.5 - Logistic regression results – achievement of sample size

						95% C.I. for OR	
	B	Wald	df	p	OR	Lower	Upper
Participant type							
Healthy					Ref		
Patient	2.197	3.168	1	0.075	9.000	0.801	101.155
Intervention length							
< 1 year					Ref		
1 year +	1.264	0.345	1	0.557	2.100	0.176	25.010

$X^2 = 3.917$, p = 0.141

The continuous variable 'percentage of sample size achieved' was calculated for studies reporting a sample size calculation. The majority (89.4%) of studies over-recruited, achieving more than 100% of their original sample size calculation (M = 112.38, SD = 27.079).

Single predictor linear regression was conducted for the 9 study level variables (participant age, participant type, recruitment setting, intervention setting, number of sites, number of arms, total length, intervention length and number of appointments) to determine whether they predicted percentage of sample size achieved. No variables had a significant impact on the dependant variable (sample size achieved) (table 5.6).

Table 5.6 – Univariable linear regression results – percentage of sample size achieved

							95% C.I. for B	
	N	**Df**	**R^2**	**F**	**p**	**B**	**Lower**	**Upper**
Age	53	1	0.013	0.678	0.414	-4.473	-15.372	6.426
Participant type	54	1	0.014	0.730	0.397			
Healthy	10				Ref			
Patient	44					-8.192	-27.439	11.054
Recruitment setting	55	1	0.020	1.079	0.304			
Healthcare	44				Ref			
Community	11					9.474	-8.822	27.769
Intervention setting	55	1	0.025	1.366	0.248			
Healthcare	45				Ref			
Community	10					11.026	-7.898	29.934
No. sites	51	1	0.014	0.704	0.406			
Single-site	33				Ref			
Multi-site	18					6.688	-9.607	23.379
No. arms	55	1	0.000	0.009	0.925			
2	41				Ref			
>2	14					0.800	-16.169	17.769
Total study length	55	1	0.006	0.320	0.574			
< 1 year	22				Ref			
1 year +	33					4.242	-10.802	19.287
Intervention length	54	1	0.035	1.883	0.176			
< 1 year	32				Ref			
1 year +	22					10.281	-4.755	25.316
No. appointments	52	1	0.005	0.240	0.626	-0.862	-4.392	2.669

5.6.4 Retention

5.6.4.1 Retention success

The number of participants analysed was reported in 192 studies. Studies only one day in length (n=35) were excluded from analysis of retention. Single predictor logistic regression was performed for the variable retention success (0 = fail, 1 = success) and 9 predictor variables (child age, participant type, recruitment setting, intervention setting, number of arms, number of sites, intervention length, total length and number of appointments that participants were expected to attend) to determine the relationships. Three variables were found to have a statistically significant relationship with achievement of retention success: child age, participant type (healthy or patient) and intervention setting (health or community (table 5.7). Results indicated that studies with older children, patients and based in healthcare settings were more likely to achieve retention success than trials with younger, 'healthy' children in community settings.

Table 5.7 – Single predictor logistic regression results - retention success

							95% C.I. for OR	
	N	**df**	**B**	**Wald**	**P**	**OR**	**Lower**	**Upper**
Age of children	151	1	0.753	4.184	0.041*	2.124	1.032	4.370
Participant type	150							
Healthy	38				Ref			
Patient	112	1	1.293	9.317	0.002*	3.645	1.589	8.361
Recruitment setting	150							
Healthcare	124				Ref			
Community	26	1	-0.844	3.187	0.074	0.430	0.170	1.086
Intervention Setting	150							
Healthcare	123				Ref			
Community	27	1	-0.993	4.608	0.032*	0.370	0.149	0.917
No. sites	123							
Single-site	89				Ref			
Multi-site	34	1	-0.351	0.470	0.455	0.704	0.280	1.769
No. arms	151							
2	107				Ref			
>2	44	1	0.063	0.020	0.887	1.065	0.448	2.531
Total study length	171							
< 1 year	38				Ref			
1 year +	133	1	-0.729	1.903	0.168	0.483	0.170	1.359
Intervention length	150							
< 1 year	96				Ref			
1 year +	54	1	-0.581	2.059	0.151	0.559	0.253	1.237
No. appointments	150	1	0.206	2.441	0.118	1.228	0.949	1.590

* $p < 0.05$

The seven variables with a p-value < 0.2 were tested for multicollinearity (age, participant type, recruitment setting, intervention setting, study length, intervention length and number of appointments). The variables recruitment and intervention setting were not included in the model due to tests indicting that the variables were highly correlated to participant type. Intervention length was also excluded due to correlation with total study length. Direct logistic regression was performed to assess the impact of the four remaining variables on the likelihood of retention success (retaining 80% of participants or more) or fail (retaining < 80% of participants). The overall model was significant (p=0.001). The model indicated that the adjusted odds of retention success were 3.21 higher in trials with patients that trials with healthy participants. The remaining three variables were not significant in the final model (table 5.8).

Table 5.8 - Logistic regression results - retention success

						95% C.I. for OR	
	B	**Wald**	**df**	**p**	**OR**	**Lower**	**Upper**
Age	0.723	3.393	1	0.065	2.061	0.955	4.451
Participant type							
Healthy				Ref			
Patient	1.166	6.475	1	0.011*	3.208	1.307	7.875
Study length							
< 1 year				Ref			
1 year +	-0.732	1.364	1	0.243	0.481	0.141	1.643
No. appointments	0.286	3.484	1	0.062	1.331	0.986	1.797

$X^2 = 17.818$, $p = 0.001$

* $p < 0.05$

5.6.4.2 Percentage of participants retained

Single variable linear regression models were computed for percentage of participants retained against the nine predictor variables (age, participant type, recruitment setting, intervention setting, number of sites, number of arms, total length, intervention length and number of appointments). Three variables were found to be significant predictors of percentage of participants retained. Studies with older children retained a higher percentage of participants than studies with younger children. Studies with patients retained 9.14% more participants than studies with healthy volunteers and studies over a year in length retained 7.57% less participants than studies under a year in length. The results are presented in table 5.9.

Table 5.9 – Univariable linear regression results - percentage of participants retained

	N	Df	R^2	F	p	95% C.I for B		
						B	Lower	Upper
Age of children	150	1	0.052	8.205	0.005*	6.036	1.873	10.199
Participant type	150	1	0.070	11.155	0.001*			
Healthy	38				Ref			
Patient	112					9.136	3.730	14,541
Recruitment setting	150	1	0.016	2.361	0.127			
Healthcare	124				Ref			
Community	26					-4.968	-11.357	1.421
Intervention setting	150	1	0.021	3.239	0.074			
Healthcare	123				Ref			
Community	27					-5.716	-11.993	0.561
No. sites	123	1	0.012	2.544	0.133			
Single-site	89				Ref			
Multi-site	34					-4.673	-10.472	1.127
No. arms	151	1	0.001	0.129	0.720			
2	107				Ref			
> 2	44					-0.969	-6.299	4.360
Total study length	151	1	0.048	7.548	0.007*			
< 1 year	38				Ref			
1 year +	113					-7.573	-13.019	-2.126
Intervention length	150	1	0.007	1.006	0.317			
< 1 year	96				Ref			
1 year +	54					-2.571	-7.634	2.493
No. appointments	149	1	0.006	0.859	0.356	0.722	-0.818	2.263

*$p < 0.05$

Three additional variables were found to have a p value <0.2 (recruitment setting, intervention setting and number of sites). The six variables were tested for multicollinearity. Recruitment setting and intervention setting were excluded from further analysis due their correlation with participant type. Multiple regression was used to assess the ability of the remaining four significant variables (participant type, child age, total study length and number of sites) to predict percentage retention. The four measures explained 15% of variance in retention R squared = 0.148, p = 0.001. Two measures were statistically significant in the model (participant type and child age). The model, containing 122 studies, suggests that trials involving patients retain 8.9% more participants than trials involving the healthy participants. For every unit increase in child age, percentage of participants retained increases by 5.0%. Number of sites and length of study were not significant in the final model. The results are presented in table 5.10.

Table 5.10 - Multiple regression results - percentage of participants retained

				95% C.I. for B	
	P	**B**	**SE**	**Lower**	**Upper**
Child age	0.027*	5.030	2.244	0.586	9.473
Participant type	0.007*				
Healthy			Ref		
Patient		8.963	3.282	2.464	15.462
Total study length	0.354				
< 1 year			Ref		
1 year +		-2.827	3.038	-8.842	3.189
No. sites	0.605				
Single-site			Ref		
Multi-site		-1.594	3.076	-7.685	4.493

$R^2 =$ 0.148, p = 0.001, N=122

*p < 0.05

5.6.5 Multiple imputation analysis

To assess the impact of missing data on the results, a multiple imputation analysis was carried out. Both retention outcomes (retention success and percentage retained) along with the 9 predictor variables were included in the imputation model. Data for recruitment was not imputed due to the large amounts of missing outcome data.

5.6.5.1 Retention success – imputation analysis

Direct single predictor logistic regression was performed with the imputed dataset for retention success (success or fail) and the nine predictor variables to determine relationships. Two of the three variables found to be statistically significant in the original dataset remained significant with the imputed data (participant type and intervention setting (table 5.11).

Table 5.11 – Imputed single predictor logistic regression results - retention success

	B	P	OR	95% C.I. for OR Lower	Upper
Child age	0.666	0.063	1.947	0.964	3.933
Participant type					
Healthy			Ref		
Patient	1.194	0.006*	3.300	1.42	7.655
Recruitment setting					
Healthcare			Ref		
Community	-0.801	0.094	0.449	0.176	1.146
Intervention setting					
Healthcare				Ref	
Community	-0.946	0.045*	0.388	0.154	0.976
No. arms					
2			Ref		
> 2	-0.012	0.978	0.988	0.419	2.329
No. sites					
Single-site			Ref		
Multi-site	-0.233	0.604	0.792	0.326	1.924
Intervention length					
> 1 year			Ref		
1 year +	-0.386	0.352	0.680	0.301	1.535
Total study length					
> 1 year			Ref		
1 year +	-0.660	0.224	0.517	0.177	1.506
No. appointments	0.040	0.355	1.041	0.956	1.32

*p < 0.05

Two variables with a p value < 0.2 (child age and participant type) were included in a direct logistic regression model (intervention and recruitment setting were excluded due to collinearity with participant type) containing 161 studies. The model as a whole was significant X^2 = 12.192, - = 0.002). As with the original dataset logistic regression, trials with patients remained significant in the final model, the adjusted odds of achieving retention success were 3.11 higher in trials with patients (table 5.12). Child age was not significant in the final model.

Table 5.12 – Original and imputed logistic regression results – retention success

ORIGINAL						95% C.I. for OR	
	B	**Wald**	**Df**	**p**	**OR**	**Lower**	**Upper**
Age	0.723	3.393	1	0.065	2.061	0.955	4.451
Participant type							
Healthy				Ref			
Patient	1.166	6.475	1	0.011*	3.208	1.307	7.875
Study length							
< 1 year				Ref			
1 year +	-0.732	1.364	1	0.243	0.481	0.141	1.643
No. appointments	0.286	3.484	1	0.062	1.331	0.986	1.797

IMPUTED				95% C.I. for OR	
	B	**P**	**OR**	**Lower**	**Upper**
Age	0.574	0.122	1.775	1.331	7.287
Participant type					
Healthy			Ref		
Patient	1.136	0.009*	3.114	0.342	2.221

*p < 0.05

5.6.5.2 Percentage of participants retained – imputation analysis

Single variable linear regression models were computed for the imputed dataset for percentage of participants retained against the 9 predictor variables. As with the results of linear regression for the original data, child age, participant type and total study length were significant predictors of percentage retained (table 5.13).

Table 5.13 – Imputed linear regression results - percentage of participants retained

			95% C.I. for B	
	P	**B**	**Lower**	**Upper**
Age	0.007*	5.752	1.566	9.938
Participant type	0.004*			
Patient			Ref	
Healthy		8.913	2.886	14.940
Recruitment setting	0.145			
Healthcare			Ref	
Community		-5.173	-12.158	1.812
Intervention setting	0.086			
Healthcare			Ref	
Community		-5.921	-12.695	0.854
No. sites	0.166			
Single-site			Ref	
Multi-site		-3.733	-9.013	1.547
No. arms	0.640			
2			Ref	
> 2		-1.249	-6.479	3.981
Total study length	0.008*			
< 1 year			Ref	
1 year +		-7.231	-12.593	-1.868
Intervention length	0.507			
< 1 year			Ref	
1 year +		-1.726	-6.825	3.373
No. appointments	0.209	1.012	-0.568	2.592

*$p < 0.05$

Multiple regression was used to assess the ability of the three significant variables along with number of sites ($p < 0.2$) to predict percentage of participants retained. Two variables were significant in the final model. As with the original model, trials with patients were more likely to retain a higher percentage of participants (6.9% more than trials involving healthy participants) and studies involving older children retained 4.7% more participants than studies with younger children (table 5.14). Total study length and number of sites were not significant in the final model, as was the case in the original model.

Table 5.14 – Original and imputed multiple regression analysis – percentage of participants retained

ORIGINAL				95% C.I. for B	
	P	B	SE	Lower	Upper
Child age	0.027*	5.030	2.244	0.586	9.473
Participant type	0.007*				
Healthy			Ref		
Patient		8.963	3.282	2.464	15.462
Total study length	0.354				
< 1 year			Ref		
1 year +		-2.827	3.038	-8.842	3.189
No. sites	0.605				
Single-site			Ref		
Multi-site		-1.594	3.076	-7.685	4.493

IMPUTED			95% C.I. for B	
	P	B	Lower	Upper
Child age	0.026*	4.732	0.554	8.910
Participant type	0.047*			
Healthy		Ref		
Patient		6.895	0.108	13.682
Total length	0.873			
< 1 year		Ref		
1 year +		-0.461	-6.134	5.212
No. sites	0.119			
Single-site		Ref		
Multi-site		-4.382	-9.893	1.128

*p < 0.05

5.6.6 Variables immutable to change

Four variables collected during the data collection phase were also tested for their significance to predict recruitment and retention. Unlike the nine variables tested previously, these variables are less easy to influence and are not decided at the design stage. Nevertheless, they could be associated with recruitment and retention success. WBI (a measure of a countries income), year of publishing, risk of bias in reporting and presence of a CONSORT diagram were included in single predictor linear regression (for outcome variables percentage of eligible enrolled, percentage of sample size achieved and

percentage retained) and logistic regression (for categorical outcome variables recruitment success and retention success).

Studies that included a CONSORT diagram in their reporting were significantly more likely to have achieved a higher percentage of their original sample size than studies without a CONSORT diagram. Studies published in a country with a high' World Bank Index also achieved a significantly higher percentage of their sample size than studies published in 'low' WBI countries. The remaining two variables were not significant predictors of sample size achieved (table 5.15).

Table 5.15 – Single predictor linear regression - percentage sample size achieved

					95% C.I. for B	
	R^2	F	P	B	Lower	Upper
CONSORT	0.113	6.775	0.012*			
No				Ref		
Yes				18.142	4.162	32.121
Risk of bias	0.021	1.124	0.294			
Low				Ref		
High				7.892	-7.040	22.824
Year	0.001	0.066	0.798	-0.264	-2.322	1.793
WBI	0.079	4.529	0.038*			
Low				Ref		
High				40.218	2.314	78.122

*p< 0.05

The two significant predictors were included in a multiple linear regression analysis. World Bank Index remained significant in the final model, however the model overall was not significant (table 5.16).

Table 5.16 – Multiple regression analysis – percentage sample size achieved

				95% C.I. for B	
	P	**B**	**SE**	**Lower**	**Upper**
CONSORT	0.782				
No			Ref		
Yes		-0.276	0.944	-2.270	1.719
WBI	0.040*				
Low			Ref		
High		40.247	19.065	1.991	78.503

$R^{2 =}$ 0.079, p = 0.122, N=51

*p < 0.05

None of the four variables tested were associated with percentage of eligible enrolled (table 5.17) or recruitment success (table 5.18).

Table 5.17 – Single predictor linear regression - percentage of eligible enrolled

					95% C.I. for B	
	R^2	**F**	**P**	**B**	**Lower**	**Upper**
CONSORT	0.019	0.726	0.400			
No				Ref		
Yes				8.738	-12.037	29.512
Risk of bias	0.000	0.002	0.961			
Low				Ref		
High				-0.428	-18.251	17.394
Year	0.067	2.640	0.113	1.752	-0.433	3.937
WBI	0.013	0.498	0.485			
Low				Ref		
High				-19.342	-74.885	36.201

Table 5.18 - Single predictor logistic regression – recruitment success

						95% C.I. for Exp B	
	N	**B**	**Wald**	**P**	**OR**	**Lower**	**Upper**
CONSORT	55						
No	25				Ref		
Yes	30	0.205	0.056	0.813	1.227	0.225	6.694
Risk of bias*	55	19.699	0.000	0.998	0.000	0.000	
Year	55	0.064	0.304	0.581	1.067	0.848	1.341
WBI	55						
Low	2				Ref		
High	53	2.262	2.303	0.129	9.600	0.517	178.144

* Unable to calculate an odds ratio for risk of bias because 100% of studies with high risk of bias had recruitment success.

Studies without a CONSORT diagram retained a significantly higher percentage of participants than studies with a CONSORT diagram. Risk of bias rating also predicted retention success with studies reporting a high risk of bias retaining a significantly smaller percentage of participants than studies that reported no risk of bias. The results are presented in table 5.19.

Table 5.19 – Single predictor linear regression - percentage retained

					95% C.I. for B	
	R^2	**F**	**P**	**B**	**Lower**	**Upper**
CONSORT	0.041	6.252	0.013*			
No				Ref		
Yes				-6.503	-11.643	-1.364
WBI	0.022	3.342	0.070			
Low				Ref		
High				-7.442	-15.488	0.603
Risk of bias	0.073	11.679	0.001*			
Low				Ref		
High				-8.123	-12.820	-3.426
Year published	0.023	3.535	0.062	0.523	-0.027	1.073

*p< 0.05

Finally, logistic regression indicated that the odds of retention success were 1.11 times higher with each increasing year of publishing. Studies with a high risk of bias were less

likely (odds ratio 0.44) to achieve retention success than studies with a low risk of bias (table 5.20).

Table 5.20 – Single predictor logistic regression – retention success

	N	df	B	Wald	p	OR	95% C.I. for Exp B Lower	Upper
Consort	150							
No	103				Ref			
Yes	47	1	-0.695	2.856	0.091	0.449	0.223	1.117
WBI	149							
Low	15				Ref			
High	134	1	-1.438	1.859	0.173	0.237	0.030	1.877
ROB	150							
Low	80				Ref			
High	70	1	-0.818	3.985	0.046*	0.441	0.198	0.985
Year published	151	1	0.106	5.437	0.020*	1.112	1.017	1.215

*p< 0.05

5.6.7 Reporting

75% of the published articles did not contain a CONSORT diagram in their reporting. Direct single predictor logistic regression was performed for the variable CONSORT diagram (0 = no, 1 = yes) and six predictor variables (WBI, year of publishing, recruitment success, retention success, risk of bias and participant type) to determine association with the presence of a CONSORT diagram. WBI rating and year of publishing were significant predictors of the presence of a CONSORT diagram (table 5.21).

Table 5.21 – Single predictor logistic regression – CONSORT diagram

							95% C.I. for Exp B	
	N	**df**	**B**	**Wald**	**p**	**OR**	**Lower**	**Upper**
Recruitment success	55							
Fail	6				Ref			
Success	49	1	0.205	0.056	0.813	1.227	0.225	6.694
Retention success	150							
Fail	32				Ref			
Success	118	1	-0.755	3.700	0.054	0.470	0.218	1.014
Risk of bias	199							
Low	101						Ref	
High	98	1	-0.014	0.002	0.966	0.996	0.517	1.879
Year published	200	1	0.181	14.288	<0.001*	0.198	1.095	1.316
WBI	198							
Low	24				Ref			
High	174	1	2.170	4.393	0.036*	8.762	1.151	66.683
Participant type	199							
Healthy	40				Ref			
Patient	159	1	-0.060	0.021	0.884	0.942	0.422	2.103

*$p < 0.05$

Three predictors (retention success, year and WBI) were included in a logistic linear regression model. The model as a whole correctly classified 80.1% of the cases. All three significant independent variables made a uniquely statistically significant contribution to the model. The model indicated that the adjusted odds of including a CONSORT diagram were 10.04 higher in countries with a high WBI than countries classified as low. Furthermore, for every increase in year of publishing studies more likely to include a CONSORT diagram (adjusted odds ratio 1.26). Studies that achieved 'retention success' were less likely to include a CONSORT diagram (adjusted odds ratio 0.32). The results are presented in table 5.22.

Table 5.22 - Logistic regression results - CONSORT diagram

	B	Wald	Df	p	OR	95% C.I. for OR Lower	Upper
WBI index							
Low				Ref			
High	2.307	4.729	1	0.030*	10.045	1.256	80.354
Year published	0.232	18.402	1	<0.001*	1.262	1.135	1.403
Retention success							
Fail				Ref			
Success	-1.154	6.331	1	0.012*	0.316	0.128	0.775

***p < 0.05**

5.7 Discussion

Being able to predict which participants are more likely to refuse enrolment or drop out of trials is useful because it can inform targeted recruitment and retention strategies (Driscoll et al., 2009). Insight into which study designs are more likely to have difficulties in recruiting and retaining participants also allows early planning and adoption of appropriate strategies to address these issues. This study adds a unique contribution to the literature as no previous studies have identified study characteristics that predict recruitment and retention of children to oral health RCTs.

When potential participants are approached to enter a trial, the information sheet and discussion (with the recruiting clinician or member of research staff) provides information on study characteristics such as the study length, number of study visits and location of study visits. These trial design characteristics may influence a participant's decision to take part in a trial, and thus affect the recruitment rate. In this study recruitment success was measured by the percentage of eligible participants that went on to be enrolled and percentage of sample size achieved. Conversion of eligible to enrolled participants significantly increased in studies less than a year in total length and with interventions less than a year, indicating that longer studies with a greater burden may be off-putting to potential participants when making a decision on whether to agree to take part. Trials based in health settings (compared to community) and with patients rather than healthy volunteers had a significantly higher success rate at recruiting eligible participants. This finding suggests that studies in hospital based settings with patient participants are more attractive to potential patients than community based settings. However, confounding

factors such as patient availability should be considered, for example a decision making period between the initial discussion about the study and informed consent appointment may favour health based settings due to attendance at scheduled or routine appointments. In community settings, recruitment may be more opportunistic or based on a one-off opportunity for recruitment. The finding also suggests that parents of children requiring treatment are more likely to agree to take part in a trial than parents of healthy children. This mirrors previous findings indicating differences in 'healthy' and 'unhealthy' patients (Fisher et al., 2011, Janus and Goldberg, 1997). To our knowledge no previous studies have investigated the impact of severity of illness on recruitment in oral health trials, and findings from other conditions may not be transferrable. Further investigation would therefore be warranted.

Whilst there were no significant predictors of percentage of sample size achieved, or sample size achievement this result should be interpreted with caution as the majority of studies over-achieved their sample size and it may have been that the same studies simply ceased recruitment when they met their desired sample size instead of over-recruiting. It has been suggested that over-recruitment in RCTs is unethical due to inconvenience to the participant and potential risk if the intervention is ineffective (Wade, 2001). Therefore, percentage of sample size achieved in this study cannot be used as an accurate measure of success.

As with recruitment, it is feasible to suppose that retention of participants may also be impacted by design factors such as length of the study, number of study visits, convenience of the location of visits, burden of the intervention and other factors influencing participation. It would be sensible to assume that a greater number of study visits, additional to routine appointments could deter participants from taking part. However number of study visits was not a significant predictor of retention in this study. This finding mirrors previous reviews, where the number of assessment visits was found to have no impact on retention (Wakim et al., 2011, Cui et al., 2015). Wakim et al., (2011) hypothesised the reason for the lack of significance was the influence of factors such as number of appointments may be more subtle and intertwined with other study characteristics.

Contrary to the Wakim et al. (2011) review, study length did predict retention success in this study of oral health trials. Studies over a year in length retained 7.6% less participants than

studies under a year in length. Likewise, an obesity treatment and prevention review of recruitment and retention found that studies less than a year in length retained 14% more participants than studies over a year in length (Cui et al., 2015). These findings around study length were to be expected, as it is well documented that longitudinal studies encounter greater difficulties in retaining participants due to loss-to-follow up, greater burden on the participants due to a greater number of study visits and increased resources associated with long term tracking of patients (Cotter et al., 2005, Kleschinsky et al., 2009, Gustavson et al., 2012, Gul and Ali, 2010).

As with recruitment, retention success was significantly impacted by the setting of the intervention appointments. Community settings, for example schools and home based trials were significantly more likely to fail the 80% retention target than health based settings (e.g. dental hospitals and practices). Contrary to this, one previous recruitment and retention study investigated the impact of setting and found that home based interventions had increased retention success (Grill and Karlawish, 2010). However the study was within Alzheimer's patients who may have specific issues with transport to health based settings and a greater interest in receiving the medication (Grill and Karlawish, 2010). This highlights that the impact of setting is influenced by the condition and population under investigation. The findings of this oral health study support the research of Badger and Werrett (2005), who found that response rates for qualitative studies published in nursing journals in 2002 were better in hospital settings than community settings (Badger and Werrett, 2005). Cui et al., (2015) also found that setting impacted retention with home or community based studies retaining less participants than school based studies. Unfortunately health settings were not included in their review and in this oral health review schools were categorised as 'community' so the findings should be likened with care. Evidence for the specific reasons for the impact of setting is limited in the literature, however some studies have demonstrated that community studies may be off-putting for participants due to factors such as transportation, unfamiliarity with study sites and inflexible appointment times (Treweek et al., 2013b). Research with study staff has indicated that clinicians are less likely to engage with community based studies if the burden of recruitment and intervention delivery is greater than in a hospital setting (Asch et al., 2000) and that protocol burden has a negative relationship with trial success (Getz et al., 2008).

The trial setting is closely correlated to participant type, this was confirmed with collinearity tests. Findings for the impact of setting are therefore likely to be confounded with whether the patient is a healthy volunteer (more likely to be in a community setting) or a patient requiring treatment (in a healthcare setting). Previous research has suggested that patients are more likely to be motivated to take part, or continue with their participation because of the benefits they receive e.g. the possibility of a better treatment or better access to care (Fisher et al., 2011). Parents of healthy volunteers may have different motivations for taking part in oral health trials than patients; as this is a relatively unexplored area further qualitative investigation would be worthwhile.

School aged children (age 5 and above) were also significantly more likely to remain on the trials than pre-school children. Study 1 of this thesis included two studies that also found that lower aged children were more likely to drop out of their RCTs (Firestone and Witt, 1982, Roggman et al., 2008). In contrast, the obesity review found that child age had no impact on retention (Cui et al., 2015). There is little explanation in the existing literature for why parents of older children are more likely to remain on a trial than younger children. This could be accredited to greater involvement by the child, therefore adding to the commitment of the parent. Given the lack of literature in this field, a more detailed investigation into the barriers faced by parents of younger children in oral health trials would be warranted.

The study design variables discussed to date are all amenable to change at the design stage of the trial. Analysis of variables obtained during the data extraction phase that may have impacted the reported recruitment and retention rates were also investigated as part of the analysis. The impact of national income, or WBI rating is relatively unexplored in the existing retention literature. A previous study into the reporting of positive results in RCTs found potential sources of publication bias from some countries and these findings should therefore be interpreted with care. The authors found that trials reported in Russia, China and USSR were very unlikely to report test treatments as ineffective (Vickers et al., 1998). It is therefore possible that reporting of recruitment and retention differs between countries and the possibility of publication bias should not be disregarded.

Year of publication was also significantly related to increased retention. Retention success was more likely to be achieved with every year increase in publication date. This finding could be accredited to advances in knowledge in effective retention techniques. Several systematic reviews of retention techniques for RCTs have been conducted (Brueton et al., 2011, Robinson et al., 2007), with one focussed on community based trials (Davis et al., 2002) and another on cohort studies (Booker et al., 2011). A small number of studies have focussed on families and children, however these are predominantly condition (Cui et al., 2015) or intervention type (Schoeppe et al., 2014) specific, with no separate recommendations available for oral health trials.

Two indicators of study quality, or quality of reporting were also found to be significant predictors of participant retention. Risk of bias ratings were found to be significantly correlated with percentage of participants retained. The percentage of participants retained decreased as risk of bias in reporting increased. Whilst it is unlikely that risk of bias will impact the decision of a participant to enrol or remain on a trial, the quality of reporting variables could act as proxies for other factors. Cochrane risk of bias ratings are composed of several measures including insufficient reporting of recruitment and retention, blinding of participants and study staff. Whilst the specific reason for the risk of bias rating was not included in the analysis it is possible that the finding of increased risk of bias having a negative impact on retention is an indicator that some of these factors impact a participants decision. For example previous research has found that open designs (where the participants know which group they have been allocated to) can increase recruitment (Treweek et al., 2013a).

Conversely, studies that included a CONSORT diagram in their report were significantly less likely to retain participants than studies that did not include a CONSORT diagram. This finding could indicate a lack of reporting quality in the studies that did not include a CONSORT diagram and bring into question the reliability of results for these studies. The lack of clarity in reporting is further highlighted by the 126 articles in which ‘participant blinding’ was classified as ‘unclear’. Lack of reporting of eligibility for recruitment was also present in this study, this is common in other fields of health as reported by Donovan et al. (2014a), who also found that 40% of trials failed to report the numbers assessed for eligibility in their review of reporting of participant flow.

All trials were published post 1997 when the CONSORT guidelines for reporting of RCTs were published. Despite this, 75% of studies did not include a CONSORT diagram in their report. This finding supports previous research (Froud et al., 2012, Cioffi and Farella, 2011, Needleman et al., 2008) that suggested that CONSORT is under-used in reports of oral health trials. In a review of 133 RCTs published in 2004, 79% were found to contain a CONSORT diagram in their reporting (Toerien et al., 2009). In a later review of HTA funded studies 63% of studies demonstrated complete compliance with the CONSORT statement (but CONSORT diagram use was not reported) (Walters et al., 2017). Comparison with these studies highlights the lack of reporting in oral health trials compared with other fields of health. Lack of CONSORT diagram impacted the obtainable data for analysis, most studies did not report sample size calculation and many did not report drop outs or reasons for withdrawal. The analysis of WBI and year suggested that higher WBI countries were more likely to include a CONSORT diagram, indicating a higher quality of reporting. Inclusion of a CONSORT diagram also increased with every year increase in the year of publishing, indicating a trend of increased use over time.

There are many other factors that have been highlighted in previous studies to be important influences on recruitment and retention. The nature and experience of staff working on the trial, willingness of the clinician to recruit staff, retention efforts of the study team and incentives offered to participants have all been recognised as predictors of success (Wakim et al., 2011). Unfortunately factors relating to study staff were outside of the scope of this review and data was not obtainable. Nevertheless, the impact of these factors in oral health trials involving children would warrant further investigation in a qualitative study, as these variables have been relatively unexplored in this specific context.

5.8 Limitations

Although trials were identified from only one key database (Cochrane) and may therefore have lacked sensitivity (other dental and oral health trials involving children not identified) it did provide data on 201 trials which is not an inconsiderable dataset on which to base the analysis. Whilst a traditional systematic review would have included several databases, and therefore increased sensitivity the research aim was too broad for a systematic review. To reduce possible bias, aspects of systematic review methodology were adopted throughout.

Similarly, by limiting the inclusion of studies published prior to 1997 (when the CONSORT guidelines were published) the sensitivity of this study could have been reduced.

Another limitation of this study was also highlighted in a previous 'post hoc analyses' of recruitment and retention data (Wakim et al., 2011). The data analysed in this oral health study was not originally collected with the view of analysis for the success of recruitment and retention, and it was therefore not possible to assess the data in relation to reasons for participants' drop out or how long they remained on the trial. Assumptions based on previous evidence the dental context have therefore been made. A more detailed exploration of parents reasons for enrolling and remaining (or non-participation) on a trial would allow a more in-depth understand of the factors affecting parents decisions to take part in oral health trials.

A further limitation of the current study is the amount of missing data, particularly in relation to recruitment. Findings of factors impacting recruitment should therefore be interpreted with caution. The quality of reporting has also been highlighted as an area of possible limitation. It is also possible that some studies did not report dropouts, or reported the number of participants remaining in their final analysis as their sample size, rather than the number actually enrolled and randomised. This limitation highlights the need for clear reporting in line with CONSORT guidelines to allow full understanding of the participant flow through oral health trials.

Finally, information gathered on quality and risk of bias of the included studies was taken from the published Cochrane Reviews and was therefore not undertaken by the author. Whilst an effective tool, this introduces a source of subjectivity and interpretation from the authors whom originally undertook the reviews.

5.9 Recommendations for further research

This study's findings highlight the importance of study design related factors in the recruitment and retention of children and families to oral health trials. Due to the lack of previous research in this area the findings of this study would warrant additional investigation. A detailed exploration into the barriers of participating in community based trials with volunteers, particularly in longitudinal studies would be beneficial.

As very little research has been done specifically within oral health, it is currently difficult to know whether findings from other studies are transferrable to this field. An investigation the perception of seriousness of oral health and whether that impacts the decision of healthy volunteers on whether to take part would therefore also be worthwhile.

Studies were more likely retain children as they increased in age. Studies with school aged children (> 5 years) achieved more retention success than studies involving pre-school children. As very little research has looked at the impact of child age, aside from studies with neonates and adolescents research into the barriers of taking part in oral health trials with young children would also be beneficial.

5.10 Conclusion

This study suggests that study design can predict recruitment and retention success in oral health trials involving children and their families. Insufficiencies in reporting of participant flow have also been highlighted.

This study suggests that study length (and intervention length), type of participant (healthy or patient) and study setting, impact recruitment and retention; with shorter studies aimed at patients in healthcare settings experiencing the greatest levels of success. The study confirms that retention methods for longitudinal studies are essential to ensure that required sample sizes are retained.

Quality of reporting increased over time, with evidence to suggest the use of the CONSORT guidelines is increasing. A country's income also seemed to impact retention, although questions around the quality of reporting were raised and further investigation would be required to investigate this in more depth. Finally, it appeared that studies involving school-aged children were easier to retain participants than trials involving pre-schoolers. Due to the relative lack of investigation into recruitment and retention with children in oral health trials further investigation into actual barriers and facilitators is recommended.

The analysis suggested that a greater number of variables impact retention than recruitment. This finding could indicate that the burden of the study design becomes more important over time in a longitudinal study and is less of an issue at recruitment. However,

the volume of missing data around recruitment means this conclusion should be interpreted with caution.

It is not always feasible to amend factors such as year of study, national income or setting. However, further investigation into the study designs at risk of higher refusal or drop out could provide insight into the specific barriers and facilitators. This would allow sensitive and effective use of retention strategies.

Chapter 6
A qualitative investigation of factors influencing recruitment and retention in a community-based, pre-school, dental RCT – 'Study 3'

6.1 Overview

Study 3 was a qualitative focus group and interview study designed to explore the barriers and facilitators to recruitment and retention of families in a dental randomised controlled trial (RCT). This study involved parents who enrolled onto the Salford Bright Smiles Baby Study trial and continued their involvement to the end, as well as parents who chose to drop out prior to completion. The study was designed retrospectively as issues around recruitment and retention became more apparent during the later stages of the trial. The study aimed to expand on the quantitative findings of study 1 and 2 by exploring the actual barriers and facilitators experienced by families enrolled on a dental RCT.

This chapter begins by outlining the rationale for study 3. An overview of the RCT from which the participants for this study were sampled is provided in the introduction chapter of this thesis. A critical discussion of the chosen data collection methods and method of analysis is presented, alongside an outline of the procedures used in this study. Next, the results are presented in categories and the emergent themes are discussed. Limitations of the study are discussed before recommendations and potential areas for future research are presented.

6.2 Rationale for study 3

Quantitative studies, such as those conducted in chapters three and four of this thesis, can generate hypotheses on which groups are more or less likely to take part in trials. However, these studies provide little in the way of understanding of the actual barriers and facilitators faced by participants when making a decision about participation on a trial. Many of the demographic variables identified as predictors are not modifiable and recommendations to improve recruitment and retention are difficult to draw from these reviews. Furthermore, these studies do not provide practical recommendations on how to intervene with those at most risk of non-enrolment or drop out. Qualitative methodology studies allow the participants to give accounts of their experiences and thoughts in their own words. This can lead to a more open-ended investigation which deepens understanding of the issues (Murphy et al., 1999).

There is little evidence of qualitative work on recruitment or retention of participants in dental RCTs. There is currently no evidence of studies conducted on dental or oral health

trials with heathy or non-patient participants. Existing qualitative studies are predominantly with adults, in healthcare settings and with patients rather than healthy participants. Studies in children have focussed on parent recall of information at recruitment or motivations for enrolment. As demonstrated in the literature reviewed in chapter 3 (where the majority of qualitative studies are focussed on recruitment), there is little evidence of investigation on reasons for retention or drop out from studies (chapter 3, section 3.4). In addition it can be summarised that the majority of studies are concerned with trials involving severely ill children or neonates and research into healthy children is limited and predominantly based in healthcare settings. There is limited qualitative research into the factors affecting recruitment and retention of children and families to community based trials or trials with a non-clinical focus, and even fewer examples of this in the dental field. Common influencing factors in parents' decision making are risk, which appears to be of more importance to the parents of less severely ill children, altruism, which conversely appears to be linked with those who are most ill, access to care and perceptions and feelings about research. Practicalities have also been demonstrated to be of importance to parents in some studies. Perceived seriousness of the illness may be an important factor to parents of children being invited to take part in non-clinical studies but this requires further investigation.

6.3 Study aim:

This study aimed to use qualitative research methods to explore participants' motivations for enrolling onto the trial and the factors that influenced their continuation or drop out.

6.4 Study objectives:

- What motivated parents to enrol onto the Salford Bright Smiles Baby study?
- What do interviewed parents perceive to be barriers to recruitment for families that chose not to enrol on the trial?
- What factors made it easier for the enrolled participants to continue on the trial to the end?
- What factors made it difficult for the enrolled participants to continue on the trial to the end?

6.5 Methods:

6.5.1 Design and justification of methods

Three focus groups and 15 semi-structured face to face and telephone interviews were conducted with parents of participants enrolled on the Bright Smiles Baby Study. Focus groups were held first with parents who were able to attend the scheduled sessions. Parents who were unable to attend the scheduled group sessions were interviewed. Data analysis started with an initial analysis of themes within the focus group data. This informed the production of a topic guide for interviewing enabling a deepening exploration and testing of emergent findings.

Interviews and focus groups are the most commonly used methods of data collection in qualitative research (Gill et al., 2008, Tong et al., 2007). An overview of these two research methods and their strengths and limitations will be discussed here.

6.5.1.1 Focus groups

Robinson (1999) defines focus groups as '*an in-depth, open ended group discussion of 1-2 hours' duration that explores a specific set of issues on a predefined and limited topic'* (pg., 905). Their origin dates back to the 1920s when market researchers used the technique to gain information about product preference (Robinson, 1999, Powell and Single, 1996). Focus groups were later used in the 1950s to examine reactions to wartime propaganda (Kitzinger, 1994). Today, focus groups are widely accepted as an effective qualitative data collection technique and are used in various settings, across various disciplines (Morgan, 1996). The use of focus groups for health care research has been attributed to the 'consumer movement' and NHS reforms requiring quantification of the quality and outcomes of care delivery (Robinson, 1999). There are many examples of focus groups being used widely across health research to evaluate services, examine healthy attitudes and experiences as well as the needs and attitudes of staff (Robinson, 1999).

In their summary of when a focus group is an appropriate technique to use, Powell and Single (1996) identify several reasons that are particularly relevant to this study; namely: when existing knowledge on a subject is inadequate to answer the research question, or when the results of a quantitative study are ambiguous or require clarification (as is the case

with the results from study one and two in this thesis). They support the use of mixed methods, reporting that focus groups can be used to address such issues either concurrently with, or after a quantitative research study, as well as having their uses separately.

6.5.1.2 Strengths of focus groups

From a practical point of view, focus groups allow researchers to collect data from more than one person at the same time, thus reducing time and increasing cost effectiveness (Reed and Payton, 1997). However, in their discussion of focus groups Kidd and Parshall (2000) highlight that the time saved by inviting a group may be lost in recruitment and logistics; and that the practicalities of convening a group is far more difficult than the convenience of conducting one-to-one interviews. This will be explored further in relation to this study throughout the chapter.

Kitzinger (1994) advocates the use of focus groups, claiming that the technique can 'reach the parts that other methods cannot reach' (pg. 109) because of the unique interaction between the participants. The focus group allows everyday forms of communication to occur and rich data be collected that may not be present in a more formal one-to-one interview (Kitzinger, 1994). Wilkinson (1998) also highlights that focus groups allow the researcher a unique opportunity to observe the co-construction of meaning in action, and the group setting allows observation of development of beliefs, which are naturally shaped by exchange with others.

Group scenarios can empower people to speak about issues through encouragement or other less inhibited members of the group breaking the ice on taboo subjects (Kitzinger, 1994). Wilkinson argues that contrary to popular belief that the group environment inhibits discussion, focus groups can facilitate openness and disclosure. Rabiee (2004) also argues that it is the technique's unique access to group interaction that makes it an attractive method for many areas of research, allowing the concurrent exploration of individual views with group perspectives and the differences between them.

6.5.1.3 Limitations of focus groups

There are several reported limitations to using focus groups. Criticisms of the technique have been that it is a method employed by researchers who are too naïve or impatient to

use traditional methods (Kidd and Parshall, 2000), or that they are an *'inexpensive substitute'* for individual interviews (Lambert and Loiselle, 2008). It has also been claimed that groups can act to censor deviation from the standard group opinion (Kitzinger, 1994). Morgan (1996) discusses the 'polarization effect' whereby attitudes may become polarized towards the group opinion and thereby lose individual opinions. Whilst previous studies have indicated that the effect is small and unlikely to skew results, they highlight it remains a possibility for error nonetheless (Morgan, 1996).

A further weakness has been identified in relation to the control that the moderator can have over the discussion, and how who is talking in the group, can also impact results (Gill et al., 2008). Kidd and Parshall (2000) advise reducing the number of different moderators and coders to decrease heterogeneity; a technique employed during this study, by the use of one moderator (LR) for all focus groups and interviews.

Focus groups may be inappropriate for use in some areas of research, particularly around 'sensitive topics' due to the open nature and disclosure to a group of people that are often strangers to each other (Morgan, 1996). Due to the non-sensitive nature of the topic, this was not felt to be an issue for this study. Furthermore, all parents were offered the option of a one-to-one interview to overcome any resistance to taking part due to parents not feeling comfortable speaking in front of a group.

A further weakness of focus groups is the potential for polarization of views (Morgan, 1996) or 'group voice'. This is particularly a problem for less assertive members of the group, whose views may be dominated by more assertive members and minority members, who have the tendency to acquiesce to the views of the majority (Carey and Smith, 1994). The risk of conducting mixed social class groups is that minority members may not voice their true opinion and get falsely assumed to hold the same view as the majority. This can be overcome by directed questioning by the moderator (Sim, 1998).

6.5.1.4 Interviews

There are many similarities between focus groups and interviews. Like focus groups, interviews are used to gain a more in-depth understanding of an area where detailed insights from relevant individuals are required. Gill et al. (2008) identify three types of

interview: ‘structured’ (essentially a verbally administered questionnaire), ‘unstructured’, which are performed with very little structure or preconceived theories and thirdly, ‘semi-structured’, consisting of several key questions that guide the discussion around the area to be explored. The latter technique allows divergence and exploration of topics that arise, without straying from the original aim of the interview; in doing so the researcher may discover information that was not previously thought of or considered by the research team (Gill et al., 2008). The third type (semi-structured) was deemed most appropriate for this study to allow exploration of a-priori themes (from the literature and previous two studies) as well as emergent themes. This design also complemented the focus group structure and allowed comparison of results from the two techniques during the analysis

6.5.1.5 Strengths of interviews

Interviews are said to be the most widespread approach in qualitative methodology. The method’s attractiveness is its flexibility, particularly in contrast to techniques such as participant observation, which is much more intense and time consuming for the researcher (Bryman, 2012). Compared to a more structured interview approach, semi structured interviews are beneficial for a greater depth of understanding through exploration of topics in response to the interviewee’s answers (Bryman, 2012).

An advantage of face to face interviews is that they allow rich data to be gathered from social cues. These provide the interviewer with valuable information from cues such as voice, body language, facial expressions and intonation (Opdenakker, 2006).

Whilst It is argued that focus groups facilitate openness through encouragement (Kitzinger, 1994), others argue that interviews are the best method of data collection if the topics are sensitive or of a matter that does not suit group discussion (Gill et al., 2008). Whilst the subject of this study was not sensitive, it is possible that parents found interviews more attractive if they felt any guilt or shame because of their actions, or felt there was a problem with the study design that they had not previously felt comfortable discussing.

6.5.1.6 Limitations of interviews

Similar to focus group censorship, interviewees may choose to withhold answers or equally embellish their responses to improve their own self-image, or to impress the interviewer;

furthermore, if the interviewer inadvertently demonstrates a preference towards certain responses, they may influence the perspective portrayed by the interviewee (Lambert and Loiselle, 2008). It is advised that some of this can be overcome by the interviewer having similar demographics to the interviewee as this encourages the interview to be conducted in a more natural way (Lambert and Loiselle, 2008). Often this is not possible if there is a limited research team. In this study the researcher (LR) was a similar age to the parents being interviewed, and ensured that a friendly, empathetic disposition was maintained in the interviews, to put participants at ease.

6.5.1.7 Telephone interviews

Telephone interviews are more traditionally used as a data collection method in quantitative research (Novick, 2008). However, the use of telephone interviews as a data collection method for qualitative research has increased, in line with increasing use of telephone technology (Carr and Worth, 2001, Barriball et al., 1996).

Whilst literature on telephone interviews is scarce (Novick, 2008, Barriball et al., 1996) Novick (2008) claims that telephone interviews are generally received with scepticism, with face to face interviews being viewed as the gold standard, despite there being very little evidence available to support this. The method is often criticised due to the lack of visual cues, making it more difficult than face to face interviews to establish rapport. However, past researchers have successfully overcome these issues through the use of politeness, an interested tone of voice, careful timing of pauses and positive phrases (Barriball et al., 1996). Whilst some researchers have claimed that the lack of visual cues can deter disclosure of sensitive information, Novick (2008) argues that telephone interviews are in fact more confidential, and respondents are more likely to give an honest answer, or less likely to give what they consider to be a socially desirable answer.

The benefits of telephone interviews seem to outweigh the disadvantages with cost, speed, geographical accessibility and convenience all advantages of telephone interviews (Novick, 2008). Barriball et al. (1996) highlighted the ability to control quality as all data collection is usually conducted in one central place. Additionally, they reported better response rates from telephone interviews than questionnaires. The benefit of telephone interviews were

evident in the current study, using this method alongside the focus groups allowed more people to take part than would have done otherwise, due to family or work commitments.

6.5.1.8 The use of interviews with focus groups

The use of both interviews and focus groups within the same research study is common in qualitative research. Lambert and Loiselle (2008) suggest that there are three broadly used rationales for the combination of methods: 1) pragmatic reasons, 2) in parallel – for comparison and contrast of perspectives from the two techniques, 3) for data completeness and/ or combination. The latter use has been critiqued for implying that the shortcomings of one method by can be overcome by employing the other. Barbour (1998) argues that in doing so the researcher's views and prejudices about the shortcomings of methods will influence the results. Whilst it is common for researchers to adopt the second method of combination (techniques running in parallel), there is often a lack of rationale reported for doing so, and little justification of why one technique is more appropriate for one group than for others (Lambert and Loiselle, 2008).

This study was designed using the first rationale, a 'pragmatic approach', in that the two techniques were used within the same study to maximise the number of responses. A pragmatic approach adopts the methods most appropriate to answer the research question (Johnson et al., 2007) (this is further discussed in Chapter 2). Parents who were unable or unwilling to attend a focus group, were offered a one-to-one interview. This was of particular use for the group of withdrawn participants, who were too geographically dispersed and small in numbers to form a focus group. Furthermore, given that the group of withdrawn participants had already decided they no longer wanted to take part in the main trial, it is possible that they did not wish to take part in this sub-study for the same reasons. Therefore, employing the two methods increased the number of people that could be involved in the study and allowed parents who were unable to travel (e.g. for work, or child care reasons) to take part in the study, thus reducing bias. Combining the two methods also allowed exploration of themes that arose from preliminary data analysis of the focus groups in more depth during the interview phase. This is the most common application of the two methods within the same study (Morgan, 1996).

It is acknowledged that the interviews and focus groups have distinct methodologies and traditions (Barbour, 1998). It is also recognised that the two techniques generate different types of data, and this requires consideration during the analysis phase. Different findings can be accredited to the effects of different research environments. For example, in a study involving groups of young males, different results from the two techniques were attributed to the effects of conformity (Morgan, 1996). These differences have led to criticism of combining the two techniques (Morgan, 1996). However, others have argued that if the researcher is conscious that different perspectives arise from the different settings and/or techniques then they can be addressed and context can be considered (Kitzinger, 1994). The implications and possible limitations of the combination of the two methods, for example around the bias that may be introduced because of the types of people that accepted to be included in either technique, will be explored further in the discussion section of this chapter.

6.5.2 Ethical approval

Ethical approval was obtained from the University ethics committee (University of Salford, Research Innovation and Academic Engagement Ethical Approval Panel, College of Health and Social Care, reference: HSCR14/02) (appendix 7). NHS Research Governance approval was obtained from the NRES Committee North West - Greater Manchester East (reference: 10/11013/2) (appendix 8).

6.5.3 Setting

Focus groups and one-to-one face to face interviews were held in local Sure Start Children's Centres. The venues were chosen due to their community locations, and because they had been frequently used for appointments in the main trial. Participants were therefore familiar with the locations; centres were also within short travelling distances from their homes. Light refreshments were provided as this is a recognised way of thanking participants for their involvement (Bender and Ewbank, 1994). Participants were invited to bring their children if childcare was not available, toys and refreshments were also available for the children. All participants were given a £10 high street shopping voucher as a reimbursement for their efforts in this qualitative study in line with national guidelines (INVOLVE, 2010). In the main trial parents in the behavioural arm were given a £5 high

street shopping voucher and toothbrushes and toothpaste for their child. No other payments were made.

6.5.4 Study participants and recruitment

Participants were sampled from an existing cohort of RCT participants on the Bright Smiles Baby Study (Pine et al., 2014). All interview and focus group participants had enrolled and given informed consent to take part during the recruitment period (November 2010 – November 2011). Participants were the parents of a child (aged 1 -3 years) enrolled on the Bright Smiles Baby Study. At the time of this qualitative study participants were approaching, or had completed their final data collection visit (two years post enrolment) or had previously withdrawn from the study.

A purposive sampling technique was used to identify potential participants. Purposive sampling is a non-random method of sampling which aims to identify a sample with specific characteristics of interest to the researcher (Bowling, 2009, Robinson, 1999). A purposive sampling technique selects participants because of their focus on a given topic (Rabiee, 2004), i.e. that they have specific knowledge on the topic under investigation. Purposive sampling was appropriate for this study because participants were required to have participated on the Bright Smiles Baby Study and have either continued their participation to the end of the study or, have withdrawn from the study before completion. Participants were also chosen based on their likelihood to respond to the invitation and based on their preferred Sure Start Children's Centre venue to maximise the number of participants taking part.

Purposive sampling has been criticised because of the questionability of the representativeness of the chosen sample (Bryman, 2012), however, representativeness was not the aim of this study. Sampling of the withdrawn participants was largely driven by the availability of parents. A list of all continuing and withdrawn participants was obtained from the trial administrator, grouped according to parents' preferred children's centre location. The administrator also gave an indication of the participants' availability during the week and their likelihood to respond to the request (based on her experience of extensive contact during the trial). Focus groups were arranged in the most 'popular' children's centres and invitations were initially sent to participants who were most likely to respond (this was later

extended to those who lived in the area regardless of their response likelihood as detailed below). Invitations to take part were sent to most of the withdrawn participants. Withdrawn participants were only excluded if their reason for withdrawal was that they no longer wished to be contacted (for ethical reasons) or had moved out of the area. All possible participants wishing to be involved were included in the study. Concurrent analysis during the focus groups and interviews continued until data saturation (a point at which no new concepts were being uncovered (Sargeant, 2012)) was reached.

Six focus groups were arranged to allow one group for 'continuing' and 'withdrawn' participants in each of the three arms of the trial (test group 1 – behavioural intervention, test group 2 – fluoride varnish, control group – usual care). Keeping the trial groups separate during focus groups has been found to facilitate free discussion (Caldwell et al., 2003) and avoids contamination of groups for parents who were still participating on the trial.

Participants meeting the eligibility criteria outlined above were sent an invitation letter containing the forthcoming focus group date and time, participant information leaflet (PIL) (appendix 9) and enrolment form (appendix 10). Participants were asked to complete and return the enrolment form if they wished to take part in the focus groups. It is widely acknowledged in the literature that it is necessary to invite more participants than are required to achieve the sample size. The amount of attrition to expect varies between studies involving focus groups with some suggesting 20% (Robinson, 1999) and others 25% (Powell and Single, 1996). As this study invited participants who were already known to be difficult to reach or too busy to attend additional sessions (the withdrawn group), a higher attrition rate was expected. If participants did not respond to the mail-out within two weeks of postage, a text message or email was sent to the selected trial participants reminding them of the opportunity to participate. Following a poor response to the initial mail outs further eligible participants were identified and contacted. Participants that expressed interest but were not able to attend the scheduled focus groups were invited to attend a face-to-face interview, or where this was not convenient for the parent, a telephone interview. Participants were contacted by telephone to arrange the interviews.

6.5.5 Procedure

An initial topic guide (appendix 11) was designed to explore the motivations, experiences,

barriers and facilitators to taking part on the Bright Smiles Baby Study. This was based on *a priori* themes drawn from the literature review and findings from study 1 and 2. The topic guide used in the interviews was adapted from the initial guide to further explore themes that had emerged from the focus groups, and continued to be adapted as the analysis progressed. Refining the topic guide and research question during the research process is recommended as a reflexive process of qualitative enquiry (Agee, 2009). Allowing the topic guide to be led by the themes brought up by the participants themselves, enabled a more in-depth exploration of the barriers and facilitators to participation than a structured topic guide would have allowed. Using a semi-structured approach to interviewing and focus groups also permitted exploration of themes as they arose during the interviews and supplementary questions were added as necessary.

At the start of the focus group or interview participants were asked to complete a written consent form (appendix 12) confirming their willingness to participate (telephone interviewees were asked to give verbal consent). Consent forms included permission to audio record the group/ interview, as outlined in the information leaflet. Additional verbal consent for audio recording was obtained and anonymity was confirmed in all cases. Whilst concerns have been noted around censorship and conformity (Kidd and Parshall, 2000), the literature suggests that there is generally little concern that recording will impact the responses given by the group (Bender and Ewbank, 1994). Despite this, it is possible that parents were reluctant to give their true views of the research for fear of this being fed back to the research team, or if it did not fall in line with other parent' views. This will be discussed further in the discussion section. Focus group participants were also reminded that the discussion was confidential in terms of anonymisation of data and that discussions within the room should remain confidential and not be discussed elsewhere. Participants were encouraged to be as honest as possible in their answers.

All focus groups and interviews were conducted by one researcher (LR) who acted as the 'moderator'. The role of the moderator has been well discussed in the literature. Generally, their aim is to guide the discussion to ensure that the research aims are met, whilst ensuring that all members of the group are able to contribute and feel relaxed in doing so (Robinson, 1999). Group interaction allows the exploration of shared and individual perspectives and a successful moderator is able to facilitate this, encouraging members of the group to talk and

interact with each other (Tong et al., 2007). The amount of involvement by the moderator depends on the research goals. A more structured approach can be useful for answering specific questions, whereas a less structured approach can allow the group to pursue their own interests more (Morgan, 1996). During this study the moderator guided conversation through the semi-structured topic guide ensuring that the discussion stayed on track, whilst also allowing exploration of emergent themes. When the discussion strayed from the topic guide the moderator allowed sufficient time for exploration of the discussion (to determine whether it would be of any benefit to the findings); and the group were redirected back onto the area of interest if and when appropriate.

In line with recommendations, questions were open ended to facilitate discussion in the beginning and were ordered relative to the importance of issues with more specific questions coming later in the session (Gill et al., 2008, Tong et al., 2007, Robinson, 1999). Prepared questions were supplemented with sub-questions that allowed further exploration of a topic (Powell and Single, 1996).

The focus groups were audio recorded using a Dictaphone with spider microphones and a separate mobile device was used to gather secondary back-up recordings. It is generally agreed that audio recording is an effective and reliable method for collecting responses, whereas videotaping is less well accepted due to the intrusive nature (Gill et al., 2008). A note-taker was present at focus groups with two or more participants, and was able to record non-verbal responses, for example body language. All telephone interviews were conducted using the same mobile telephone in a quiet meeting room. Audio was recorded using the same Dictaphone and mobile device as in the focus groups. Speakers were given a unique identification code to ensure anonymisation during the analysis of data. A note taker was present during the focus groups so speakers could be identified during analysis.

The researcher adopted a reflexive approach to the research process writing memos in a journal throughout the analysis process. The journal was reference for confirmation of ideas and emerging theories, as well as enabling the researcher to be aware of potential influences shaping the research and challenge personal assumptions and behaviour that could impact responses and interpretation of results. As highlighted by Watt (2007), keeping a journal is particularly useful for a less experienced researcher. The value of reflexivity is

widely acknowledged in qualitative research (Mauthner and Doucet, 2003, Finlay, 2002, Ward et al., 2013).

6.5.6 Analysis

Field notes were written up immediately after the focus groups and interviews. An initial analysis, involving identification of dominant topics and potential themes was carried out after each focus group and interview. This early analysis of the focus groups influenced the script for the interviews, as discussed previously.

When all of the focus groups and interviews had been completed audio recordings were transcribed verbatim by a specialist audiotyping transcription company. LR checked all transcriptions against the original recordings for accuracy during the first phase of framework analysis (FA), when transcripts were read and re-read alongside field notes and emergent themes were noted.

Data was analysed using the framework analysis technique (Ritchie and Spencer, 2002). Focus group and interview data were combined from the outset. This combination of data is recommended in the FA technique (Ritchie et al., 2003) and has been carried out in previous FA studies (Furber, 2010). As highlighted in section 6.5.1.8 awareness of the context and different types of data generated was maintained throughout the analysis and interpretation stages.

6.5.7 Framework analysis – overview and justification

FA originated from social policy research carried out in the UK in the 1980s (Ritchie and Spencer, 1994, Furber, 2010, Ward et al., 2013). Today it is used by many qualitative researchers in health (Gale et al., 2013). FA is a type of thematic analysis (Rabiee, 2004, Gale et al., 2013). Unlike grounded theory research, FA can be shaped by a priori as well emerging themes (Lacey and Luff, 2001, Rabiee, 2004, Thomas, 2006). This semi-inductive approach reflects the technique's origins in applied policy research, allowing the researcher to address specific questions as well as exploring emerging themes (Ward et al., 2013).

FA lends itself well to both deductive and inductive forms of enquiry (Gale et al., 2013). Given that two studies investigating recruitment and retention of participants had already

been conducted (studies 1 & 2), generation of a tentative framework was possible. FA allowed this to be tested and developed further; thus an aim of study three was to investigate these *a priori* themes whilst also investigating new or emerging themes.

Framework analysis is characterised by five stages (Lacey and Luff, 2001). Step one of FA is 'familiarisation'. This was done over several readings of the transcripts and re-listening to the audio tapes of the focus groups and interviews. Additionally the moderator's field notes and note takers' accounts of the focus groups were read alongside the transcripts. The aim of this stage of analysis is to become fully immersed in the data prior to identifying themes (Ward et al., 2013).

Next, the a priori issues that formed the basis of the focus group and interview questions, and emergent themes were identified and assigned labels. An index of themes and subthemes and their associated labels was drafted and written down. Initially transcripts were read and themes identified one group at a time (test 1, test 2 and control) and then later by participation status (continued or withdrawn). The index and themes were checked throughout to ensure that they were relevant to data from all groups. This process is defined as stage two of framework analysis 'developing a thematic framework' (Gale et al., 2013).

When an initial thematic framework was established this was checked and verified with another researcher. This draft framework was then applied back to the transcripts; this phase (phase three) of analysis is called 'indexing' whereby the labels or tags are applied to text within the transcript. In this study the researcher used textual labels e.g. 'barrier' instead of numerical labels, which can also be used during this stage (Ritchie et al., 2003). Each time a theme arose in the data, the label was noted in the margin of the transcripts. This was done over a length of time, often re-labelling transcripts at different times to ensure that the correct tags were being allocated. Initially this was done in the margins of the transcripts, but once the researcher became more confident with the labelling, tags and indexes were transferred to Microsoft Excel, by copying and pasting excerpts from the transcripts into a tabular index. During the indexing phase themes and subthemes were refined further.

A decision was made at this point to label and index initially by hand and then to transfer this onto Excel. Whilst some researchers advocate the use of Computer Assisted Qualitative Data Analysis Software (CAQDAS) e.g. NVivo (Gale et al., 2013, Bernauer et al.) or NUD*IST (Kidd and Parshall, 2000), others highlight caution against their use for reasons such as separation of the researcher from the data and their risk of oversimplified analysis (Bender and Ewbank, 1994). The PhD student attended a two-day training course in NVivo software and subsequently spent time experimenting with the package. Whilst the benefits were evident, when used in practice it was felt that the software was a distraction away from the transcripts, with more time being spent perfecting the index and layout of the software rather than immersion in the data. Furthermore, the use of Excel allowed easy manipulation during the indexing phase, and also fitted in well with the techniques used in the previous two systematic review studies.

Stage four of FA is 'charting' where a matrix (or grid) comprised of themes, subthemes and cases (or participants) is created (Gale et al., 2013). This was done in Microsoft Excel. There are two types of matrix, 'thematic' where the chart is headed by themes and rows are comprised of participants; or 'case', where the structure is transposed (Lacey and Luff, 2001). A thematic chart was designed using the themes and sub-themes identified and developed in stages two and three. Excerpts of text from the transcripts were pasted into the matrix cells. It is generally agreed that the level of detail included in the matrix should be brief enough to keep the chart manageable but detailed enough to allow understanding (Ward et al., 2013, Furber, 2010).

The final stage of FA, stage 5 'mapping and interpreting' involved the review of the whole data set for refinement of themes and exploration of possible explanations for the themes. Furber (2010) describes this phase as the stage at which whole data sets are re-read and examined in search of explanatory accounts which provide clarification and meaning to the participants' responses. At this stage new descriptive or analytical themes were identified and added to the thematic framework and others changed. The framework was reviewed by a second researcher (MC) and restructuring occurred before a final framework was generated. This was sectioned by the three main themes: 'motivations for participation', 'barriers to participation' and 'reducing the burden'. This will be detailed further in sections 6.6.3 – 6.6.5.

Stages one to four of framework analysis can be described as 'data management' exercises. It is not until stage five of the process that the data is explored for explanatory accounts (Ritchie et al., 2003). Stage five often appears to be overlooked, or is not clearly reported in the literature, with some reports appearing to use the themes identified during the 'data management' phases as their final themes for discussion. However, Ritchie et al. (2003) describe the thematic framework generated in the data management phase (stages 1 – 4) as an investment for the more detailed analysis in stage five, where associations and interpretations become more abstract or theoretical.

6.5.7.1 Clarification of terms

Whilst a major benefit of FA is said to be its transparency and accountability, the reporting of studies adopting a framework analysis technique is sometimes ambiguous. Specifically, in addition to the limitations highlighted above (in relation to the quality of analysis conducted in the final stage of the process) the terminology used in the literature surrounding FA often appears confused and contradictory. This seems to be a product of its origins, in that FA *"borrows principles from different epistemological traditions in the social science field"* (Ward et al., 2013, pg. 3). In doing so FA appears to have adopted terms from different techniques, which are used interchangeably by researchers. The transferable use of terms is not uncommon in qualitative research (Morse, 2008). It is therefore felt that a clarification of the terms used throughout this chapter should be addressed here to assist in the interpretation of reporting.

The '**themes**' that are identified during phase two and three may be best defined as broad topics, relevant to the research questions, that occur repeatedly throughout the data (Bryman, 2012). In other areas of qualitative research, these 'themes' are sometimes called 'codes' or 'categories' (Graneheim and Lundman, 2004).

The term 'theme' has different connotations in different methods of qualitative enquiry. Themes have been described as 'underlying meanings' used on an interpretive level in some reports of content analysis (Graneheim and Lundman, 2004). Others have described themes as an essence of meaning that are abstract and difficult to identify (Bowen, 2008).

'**Subthemes**', which in FA are used beneath themes to provide more detailed and specific

topics than the themes they fall under.

'Indexing', carried out in stage 2 of FA, is a process of attaching labels to the data to identify where themes are arising. This is similar to the technique of coding used in grounded theory and content analysis; although the latter two methods use different techniques for generating the codes, which are not relevant for discussion here (Cho and Lee, 2014). Whilst some researchers interchangeably use the terms indexing and coding in their reports (e.g. Ward et al., 2013; Uppal et al., 2013; Furber2010), Ritchie et al. (2003) caution against using the term coding at this stage in the analysis. They argue that coding relates to a more advanced process, where the content has been more precisely defined and labelled (Ritchie et al., 2003). This level of detail and analysis does not occur until stage five of FA and the term indexing is therefore more appropriate.

6.5.7.2 Limitations of Framework Analysis

FA has been criticised by some for lacking the theoretical underpinning characterised by other methods such as grounded theory and ethnography (Smith et al., 2011). However, Ward et al. (2013) argue that this lack of firm ontological position complements the aim of the technique, which is to address specific questions rather that constructing new theory.

Whilst considered an advantage by some, the relatively simple framework, step-by-step approach has been criticised due to its attractiveness to inexperienced qualitative researchers, or quantitative researchers slipping into the qualitative research paradigm (Gale et al., 2013). Its flexibility has also been highlighted as a possible limitation because there is a risk of researchers exploiting this flexibility and assuming short-cuts can be taken (Ward et al., 2013).

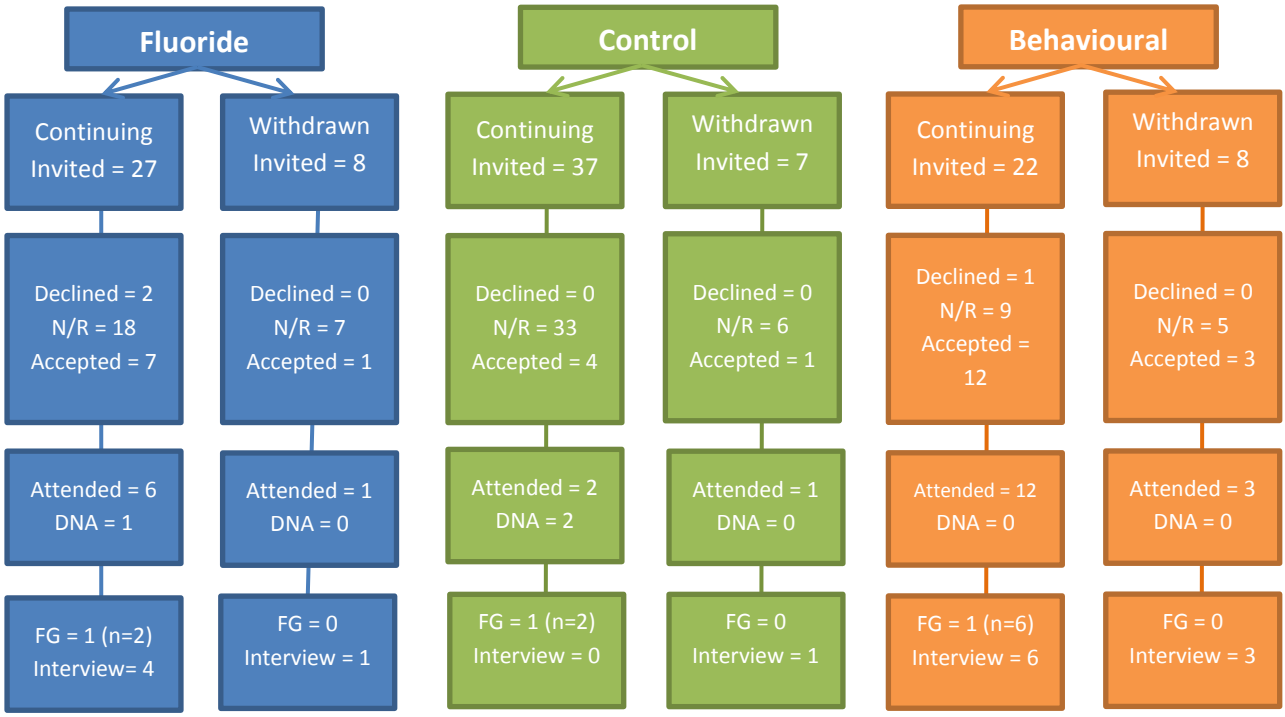
6.6 Results

Invitations were initially mailed to 80 trial participants aiming to achieve a sample size of 8-12 per group (48 – 72 in total). Forty-six participants from the first sample did not respond to the invite or were unable to make the scheduled sessions, a further 29 invitations were therefore sent to a new sample of participants.

A total of 25 participants took part in the study. 15 participants that expressed interest but

were not able to attend the scheduled focus groups were invited to attend interviews. Three focus groups were conducted. A breakdown of the invitation process and participants by group and participation status is presented in figure 6.1.

Figure 6.1 - Flow diagram of invitations, refusals, acceptances and attendances by groups



Key: FG = focus group, DNA = did not attend, N/R = no response

6.6.1 Participant characteristics

Table 6.1 presents the characteristics of participants in the interviews and focus groups. All of the participants were the child's mother; only two fathers enrolled onto the main Bright Smiles Baby Study and were not eligible to be included in the sample for this study. The majority of mothers in this study were aged between 31 and 40, white British, married and had attended higher education (table 6.1).

Index of Multiple Deprivation (IMD) data from the 2007 census has been used as a proxy for SES. Salford is generally described as a low SES area. In this study postcode data for the parents was used to calculate an IMD score and national rank using 'Geoconvert' (part of UK Data Service Census Support). National ranks were then split evenly into three categories 'low', 'medium' and 'high' SES; using this categorization the majority of parents that took part in the study were classed as low SES (table 6.1). When IMD scores were compared to

the nationally used quintiles of deprivation (lower super output area scores ranked from 1 to 5, 1 being the highest deprived and 5 being the least deprived) it showed that the majority of participants were in the 5th or 4th quintile (Table 6.2). Or if compared to the national average IMD score (21.27) 18 parents were more deprived than the national average and 8 were less deprived. In general it can be summarised that parents from a range of SES were interviewed, but the majority were classified as low SES.

80% of parents enrolled their first born child onto the study. As previously stated the majority of participants were parents who continued on the trial and were randomised to the behavioural intervention group. The five withdrawn participants were all participating with their first born child. Three of the withdrawn mothers were aged 20-30 with the remaining aged 31-40 years. All five mothers were educated to a further or higher education level and classified as low SES.

Table 6.1. Characteristics of participants

Participant Information		**N**	**%**
Age	**20-30**	10	40%
	31-40	14	56%
	>40	1	4%
Race	**White British**	21	84%
	White Other	1	4%
	Black African	2	8%
	Asian Pakistani	1	4%
SES	**High**	2	8%
	Medium	0	0%
	Low	23	92%
Education	**Higher**	14	56%
	Further	9	36%
	Secondary	2	8%
Marital Status	**Married**	14	56%
	Co-habiting	3	12%
	Single	8	32%
Birth order of child	**1st child**	20	80%
	>1	5	20%
Group	**Fluoride**	7	28%
	Control	3	12%
	Behavioural	15	60%
Participation Status	**Continuing**	20	80%
	Withdrawn	5	20%

Table 6.2. Index of Multiple Deprivation by rank

Rank of Index of Multiple Deprivation	Quintile	N	%
1 – 6496 (most deprived)	**1**	7	28%
6496 – 12993	**2**	11	44%
12993 – 19489	**3**	4	16%
19489 – 25986	**4**	2	8%
25986 – 32482 (least deprived)	**5**	1	4%

6.6.2 Theme development

In exploring the three research questions three main descriptive themes emerged from the data and were utilised as the foundation for the framework analysis matrix. These were '**motivations for involvement**', '**obstacles to involvement**' and '**reducing the burden of involvement**'. The term 'involvement' has been adopted here to cover both the recruitment phase, where parents enrolled and the retention phase where parents chose to continue or discontinue their involvement with the trial. Recurrent subthemes (or topics of discussion) were charted under each main descriptive theme to create the final framework. The final output of the framework analysis was 8 conceptual or explanatory themes. Figure 6.2 charts the process in developing themes, beginning with identification or recurring descriptive themes during the framework analysis process and extraction of underlying conceptual themes for reporting.

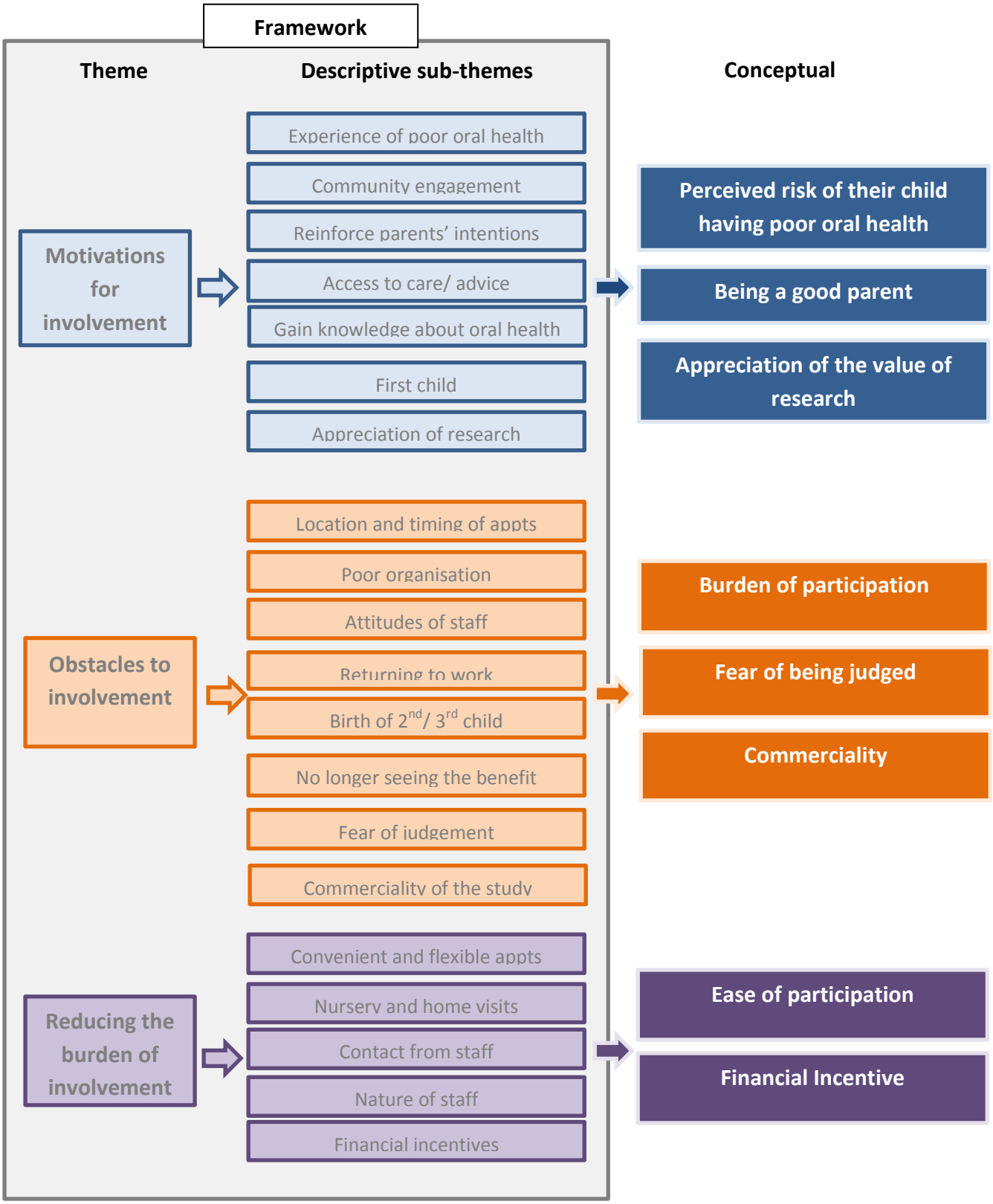
The first theme in the FA chart is '**motivations for involvement**'. Data included discussions about parents' reasons for wanting to take part in the trial with their child and reasons for their continuation for the duration of the study. Recurrent descriptive subthemes were around parents' experiences of their own poor oral health or experience of others. Parents were keen to gain knowledge about oral health and how to look after their child's teeth as well as gaining access to professional advice and have their child seen by a dental professional. A community engagement element was also uncovered with some parents discussing their wish to help the local community, whilst also enjoying feeling a part of something and getting support from their peers. A final recurring subtheme was parents' interest in research and commitment to the study. Three conceptual themes were common to the participants and appeared to be important influences and motivations for signing up to the study and continuing participation. These were 'perceived risk of their child having poor oral health', 'being a good parent' and 'appreciation of research'.

Theme 2 in the FA matrix is '**obstacles to involvement**' which incorporates subthemes that arose around the logistics of taking part, such as the location and timing of appointments. Subthemes around obstacles emerged from discussions with both withdrawn and continuing participants. Parents who continued to the end of the trial spoke about factors that made it difficult for them to attend throughout the two years. They also offered their thoughts about why some parents may have found it difficult to enrol or continue their participation, which was drawn from their own experience and observations, or that of family or friends. Study design factors were also commonly discussed such as the staff working on the trial, how the trial was organised and the perceived commerciality of the study. Returning to work after maternity leave and the birth of a second or third child were also common themes in the discussions, with parents explaining how their priorities and availability to attend the trial appointments altered during these periods of change. When discussing what made it difficult for parents to continue participation on the trial two main explanatory themes emerged from the FA. These were 'burden of participation' and 'fear of being judged' by health professionals or other parents on the trial, through exposing their child's behaviour, or their own perceived parental shortcomings to their gaze. A third, less dominant conceptual theme, that will also be explored under obstacles was 'commerciality of the study'.

A third FA theme in the matrix entitled **'reducing the burden of involvement**' arose from parents discussing the elements of the study design that made it easier for them to take part. Parents who continued on the trial to the end also spoke about what motivated them to continue at times when they considered dropping out from the trial. Drawing on their own experiences parents gave practical recommendations for the design of future studies and their opinions on how to encourage involvement from hard-to-reach parents or parents who withdrew from the trial. Discussions were focussed around the timing and location of appointments and methods adopted by research staff to maintain contact and build relationships with parents. Discussions about incentives were also positioned into this theme. Two explanatory themes emerged from this category; these were 'ease of participation' and 'incentives'.

The eight conceptual themes that emerged from the FA, will be reported hereon under the three broad categories from which they originated (see figure 6.3 below).

Figure 6.2 - Development of themes



6.6.3 Motivations

6.6.3.1 Perceived risk of poor oral health

For many parents (both continuing and withdrawn) a clear motivation for initially enrolling and then continuing in the trial was the mothers' desire to prevent their child from having poor oral health. Their collective experiences indicated that parents in the trial perceived their child to be at risk of tooth decay or problems with their teeth. Taking part was a step towards minimising the risk for their children.

The origin of this perception of risk differed between the parents. For some, this was clearly developed from their own dental experiences either in childhood or during their adult life. Some parents confessed their own shortcoming in looking after their teeth such as not attending the dentist regularly, not following advice, eating too many sweets or not brushing teeth often enough. Other parents blamed lack of knowledge or insufficient supervision by their own parents for their poor oral health. Some parents accredited their negative experiences to their genetic makeup, blaming "weak teeth".

> *"As a child and as an adult, I've got rubbish teeth. I've obviously got very weak teeth."* (12/P/B).

These parents blamed 'weak teeth' as though their own oral health problems were inevitable and not preventable. However, parents did feel that they could prevent their child from having bad teeth, and taking part in the trial was a way to do this.

Parents who did not have their own negative experiences to report had developed their perception of risk through the experience of others with poor oral health. Often parents spoke about their own mothers having problems with their teeth, and how this had impacted their own oral health behaviours, and was now influencing the care they give their child.

> *"My mum actually, yeah. I suppose it influenced me because she had a lot of problems with her teeth. She's got braces now as an adult. And even though I haven't had any problems, I'm always very conscious of, you know, dental hygiene and just wanting to spot problems there." (13/P/C).*

Some parents also felt that living in Salford was putting their child at risk of poor oral health. The mothers identified that Salford traditionally has poor oral health and saw this as a reason for their child to be at risk. Parents gave accounts of children they had seen with bad

teeth, or local mothers they had met who gave their children too many sweets. One parent spoke at length about her fears for her child's oral health because of peer pressure from parents at her child's nursery, who frequently offered her child chocolate, despite her desire to reduce the intake of sugar. This parent felt that Salford had a tradition of giving children sugary snacks as treats and that tooth decay was therefore inevitable for her child if she did not take action to prevent it. Other parents were aware that oral health in Salford is worse than other areas and felt that this was putting their child at a disadvantage. A parent spoke of her fears that her move from Yorkshire (a nearby county of England) into Salford had put her two children at increased risk of poor oral health. She joined the trial as an attempt to prevent her child from ending up like the 'others' she had heard about and seen.

> *"I just thought, well, if there's something that I can do that will get him like better teeth, if you know what I mean, that will help him with his teeth, especially like where we live, people's teeth are like terrible and like some of the children that you see, they got like black teeth or no teeth. I do agree about that teeth are a problem in this area from talking to other people and from seeing other children's teeth. I did wonder about that because I'm not from around here. I'm from East Yorkshire and I did worry about the girls because of the teeth not being as good around here."* (13/P/C).

6.6.3.2 Being a good parent

Discussions indicated a general understanding amongst continuing parents of what was a 'good' parent versus a 'bad' parent, this was particularly apparent in the parents who continued on the behavioural arm of the trial. Parents brought anecdotes of 'bad' parents that they had identified that they didn't want to be like. The mothers shared accounts of experiences in the supermarket, watching in horror as parents added sugar-laden snacks to the trolley or allowed their children to walk around with sweetened drinks. There was a general belief that the parents they recalled during these stories, and most parents in Salford, didn't know any better.

> *"In Salford I have been really quite shocked about the amount of the sweets that children have. My daughter is often offered chocolate on the way to nursery, play group... because it's never occurred to me and because I think it's a real bad idea.*

They brush their children's teeth but they think they're fine on the juice and you know the heavy, the level of sugary snacks. And I kind of assumed that… you didn't really give kids these additional sweets you know." (11/P/B).

Most participants who continued in the behavioural arm of the trial appeared critical of parents who did not share the same oral health beliefs as them. Their accounts were judgemental towards these 'bad parents', and they indicated that their advanced knowledge on how to care for their child's teeth made them a better mother than these others they discussed.

Other mothers recognised that their own parents had not given them the best start with their oral health as a child, and wanted better for their own child now they were the parent. Parents appeared to feel that involvement in the trial would make them a better parent because they would be doing more to look after their child's teeth.

I remember when I was kid, obviously my parents were great but they didn't really have any focus on dental hygiene so I had quite bad teeth when I was a kid. So I was kind of thinking I don't want [child] to grow up having bad teeth and I wanted her to have perfect teeth." (22/W/B).

Parents who believed that it was too late for their own teeth were using their child's teeth as a fresh start and an opportunity to get it right this time.

"So, I want to be able to – as much as I can as a mum – to make sure that my children haven't got teeth that are as bad as mine." (01/P/B).

The parents also wanted their child to get used to going to the dentist so they wouldn't be scared of attending appointments like they were. In these cases, parents were motivated by a belief that taking part in the trial would prevent their child from inheriting their own anxieties about going to the dentist.

"I think I've always been quite sort of nervous just to go to the dentist. I don't really…I don't remember why, I don't remember going when I was little but I think I was sort of keen for [child] to not have that, have those fears and those anxieties." (24/W/B).

The additional visits to the dentists also gave parents confidence in their abilities as a parent. A number of continuing parents talked about the value of the annual dental exam, as an opportunity to share concerns with the dentist and for reassuring them that they were doing a good job of looking after their child's teeth. This was particularly true of first time continuing parents who talked about 'doing the right thing' for their child – the trial provided comfort that they were getting it right.

> *"I was quite pleased that somebody was having a look at his teeth because that was reassuring to me that I was doing the right things at home and brushing his teeth and stuff because they said that his teeth were in good condition. You know that's another nerve wracking thing as a parent ticked off."* (15/P/F).

Parents attending the behavioural intervention groups also gained self-assurance of their success as a 'good parent' from other parents in the group. Attending the group sessions appeared to increase self-efficacy of less confident parents as they were assured that they were 'normal' given that other parents were in the same position and experiencing the same difficulties.

Parents felt like they were giving their child the best possible care by accessing the additional appointments on the trial. One parent used the trial to demonstrate to health visitors that she was going the extra mile for her child who was receiving help for his speech and language.

> *"Just letting his health visitor and things like that know that I wasn't just sticking with the health checks but because, you know, from the government, I was trying to go the extra mile. With other things as well."* (16/P/F).

Other parents used the trial to reinforce their intentions, or as a defence to use against other influences in the child's life. Parents talked of grandparents, other relatives and parents of children at nursery having a negative impact on their desired routines, often offering sweets and fizzy drinks as a treat despite their instructions. Parents used terms such as "*ammunition*" and "*shield*" to describe their use of the child being enrolled on the trial. These parents used the trial as an excuse for why the child was not allowed to have sweetened foods, thereby reinforcing their parenting choices.

Whilst many parents described feelings of assurance as a result of being on the trial, not all participants displayed these feelings of confidence. Some mothers admitted to having little or no knowledge on how to look after their child's teeth prior to entering the trial. For them, a motivation to take part was being a better parent by advancing their knowledge. Other parents already felt they knew a lot about how to care for their child's teeth but wanted to advance their knowledge, to make sure they were giving their child the best possible care. One parent was a dental nurse, who despite her training felt she could learn more about the best foods for her child. Being a first time parent she felt additional access to dental professionals would benefit her son. Other first time parents described their complete lack of knowledge when starting the trial:

> *"The reason I chose to go to the group was to listen to what people had to say because I didn't have a clue!"* (12/P/B).

Similarly, not all parents were motivated by negative dental experiences. Some parents had benefited from their parents and health professionals taking preventive action for them when they were a child or from taking care of their own teeth. These parents had experience of the benefits of taking good oral health routines and were motivated by wanting to pass on the benefits of conscientious parenting and knowledge of effective preventive care to their children.

6.6.3.3 Appreciation of the value of research

A third explanatory theme that arose from discussions about motivations for enrolling and continuing on the trial was the parents' appreciation for research and the understanding of the value of it being conducted in their local community. Parents understood that the wider aim of the research was to improve dental care and services for children. One parent explained it as a way to actively 'do something' about the state of dentistry and make improvements.

> *"There's no point moaning at like dentistry and things like that, if nobody inputs, you know, so if somebody is asking for help, you know, I don't mind giving my input."* (17/P/F)

Some parents demonstrated a desire to give something back to their local community. However, when talking about their altruistic motives parents seemed to speak about Salford, or the people that the trial was 'aimed at', in a detached way. The parents appeared to justify their involvement by helping those in need of help (i.e. the bad parents) rather than for the sake of their own child.

> *"We moved to Salford because we wanted to live in a community where we can make a difference and help people and stuff like that in lots of different ways. So, for me, it was like, that's a part of what was great, that it was a Salford study because I see a lot of that around me that is not as it should be, if you know what I mean. And if there's anything that we can do to help that problem."* (13/P/C)

The majority of parents that demonstrated altruistic or research appreciation motivations for entering the trial, had completed further or higher education. Educated parents appeared to have a greater understanding of the importance of taking part in research and the difficulties of recruiting and retaining participants on research studies. Parents that spoke about their interest in research had experience of conducting their own research through their studies or career. Some parents appreciated the difficulties of getting people to take part. Their first-hand experience was a motivation to continue with the trial, as they felt empathy towards the researchers working on the study.

> *"I've done a PhD but not where I needed to question people. But I appreciate the kind of, I think that you need volunteers and you need people to help you. So there was a picture of that in my head that, oh, well, I'm probably helping somebody do their research here which was what I wanted to do as well.* (19/P/F).

These parents were interested in completing the trial to find out the results, and had an understanding of the need for enough parents to continue with the trial for the results to be valid.

Parents in the behavioural intervention and fluoride varnish groups also expressed a commitment to the results of the trial, with an attitude of we've started so we'll finish'. These parents were all continuing participants, and appeared to think that this was an obvious reason for continuing on the trial. When pressed on why they felt that way, there

was little explanation and it was difficult to justify, other than 'we joined up so we have to stay with it'.

> *"Because well just, I just...if you sign up for something you should do it unless it's massively you know unless it's really offensive or detrimental I think you should carry on. You just think you made that commitment, you should carry it through... I just think you got to be, if you're going to sign up for it, you should carry on with it."* (11, P/B).

6.6.4 Obstacles

6.6.4.1 Burden of taking part

Parents who withdrew from the trial spoke about a 'main reason' for dropping out of the trial with other obstacles adding to their decision. Their reasons for withdrawal were varied, with two parents citing their return to work after maternity leave as the main reason for their dropping out of the trial, and two parents who were not happy with the way that the trial and sessions were organised (as discussed below). The final parent found it too difficult to attend the planned sessions. Themes that arose from interviews with withdrawn participants were analogous to the themes that came out of the analysis around obstacles with continuing participants and the results from the two groups have therefore been combined. The main conceptual theme around obstacles to participation was that the trial became a burden to the parents. The triggers for the trial becoming a burden varied between parents.

Many parents talked about the timing and locations of appointments. For many these were facilitators to participation (this will be discussed further below). However, some parents, both continuing and withdrawn, cited the location of appointments as a barrier if it involved public transport (particularly with more than one child) or going to a venue that the parent did not know. Most parents agreed that had the trial been held further away it would have prevented them from attending. Parents did not feel it was worth travelling short distances out of Salford for (for example three or four miles into Manchester) and would not have taken part if it involved travel nationally. Parents also felt that the timing of some appointments was inconvenient for a small child and chose not to attend sessions if they clashed with the child's feeding or nap times.

All five withdrawn parents, and some of the parents that continued on the trial to the end, returned to work after their maternity leave. The mothers discussed the difficulties of attending appointments once they had returned to work. They found it difficult to attend the sessions (mostly held during the day time) if they were during working hours or not on their days off. If appointments were on the parents' day off they described the difficulties of juggling their priorities, such as catching up with housework, spending time with their child and attending other appointments within their non-working days. For these parents the trial slipped down the list of priorities and became a burden or another task on an already long list.

> *"But then when you go back to work, it's like your time outside of work is very precious; you don't want to spend that with your child sitting in a room having a dental check-up necessarily."* (13/P/C).

Parents did not see taking time off work to attend the sessions as an option. The working parents that continued felt it was lucky that the appointments were on their days off, or that they were in the groups that did not require the parent to attend. One parent that withdrew from the trial explained that whilst it was something she was interested in, she didn't feel strongly enough to take time off work to attend the appointments:

> *"Even though it is something that I would have liked to taken part in, and it would have been for my benefit, I don't feel that strongly about it to take half a day off work for it, or try and fit it in when I can."* (25/W/F).

In addition to returning to work, parents also talked about how the burden of taking part in the trial increased after the birth of another child. The majority of the focus group participants enrolled onto the trial with their first child but most went on to have a second or third child during the study. These parents explained why it became more difficult to attend appointments with more than one child. Issues such as transport, childcare, and the children's behaviour at the appointments were deterrents to attending sessions on the trial.

> *"Since having two, I found everything like going to the dentist, or going to the doctor's, or anything like that so much more stressful than I did when I had one. Because I could kind of give them my attention and like, now, there's two of them,*

that they both want attention. When you're in that kind of setting where they need to sit still and do something, that's quite challenging." (13/P/C).

This participant demonstrated the challenges of keeping on top of things, particularly oral hygiene by describing her friend's third child who had developed tooth decay. She felt her friend had become more blasé about her third child's teeth. However, the parent defended her friend, explaining that this was not because she didn't care about the problem, but more that her priorities had changed since having three children. Similarly, another parent described it as being more "comfy" with her second child, which meant she had been much less inclined to join groups and take on extra commitments than she had with her first child. Other parents indicated that had they been invited to join the trial with their second child they would have been less likely to say yes to the offer. Collectively, parents indicated that the burden of taking part in the trial was greater for parents with more than one child because of changing priorities.

Overall, interviews with parents that withdrew from the study clearly highlighted that their decision to withdraw occurred at the point when the burden of taking part outweighed the benefit for their child. One parent, randomised to the behavioural arm of the trial, attended three intervention sessions before she withdrew; she described a combination of things that she found off-putting at first (low attendance by other parents and the relevance of the course content). But the parent explained that it was the organisation of the sessions that caused the parent to decide to withdraw from the study two and a half years after enrolling to the trial. A succession of failed attempts to arrange the child's final dental check at the nursery or home, alongside difficulties contacting the study team to rearrange appointments, led to the parent viewing no longer seeing the benefit of the trial because it felt more like an inconvenience.

"And at that point, I just thought, well, this is a bit daft to be honest." (23/W/B).

This was echoed by two more of the withdrawn participants, one who was finding it difficult to attend and then when her child started attending the dentist regularly felt there was no longer any benefit. And a second who found that bad organisation of the trial led to her missing multiple appointments; this parent eventually left the trial feeling she had missed too much for her child to gain a benefit anyway.

6.6.4.2 Fear of judgement

A prominent theme that arose repeatedly throughout the analysis, both in regard to recruitment and retention, was avoidance of situations in which they (or other parents) would feel judged by others. This arose both when talking to withdrawn parents and also to parents that continued with the trial. With continuing participants the theme arose predominantly when discussing why they felt other parents may have declined to enrol or stopped attending.

> *"I think maybe some people feel they're intimated by going to sessions. They feel a little bit judged."* (1/P/B).

This idea was reinforced by some parents who displayed evidence of avoidance of situations in which they felt they may be judged by other parents or health professionals. Parents in the continuing control group expressed fear of taking their children to appointments if they felt they were going to 'play-up' or misbehave at group sessions or appointments. This theme arose at a focus group attended by a mother and her two children, at which the parent felt her child was misbehaving. She described her feeling of embarrassment and anxiety in such situations, that other parents would judge her for not being able to control her child. Another parent in the group sympathised with her situation, whilst affirming her fears.

> *"Like, now, that's hard. If that…if that was my child, I've got one there doing that and the other one is crying, and I'm thinking, do they think this about me as a mum. So that's…so that's like what's going through your head. And it's like, as a parent, you only want to put yourself in so many situations like that, or is it…it makes you feel very uncomfortable."* (14/P/C).

Similarly, parents often described their child having a tantrum or refusing to open their mouth when having the fluoride varnish applied, or their teeth checked at the dental appointments. Parents that continued on the trial spoke about this as normal or expected behaviour, explaining that because their child soon recovered it did not cause them concern. However, one withdrawn participant did not feel that it was acceptable for her child to get distressed during a dental examination. When her child refused to have her teeth checked the dentist suggested restraining the child. The parent explained how the

Dentist's reaction made her reconsider her participation after she refused to hold down her child:

> *"The lady who was a dentist, she was really quite rude and abrupt about it and then after…so after she went…I just thought…and then I got, you know, another letter about filling something in, I just thought, "I'm not filling that in". But I just felt like it was a bit…well, it was a bit…one of the comments that she suggested that my child would end up with tooth decay because she couldn't comply on this one, you know? And then she said, "And you can't have a sticker," to my daughter I just felt, "Oh, boy, she's only three, you know?"* (21/W/C).

The parent was very defensive of her child's behaviour and her own decision not to restrain the child as the dentist had suggested. The parent's account of the incident indicated a feeling of judgement by the Dentist that the parent did not feel comfortable with.

Parents in the behavioural intervention group discussed their observations that the people who attended the sessions were generally 'older' parents. One parent described her niece, who had also had a baby at the same time as her, but had been reluctant to attend the sessions because she thought they were for 'older people'. When asked why she might have thought this, the parent felt it was because her niece (being a younger parent) had different priorities to the older mums and didn't see the benefit. She felt she could relate to this having had her second child as a much older parent, she felt she was *"more sorted out"* and more capable as a parent the second time round because of her age and experience. Another parent in this group also felt that younger mums would be reluctant to attend, she accredited this to a fear of feeling judged:

> *"Especially quite young mums, who might feel judged or like they don't want to talk in front of a group for whatever reason."* (5/P/B).

One parent in the behavioural group explained how there were some issues that she didn't feel comfortable discussing in a group and preferred to speak to the session deliverer on a 1:1 level for some topics, whereas she was happy to join in the group sessions for other elements.

"Some questions I need to ask Rosie in private, like if I want to ask about challenging behaviour, or if my baby…my baby did something that's not good behaviour. Just to ask her about what she knows about it." (07/P/B).

Whilst parents in the behavioural intervention group acknowledged that the group format of the sessions could be intimidating, they did not identify why younger parents might feel this way. However, the findings showed that parents who attended the sessions felt superior, because of their additional knowledge. As earlier discussed, a number of parents described their shock, and disbelief at the behaviours of other parents who did not have the same level of knowledge. They described trips to the supermarket, other people's houses and treats given by grandparents.

"And when I'm in the supermarket if I see anyone looking at the wrong toothpastes and things, I really want to go and take it off them." (03/P/B).

"I really literally don't understand, when you go round, and you see it as you go round, children with bottles of clearly, well stuff that is fruit juices or whatever, it certainly doesn't look like water or milk, and they're drinking away at it. And then really, what is it? And it's, 'Oh my God'. You can't give that to your baby or your child. You just can't. But they did it." (06/P/B).

"And I think I just, it seems so obvious that you don't give your kids sweets every day and so I couldn't give them juice. Why would you put that syrup in it? Do you know what I mean?" (11/P/B).

This superiority, when analysed across the whole sample felt increasingly like a stigma classification of 'them' and 'us' by the parents attending the groups; 'them' being the parents who don't have the knowledge or don't know how to care for their child's teeth and 'us' being the parents who do have the knowledge and are caring for their children's teeth in way that they think is more favourable.

One parent talked about her own experience of feeling judged by the other peers in her community for promoting healthy behaviours that she learnt whilst on the study. The parent had not lived in Salford for long and found that the parents in the area are *"quite prickly"* and *"defensive".* This parent was made to feel like the minority amongst her peers,

for wanting to behave outside of the norm (which she felt was giving children sweets). When asked how we could encourage more parents to take part in research studies like this the parents felt it would be difficult, particularly in a culture like she had experienced in Salford, where people don't like to hear difficult or challenging things, whereas for her the programme agreed with her existing beliefs so it was easier for her to stay on.

> *"I know that maybe people feel quite judged I think. If you're going contrary to the information or your practice with your child is, that's going to be very difficult and how to work round that I don't know."* (11/P/B).

6.6.4.2 Commerciality of the research

A third, less dominant theme under obstacles to participation was concerns about studies with commercial gain. In the behavioural focus group parents discussed their feelings about receiving toothbrushes and toothpaste and their apprehension about the perceived commercial aspect of the study. Parents felt 'dubious' of sponsored research and were less inclined to take part if the research had the possibility of commercial gain. Whilst parents understood the need for research to be funded, they did not feel comfortable with private companies gaining from the research, and felt particularly strongly that some of the companies were promoting less than optimal healthcare for children whilst being involved in studies such as this. Talk about toothpastes aimed at children but with less than the recommended dose of fluoride, led to a discussion about how the parents felt about research involving commercial gain and about companies promoting products for children that were not healthy. This feeling was mirrored in other arms of the trial where parents said they would also be reluctant to join the study if it was for commercial gain and prefer to take part if it is for the benefit of the community.

> *"I'm always a bit dubious about research when it's sponsored."* (6/P/B).

> *Maybe if it was for – I don't know – Haribo or something like that; I'd give that one a miss. If it's like a council, you know it's for the benefit of the community, really, isn't it?"* (18/P/F).

6.6.5 Reducing the burden

A third category of themes was around facilitators, or practical recommendations for how to make studies easier for parents to take part, particularly as the trial progressed. These themes appeared to be more important during the retention phase of the trial rather than at the recruitment point.

6.6.4.4 Ease of participation

As noted earlier, the study being local seemed to be an important motivator for all parents, regardless of group or participation status; this was mainly due to convenience. Overall, parents spoke about the convenience of appointments being community based and therefore close to their home. Parents found the sessions flexible, with multiple options and locations available for group sessions. If parents were unable to make group sessions they were offered 1:1 appointments at a location convenient to them. If the parent was not required to attend (for dental examinations and fluoride appointments) the research team visited the child's nursery or childminder's house. The convenience and flexibility of appointments and staff was appreciated by parents who found it easy to take part.

All continuing parents described the trial as requiring very minimum effort or inconvenience to them and could see no reason why other parents would choose to discontinue on the trial. They expressed surprise that some parents had decided to withdraw:

> *"But the fact that you went to her rather than me having to take her to you, I think that was a big plus. So I don't really understand why they would drop out if that was the case. But it's the convenience factor that…if it was inconvenient that's the only reason I could understand why people would drop out."* (20/P/F).

For some parents, particularly in the fluoride group (where the parent did not have to be present at intervention appointments), the researchers coming to the home or nursery was the difference between their remaining on the trial or withdrawing:

> *"But the fact that they said, 'No. We'll come out to you.' I said, 'Okay. We'll do it.' Because if I was going to have to make an appointment and go to Swinton Children's Centre and take two children with me, and I didn't know how [child] would react and when [child] screams, the youngest have to scream as well. (Laughter) I saw kind of my daughter doing this. So it was much better, it was much, much easier when they*

came out to us... As I say, it was probably the thing that convinced me to stay because they were coming out to us to do the last bit. That made it easy like, 'All right then. We've come this far, we'll carry on and finish it off.'" (19/P/F).

Understandably, trust of the staff looking after their child was therefore an important factor in nursery visits for all parents. Some parents said that they would wish to be there for their child's first appointment at the nursery to make sure that they reacted well to the situation, others already had a trusting relationship with the nursery staff and were confident that the child would be happy having an appointment in that environment. Conversely one parent, who explained her negative experience with her son's nursery did not trust the staff enough for the appointment to be carried out without her being there.

Four of the five parents that withdrew from the trial were not aware of the flexibility around attending appointment. One of these parents explained had they have known that nursery appointments (that the parent did not need to attend) were an option they may have been able to continue on the trial:

"I wasn't offered nursery sessions but if she was, yes. It would have made a difference because I would've been there for the initial one to see how [child] responded on what was going on and what procedure was. In going forward, I would trust someone enough to do it without me being there, i.e. in a Nursery setting." (25/W/F).

Parents who continued felt an important recruitment and retention strategy for future studies would be to promote the flexibility to parents, highlighting that as their priorities change and obstacles arise they would still be able to continue with the study.

"In terms of like the future maybe it's worth saying that to people at the beginning of the study, that when, you know, when they return to work, appointments can happen at the nursery, you don't need to be present every time, and…do you know what I mean? Things like that so that people know from the start that that's a possibility because that was very straightforward and the dentist that went to see him and stuff." (13/P/C).

When parents were asked their opinion on how future research could attract or retain more participants the majority of parents suggested conducting the research in the nursery environment, or within pre-existing groups that are already a part of the schedule. For interventions where the parent is required (the behavioural intervention) parents suggested delivering it at the start or end of nursery, as the parents have to go there anyway and are used to extended drop-offs or collections when the nursery staff need to talk to the parent. In general parents appeared to trust the nursery environment and staff, and felt that it was the answer to the problem of retention of children and families on trials.

Parents also suggested home-based interventions as a method of attracting more parents, with web based, or virtual research also being suggested as a potential facilitator. One parent who withdrew from the behavioural intervention group because she returned to work and found it difficult to attend sessions was enthusiastic at the thought of home-based research:

> *"But, yeah, if it was something like, you know, an information pack or a website you could go and you can read about it, and you can, it's more interactive and things like that, obviously that would be a perfect study. And maybe if things like text as well because, you know, if you get something like texts, you can carry on doing what you need to do and then when you're free then you can think, right I can give this my full attention now and then you can answer."* (22/W/B).

Parents also described how the friendly nature of the staff made it easy for them to continue with the trial. The majority of parents spoke fondly of the research staff appreciating their child-friendly manner and patience with the children, who were not always co-operative. Respecting the child's apprehension or behaviour appeared to be important to the parent, as well as having a welcoming environment for them to attend.

Receiving multiple forms of contact from the study staff was also highlighted as a facilitator for continuation on the trial. Parents appreciated receiving text message reminders of appointments and outstanding questionnaires. Overall they were happy to be contacted by telephone, text message and email as often as was required. Minimum effort with the questionnaire distribution and return was also highlighted by some parents, who admitted that often when things are sent in the post they get put to one side and forgotten about. By

including pre-paid envelopes in with the questionnaire parents were more inclined to send them back:

> *"Like, just things like, you know, I think we've had a few…well, I've had a few like questionnaires in the post. And they always put like an envelope in to send it back. And I just think things like that make it so easy. Like, I haven't got to find an envelope that is the right size, I haven't got to go and get stamp. Just literally fill it in and put it in, back in the post box. So that's been really good... There's no reason to drop out really. It was that…that easy to take part."* (14/P/C).

6.6.4.5 Incentives

A final theme to arise from the analysis around easing the burden of trial participation was around the incentives for parents to take part. For some these incentives were financial (parents randomised to the behavioural intervention group were given a £10 voucher as a contribution towards their expenses when attending sessions at the children's centres. All families in this group were given toothbrushes and toothpaste).

> *"There's financial incentive as well. I thought that was quite a clever incentive to kind of keep you going because, you know…I suppose people like reward, don't they? I enjoyed getting the goodie bag of toothpaste and toothbrushes and, you know, stickers and stuff. I thought they were nice."* (8/P/B).

6.7 Discussion

This study aimed to provide insight into factors affecting a parents' decision on whether to enrol their child into a trial, and motives for their subsequent continuation or drop out. The quantitative findings of studies 1 and 2 indicated that particular sociodemographic groups are more likely to take part in trials and certain study designs are less successful in recruitment and retention of participants than others; but there was little insight from these two studies into the reasons why. The majority of literature on qualitative studies is focussed on recruitment in health based settings with sick children. There is very little evidence of research with healthy participants in community based settings, particularly around retention.

The findings of this study provide unique insight into reasons for recruitment and retention to an oral health trial with a low SES population. The study uncovered motivations, obstacles and facilitators to taking part that, to our knowledge, have not been explored in the context of recruitment and retention previously. Specifically, motivations relating to risk of their child having poor oral health, being a better parent and increasing parental self-efficacy were found. Obstacles uncovered were fear of judgement and age specific barriers such as the birth of another child and returning to work after maternity leave, these too have previously been unexplored in the literature. The study also provides insight into how parents weigh up the risk, benefit and burden of taking part, which may be different in healthy populations to parents of children who are sick.

In this study the themes that were identified overlapped and appeared to be issues for both recruitment and retention. This finding is influenced by the design and timing of the study, as well as the types of questions asked (this will be explored further under limitations). Whilst themes could not be separated into recruitment and retention specific categories during the results and this discussion, the study does provide insight into the importance of different factors at different stages in the trial process. Table 6.3 presents the eight themes and their relevance to recruitment and retention respectively.

Table 6.3 - Themes by recruitment and retention

	Recruitment	Retention
Perceived risk of their child having poor oral health	✓	✓
Being a good parent	✓	✓
Appreciation of the value of research	✓	✓
Burden of participation		✓
Fear of being judged	✓	✓
Commerciality		✓
Ease of participation		✓
Financial Incentive		✓

As can be seen, many overlap across the two phases. Motivations, in particular were difficult to separate as they appear to be important factors both at the point of enrolment and when deciding whether to carry on with a trial. Themes around facilitators were more closely linked to retention, indicating that retention methods are less of a consideration for potential participants at enrolment. Similarly, concerns about the commerciality of research

only became as issue after people had enrolled, as did changes in life priorities such as returning to work after maternity or the birth of a second or third child. Further research into the importance of these influencing factors at the two different stages would be recommended, given that there is currently little evidence of research into this area.

Whilst there is acknowledgement of differences between the two stages (recruitment and retention) the discussion of themes will be merged for the remainder of this section for ease of reporting.

The most dominant theme to arise from discussions about motivations was the perceived risk of their child having poor oral health. Perception of risk has been explored in previous work on behaviour theory and participation on trials; although little work has been done on how theories translate when the parent is making the decision on behalf of their child. Multiple authors have tested and developed models of health-related behaviours as a way of explaining recruitment of adults to clinical trials (Verheggen et al., 1998, Sutherland et al., 1998, Brown and Topcu, 2003). Morrow et al. (1994) summarised the work on the four most commonly used theories (health beliefs model, subjective expected utility theory, the protection motivation theory and the theory of reasoned action) for their study into understanding recruitment to oncology trials. They state that the four models have similarities and four common concepts. The first of these could aid interpretation of results in this study. Morrow et al. hypothesise that 'probability' i.e. the probability of the participant having the health condition under investigation because of risk factors (including family history), as well as their knowledge or perception of the illness, can predict likelihood of enrolling onto a trial. They predict that participants who have a higher probability, or perceive themselves to be at risk are more likely to enrol onto a trial (Morrow et al., 1994). Whilst there has been little investigation in trials involving children in the case of a parent consenting for a child, it is possible that the decision is based on their own experiences. Therefore parents with personal experience of the consequence of poor oral health, or caries could be more inclined to enrol their child than parents who have not had experience of poor dental health. The findings of this study would support this theory as the majority of parents perceived their child to be at risk either from their own experiences, their parents or through observations of others close by. Unfortunately, there are few qualitative studies with parents of 'healthy children' who are at risk of disease to draw comparisons from.

Further investigation into perceptions of risk of illness for otherwise healthy children would therefore be warranted.

It was obvious from the analysis of discussions that parents put a high value on their child's oral health. Perception of the importance of their child's health, and the significance of its impact on health behaviours has also been observed in vaccination research. Brown et al. (2012) found that parents whose perception of the severity of diseases was greater, were more likely to have their child vaccinated than those who thought the diseases were mild. Similarly, an obesity trial found that parents who perceived obesity as low risk, or not serious, were less likely to prioritise participation on their trial (Barratt et al., 2013). This study is useful to draw comparison to as it targeted parents of children 'at risk' of obesity, i.e. they were otherwise healthy, like the children on the Bright Smiles Baby Study. Previous research around the importance of their child's oral health has highlighted that parents who perceive oral health to be important are more likely to take preventive action (Lewis et al., 2010, Wong et al., 2005). Whereas other studies have found that some parents perceive a child's first set of teeth to be unimportant because they fall out (Mofidi et al., 2009, Lewis et al., 2010, Wong et al., 2005). None of the participants on this qualitative study indicated negative perceptions of oral health. Parents who withdrew from the Bright Smiles Study appeared to place importance on their child's oral health in the same way that continuing parents did. It is therefore not possible to hypothesise that parents who withdrew from the trial placed less importance on oral health from this study. However, only a small percentage of withdrawn parents were interviewed, and these parents were possibly the more motivated of the withdrawn (given that they agreed to be interviewed for this research project). An in depth exploration of the value of child's oral health was not possible within this study but would be an interesting area for further research. Similarly, data on the parent's own dental attendance could assist in interpreting the results as previous research has indicated that parents who attend the dentist regularly are also more likely to take their child (Leroy et al., 2013). Dental anxiety has also been shown to impact a parents care for their child (Smith and Freeman, 2010). Whilst Only 2 of the 25 parents interviewed demonstrated dental anxiety (one of which withdrew from the trial) both parents were keen not to pass it on to their own child and saw the trial as a way of reducing this risk. Further investigation into the dental beliefs and behaviours of parents that stayed and withdrew

from the trial would provide further insight into the role of value on oral health in influencing recruitment and retention to trials, particularly as there is currently very little research in this area.

Parents showed a strong sense of feeling that participating on the trial would make them a better parent. The mothers acknowledged shortfalls in their own upbringing and wanted to do a better job than their own parents had for them. This desire for 'better' oral health for their child is mirrored in other qualitative studies with parents. In an interview study about child oral health with 28 parents from low income families in Washington, America, all interviewed parents expressed wanting better for their child than they had received, and felt that preventive care was a way to achieve this (Lewis et al., 2010).

Being on the trial appeared to increase the participants' confidence in their abilities as parents. The parents took assurance from their peers and the dentist and other health professionals that they were taking good care of their child's teeth. Parents described others who weren't participants, or perhaps stopped coming to the sessions as less competent and from these accounts it appeared that parents who took part in the trial, or chose to continue to the end had higher self-efficacy in their parenting and oral health skills than parents who declined or withdrew from the trial. Previous research has suggested that parental self-efficacy is positively correlated with children's oral health in several studies (Adair et al., 2004, Finlayson et al., 2007, Silva-Sanigorski et al., 2013), with higher self-efficacy equating to more positive oral health for children. However, there is no evidence of investigation into whether parental self-efficacy has any impact on parents' behaviours towards participation in oral health trials. Two trials included in the systematic review in study 1 investigated parental confidence or self-efficacy as a predictor of participation. In one of these, Ireys et al. (2001) found that parents with greater maternal confidence to look after a child with chronic illness were more likely to refuse recruitment. Conversely the other study (Gross et al., 2001) found that parental self-efficacy was unrelated to attrition in a parenting intervention trial with minority groups. The parents on this study appeared to have high confidence in their ability to look after their child's teeth, but this was concluded from a relatively small number of parents. Further quantitative investigation into the impact of parental self-efficacy on trial participation would therefore be warranted, particularly in

the field of oral health where self-efficacy has been found to relate to positive oral health behaviours.

Other themes around motivations are more in line with previous studies on recruitment and retention and appear to be common across fields of health. Previous research has identified altruism as an important motivating factor, especially in research with neonates (Zupancic et al., 1997, Mason and Allmark, 2000, Hoehn et al., 2005) and vaccine trials (Chantler et al., 2007); this was a theme emerging from the focus groups and interviews in this study, with parents from all three groups (including one withdrawn parent) expressing their wish to help the local community, or contribute to research in general. However altruism was rarely the primary reason given by parents for joining the trial; this finding challenges vaccines research which suggested that parents of healthy volunteers are motivated predominantly by altruism (Chantler et al., 2007), however, it mirrors other studies that have found altruism to be a contributing, but lower ranked, motivation for participation in research with children (Truong et al., 2011, Rothmier et al., 2003, Tait et al., 2003).

Similarly, interest in research and commitment to the trial were concepts raised in this study, with educated parents showing a greater commitment to the trial. Whilst Chantler et al. (2007) did not measure level of education, they did find that familiarity with science and medicine influenced participation in their vaccines study. Similarly Macrae (2009) found that education appeared to be linked with a greater appreciation of research in their questionnaire study inviting parents of neonates to take part in hypothetical trials. On the Salford Bright Smiles Trial, commitment to the trial was more evident in the parents randomised to the fluoride and behavioural groups, who had more contact with study staff than parents in the control arm. Promise or commitment to a study has been found to be an important motivating factor in trials with adults (CISCRP, 2013, Atwood et al., 1992) but there is little evidence of this being a motivation in previous research with children.

In the theme of 'obstacles to involvement', the most unanticipated finding was that parents described a tendency for themselves and other parents to avoid situations in which were at risk of feeling judged. Whilst not common in literature around reasons for recruitment and retention to trials, this observation does correlate to previous research, which found that

first time parents, young mums and single parents are more likely to feel judged, and avoid situations that will put them in this position (Department of Health, 2011).

Past studies have suggested that minority groups are less likely to take part in trials because of increased stress and demands due to lack of resources and family commitments (Baker et al., 2011, Janson et al., 2001, Garvey et al., 2006). These groups have been reported to traditionally feel more marginalised in research (Hussain-Gambles et al., 2004). However, there is little evidence of qualitative investigation with parents into the reasons for this feeling of marginalisation. This study uncovered a fear of situations in which parents feel judged and an avoidance of situations in which they are putting themselves at risk of stigma. Parents on the behavioural arm of the trial felt that other less competent or confident parents may have avoided the sessions. The parent with first-hand experience of feeling marginalised by her peers along with the mother that withdrew because she felt judged by the dentists, confirmed that parents prefer to avoid situations where they feel non-conformant or stigmatised.

There are few studies investigating the impact of judgement from which to draw comparison from. Research into why parents choose to have their child vaccinated against measles, mumps and rubella (MMR) in the UK, found that fear of judgement of their parenting impacted their decision on whether to give their child the MMR vaccine (Brown et al., 2012). In an interview study with parents enrolled onto a speech and language therapy (SLT) trial with their child, Glogowska et al. (2001) found that parents' perceptions of trial participation were affected by how society perceived them. Similar to this study, the parents on the SLT trial discussed how society had a classification of 'good parents' and expressed feelings of judgement because of the speech and language problems that their child was experiencing. This feeling of judgement affected participation, with parents feeling upset if they were randomised to the control arm of the trial. Mytton et al. (2014) conducted a systematic review of qualitative studies with parents enrolled on parenting programme trials. They too found that parents avoided sessions for fear of stigma or being labelled a 'bad parent'.

The lack of supporting evidence around fear of judgement as a deterrent could be explained by the paucity of research with 'healthy' children in comparison to sick children. It is

possible that fear or avoidance of situations in which parents may feel judged could be more important in trials with healthy children, where the benefit and motivation to take part is less obvious, or in parent focused behavioural intervention trials where the behaviours of the parent impact the child's health. However there is little evidence in the literature in respect of this issue, suggesting that further investigation is warranted.

The findings around practical barriers to taking part (timings, location, transport, childcare) were to be expected and are common in previous research with families. However, this study suggests that parents evaluate the benefits of taking part against the burdens of participation. At the point that the burden outweighs the benefit the parent chooses to withdraw from the trial. Previous studies have also found that parents weigh up the risk and benefits of trial participation before making a decision on whether to take part in a trial (Jollye, 2009, Tait et al., 2003). Yet these studies were with parents of sick children at the point of recruitment. It has been acknowledged that parents of children in hospital requiring treatment are under considerable stress at this decision making time (Jollye, 2009) and the perception of risk and benefit may therefore be different to parents of healthy children (such as the Bright Smiles participants). This study is the first to suggest that parents of healthy children also weigh up the benefits and risks when deciding whether to continue their participation on a trial. It is recognised that due to the post-hoc nature of the interviews this finding should be interpreted with some caution as parents may have been looking for a rationale for their withdrawal. However, parents did not refer directly to this weighing up of the risk and benefit; rather the theme emerged on analysis of accounts of both continuing and withdrawn participants. Furthermore, as this concept has been found in previous research studies with sick children it is therefore unlikely that this finding is an artefact of the research design. As relatively little research into the perception of risk and benefit has been conducted with healthy children further research would be warranted.

Finally, the acknowledgement of the benefit of the multiple retention techniques by parents on the Bright Smiles Baby Study corresponds with the findings of other community based trials in children. In particular parents found home visits and nursery visits were an important facilitator once they returned to work or their child started nursery. In an investigation with parents invited to participate in a vaccine trial, participants also appreciated the convenience of home visits as well as their child being more at ease in the

familiar surroundings of their own home (Chantler et al., 2007), this corresponds with parents' appreciation of the child friendly environments and home visits for appointments on this study and is a practical recommendation for study settings in future studies involving pre-school children. Repeated contact, a personal approach and friendly research staff were also appreciated by participants on the Bright Smiles Baby Study and have been found to be beneficial in previous community based studies with healthy children (Nicholson et al., 2011).

6.8 Limitations

This study was subject to a number of limitations, which should be taken into account when interpreting the findings.

Firstly the size and nature of the sample may have influenced the opinions obtained from the focus groups and interviews. As the sample was self-selecting it is possible that the parents that took part were already motivated parents with fewer barriers to participation in research. Parents that withdrew from the trial were difficult to contact and only a small number responded to the invitation to take part. It is possible that despite withdrawing from the main trial, the parents that responded were more likely to take part in research than others that did not respond, and their reasons for withdrawal may have been different. A similar limitation was highlighted in a study investigating recruitment in paediatric oncology trials, where it was suggested that parents who do not wish to take part in trials are also less likely to take part in other research (such as qualitative investigations such as these) (Byrne-Davis et al., 2010). Similarly, in this study, control group participants were less responsive to invitations to take part in the focus group study, however as their responses were in line with the other two groups of participants further invitations were not sent to this group.

Two focus groups were conducted with only 2 participants, this is less than the recommended number. Whilst it is recognised that these groups could have been split into individual interviews to provide consistency, the quality and richness of the discussions that arose from these small groups between peers, provided insight into parents' fear of being judged in situations, that larger groups, or one to one interviews may not have elicited.

As highlighted, the parents interviewed in this study were relatively socio-demographically homogenous. Another shared characteristic of the participants was that they were all involved with, or had visited a Sure Start Children's Centre (assumed as the majority of recruitment and appointments took place in the centres). Whilst the parents on this study have generally been classified as 'low SES' (based on IMD calculated by postcode), the findings of a report evaluating the impact of Sure Start Children's Centres in the UK, indicated that the centres fail to reach the most disadvantaged families (National Audit Office, 2006). It is possible therefore, that families who attend the centres may be more motivated to take part in group sessions and activities generally and therefore may not share the same views as parents who do not attend Sure Start Children's Centres.

The relatively high number of participants in the behavioural group of the trial may also influence the data collected in this study. Parents randomised to the behavioural intervention may have felt more committed to the trial due to the group sessions and most intensive level of contact across the three groups. This phenomenon could explain the greater number of participants from this group responding to the invitation as well as potentially influencing findings. Furthermore, participants from the behavioural and fluoride groups often expressed warmth toward the intervention deliverer, a dental hygienist also involved in management of the trial. Their relationship with this member of staff may have restricted parents' responses to questions about negative aspects of limitations of the study, although the deliverer was not present at any of the interviews and focus groups, and all parents were reminded that all answers were confidential and would not be fed back to the study staff.

This study was designed retrospectively, after recruitment to the trial had closed. This meant that access to parents who refused to take part in the trial was not possible. Reasons for why parents may decide not to enrol in a trial have been drawn from the continuing and withdrawn parents who did enrol on the trial. Many of the parents interviewed had already finished the trial and their opinions were therefore given retrospectively. Rodriguez et al. (2006) highlight that retrospective collection of data from parents may be influenced by the outcome of the research; however as the results of the Bright Smiles trial had not been published at the time of the interviews, this is unlikely. There is however a risk that the views of parents had changed over time, particularly around their reasons for enrolling on

the trial that were cited as motivations and facilitators for recruitment. Some of the reasons given for enrolment, for example gaining knowledge or receiving the fluoride varnish, were group allocation dependent, and parents therefore did not know that they were going to be allocated to that group at the time of recruitment. Studies that interview parents at the time of recruitment are likely to obtain a more complete understanding of reasons for recruitment.

Prior to completing this study, the researcher attended training on the design and methodological aspects of qualitative research delivered locally by the University of Salford. In addition, the researcher had some experience of conducting focus groups for research projects and in evaluation of health projects. Whilst formal training and experience was limited the project was supervised by two experienced qualitative researchers who provided guidance and feedback, particularly whilst developing a thematic framework and the mapping and interpreting phases of framework analysis.

Emergent themes were discussed with supervisors, and quotes have been used throughout the chapter to support themes and concepts. Further effort was made to avoid the risk of eliciting generalized or idealized accounts by asking open ended questions framed around situations, rather than direct, or closed questions. This allowed deeper exploration of the topics and participants to talk around a subject, allowing a more detailed account than direct questions would provide.

It is possible, given the students involvement in management and administration of the trial that personal experiences and beliefs as well as subjective motives impacted the analysis of data. However, the reflexive journal maintained throughout assisted in identifying and eliminating bias due to personal attachment to the study (Watt, 2007). Comparing and referring frequently to existing literature also allowed confirmation of emerging themes and prevented the researcher's personal views and experiences dominating during data analysis. The use of quotes throughout the results section allows participants to speak for themselves (Watt, 2007) and evidences that the data supports the assumptions made. Furthermore, the framework analysis technique offers a clearly presented and easily interpreted account of how interpretations were reached. Familiarity with the trial design, study staff and challenges that families had faced allowed an in depth exploration of issues and for the

researcher easily recognise issues that may have otherwise have been overlooked had it not been for her involvement.

Finally, as highlighted throughout, the trial from which participants were selected was a community based dental trial, therefore findings may not be applicable to other areas and settings. Retention techniques adopted on the trial were resource intensive and may not be feasible for all trials.

6.9 Recommendations for further research

As highlighted in the limitations of this study, the design could have benefitted from interviewing participants who chose not to enrol on the trial at the time of refusal. Similarly, interviews with parents close to the time of withdrawal could be beneficial for exploring the reasons for dropout in future studies.

Parents appeared to be motivated by their parental self-efficacy in relation to oral health behaviours and beliefs about oral health. Further analysis of the importance of these factors would be of value to explore this in more detail.

Further investigation into the perceptions of risk and benefits for parents of otherwise 'healthy' children would be warranted due to the relative lack of research in this area. Furthermore, investigation of avoidance of RCT participation due to fear of judgement or stigmatisation, and the relevance of this, particularly in healthy populations would also be of further value.

6.10 Conclusion

As very little qualitative research has been conducted around retention, and even less with the field of oral health, this study provides a rare insight into factors affecting a parents' decision to take part in oral health trials. Whilst many of the findings around motivations, obstacles and facilitators are recurrent in the existing literature, this study highlighted unique themes that are uncommon in previous recruitment and retention studies.

The results from this study indicate that parents who perceive their child to be at risk of poor oral health and put a high value on good oral health were more likely to take part on the Salford Bright Smiles Baby Study. Further investigation into oral health beliefs and

dental attendance would be warranted due to the relatively low number of participants that took part, particularly from the group of parents who chose to withdraw from the trial. Parents were also motivated by the assurance that being on the trial made them a better parent than their own, or others they had seen. There were indications that parents who remained on the trial were more confident in their parenting abilities and had a higher self-efficacy in relation to their child's oral health than those who chose to end early. An analysis of parental self-efficacy scores for the parents who left and remained on the trial would be of further benefit.

Mothers admitted to avoiding situations in which they felt judged, and felt this was a probable reason for non-involvement by some mothers. Parents who remained on the trial displayed feelings of superiority to those that had chosen not to take part or stopped attending the sessions. This finding could provide insight into why 'minority groups' are difficult to recruit and retain on trials.

Overall parents appeared to weigh up the benefits of their taking part alongside the burdens of participation. From interviewing withdrawn participants and gaining insight from the continuing parents, it was apparent that parents chose to withdraw from the trial at the point that the burden outweighed the benefit of taking part; this often coincided with a change in life priorities such as returning to work after maternity leave or the birth of a second or third child. The themes around reduction of the burden of participation and suggestions from parents provide practical recommendations for ways of facilitating participation for parents. Flexible and convenient appointments, home and nursery based research and using child friendly staff and environments were evidenced as ways to retain participants and are practical recommendations for future research with parents of children aged 1-3 years.

Chapter 7
An analysis of continuing and withdrawn participants on the Bright Smiles Baby Study – 'Study 4'

7.1 Overview

Study 4 was a secondary data analysis of the impact of sociodemographic, oral health belief and dental behaviours on retention of participants enrolled on the Bright Smiles Baby Study RCT. This study aimed to expand on the findings of study 3 by investigating the characteristics of parents that continued on the trial to the end of the study compared to those who chose to withdraw or were lost to follow up.

This chapter begins by outlining the rationale for study 4 and a justification for further research in this area is presented. The sources of data and data analysis techniques are described. The results are presented with a discussion of how the findings relate to existing literature and add to the knowledge obtained in study 3. Limitations of the study will be discussed along with recommendations for future research and retention of participants on oral health RCTs.

7.2 Rationale for study 4

Study 3 was a qualitative investigation of a small sample of participants that took part in the Bright Smiles Baby Study trial. The study indicated that understanding of their child being at risk of poor oral health, the parents' perception of importance of good oral health and confidence in their ability to care for their child oral health were motivations for participants being recruited and retained on a trial. Dental beliefs and behaviours were discussed with parents. However, the relatively small sample size, and in particular the low number of withdrawn participants that were interviewed hindered the results of the study. Several areas for further research were identified, including a quantitative analysis of the dental beliefs, parental efficacy and dental behaviours of parents that enrolled their child onto the trial. As very few studies have been conducted in community based oral health trials with children and families further research was recommended in the area.

As identified in chapter 3 of this thesis, the literature investigating predictors of recruitment and retention in oral health trials with children is limited, with the majority focussed on recruitment rather than retention of participants (chapter 3, section 3.4). Most studies that have investigated characteristics of participants have focussed on clinical variables (decay prevalence) due to a concern for the generalizability of results. There is limited evidence of

studies investigating the oral health beliefs of parents, or parental self-efficacy in relation to oral health behaviours.

7.3 Aim

To compare participants who remained on the Bright Smiles Baby Study with those that chose to withdraw or were lost to follow up.

7.4 Research questions:

1) Did sociodemographic variables predict which participants were more likely to be retained on the SBSBS?
2) Did oral health beliefs and behaviours predict which participants were more likely to be retained on the Salford Bright Smiles Baby Study?

7.5 Methods

7.5.1 Design and justification of methods

Secondary analysis of data collected on an oral health trial was conducted. Data was collected from participants during their involvement on the Bright Smiles Baby Study in the period 2010 – 2014 (Pine et al., 2014). The Salford Bright Smiles Baby Study was a randomised controlled trial conducted with children aged 1-3 and their parents in Salford and Manchester, areas of the Northwest of England. The trial is described in detail in chapter 1.

Analysis of participant data on RCTs is common practice to ensure that the results were not subject to bias due to significant differences between those who continued and dropped out (Bell et al., 2013, Groenwold et al., 2014). As highlighted above, this study of the Salford Bright Smiles Baby Study participants, aimed to identify predictors of dropout by comparing the sociodemographic and oral health beliefs and behaviours of parents, in this sense and for the purpose of this thesis the study is defined as a 'secondary analysis' of the trial dataset. A brief overview of secondary data analysis, including its strengths and weaknesses and their applicability to this study will briefly be discussed hereon.

7.5.1.1 Secondary data analysis

Secondary data analysis is the term given to studies that use data for analysis that was not included in the aim of the original study from which the data was derived (Cheng and Phillips, 2014, Casas et al., 2004, Johnston, 2017). Cheng and Phillips (2014) recommend drawing a distinction between 'secondary analysis of existing data' and 'secondary data analysis', highlighting that the latter traditionally means that the person analysing the data did not collect the data, with the former encompassing both data that was collected by the researcher and data that was not.

7.5.1.2 Benefits of secondary data analysis

Secondary analysis of data is a cost effective way of answering a research questions using data that has already been collected (Cheng and Phillips, 2014, Johnston, 2017). The use of existing datasets can also save the researcher time and therefore research questions can be answered faster than in empirical research (Johnston, 2017).

Another obvious benefit of using trial data for analysis of recruitment and retention trends is that the data is based on a 'real-life' trial. Whilst studies have been conducted investigating recruitment and retention to hypothetical trials there is evidence to suggest that the decision making process may differ between hypothetical and real trials, with parents giving more consideration to their child's views in the former (Shilling and Young, 2009).

7.5.1.3 Limitations of secondary data analysis

Secondary analysis of existing data can be criticised as the data was not collected with the current research question in mind, it is therefore possible that relevant data was not collected (Cheng and Phillips, 2014). As highlighted in study 2 of this thesis, a limitation of post-hoc analyses of trial datasets is that the data was not collected with goals of analysing predictors of recruitment and retention (Wakim et al., 2011). As discussed above, hypothetical trials can be used to investigate predictors of recruitment, however, this is less viable for retention research. Wakim et al. (2011) suggest studies that seek participants' direct reasons for dropping out of trials may allow better understanding of reasons for

retention. This had already been conducted in study three of this thesis, and therefore this limitation has been addressed.

A further drawback of secondary data analysis, is that the researcher was often not involved in the data collection and therefore did not influence the measurement tools used. This can result in the data being out of date (if a more effective tool has become available since collection of data) or the researcher may have to use proxy measures for missing data that is relevant to the secondary analysis research question (Clarke and Cossette, 2016). In the current study, oral health beliefs and behaviours were measured using data collected from the questionnaire administered to participants on the trial; limitations of this data collection method are discussed further in section 7.8.

Finally, Johnston (2017) highlights that if the researcher was not involved in the original data collection they may not know whether data is missing due to incompleteness and ineffectiveness of the data collection technique. As an original member of the clinical trial research team, this pitfall is not a concern of this study.

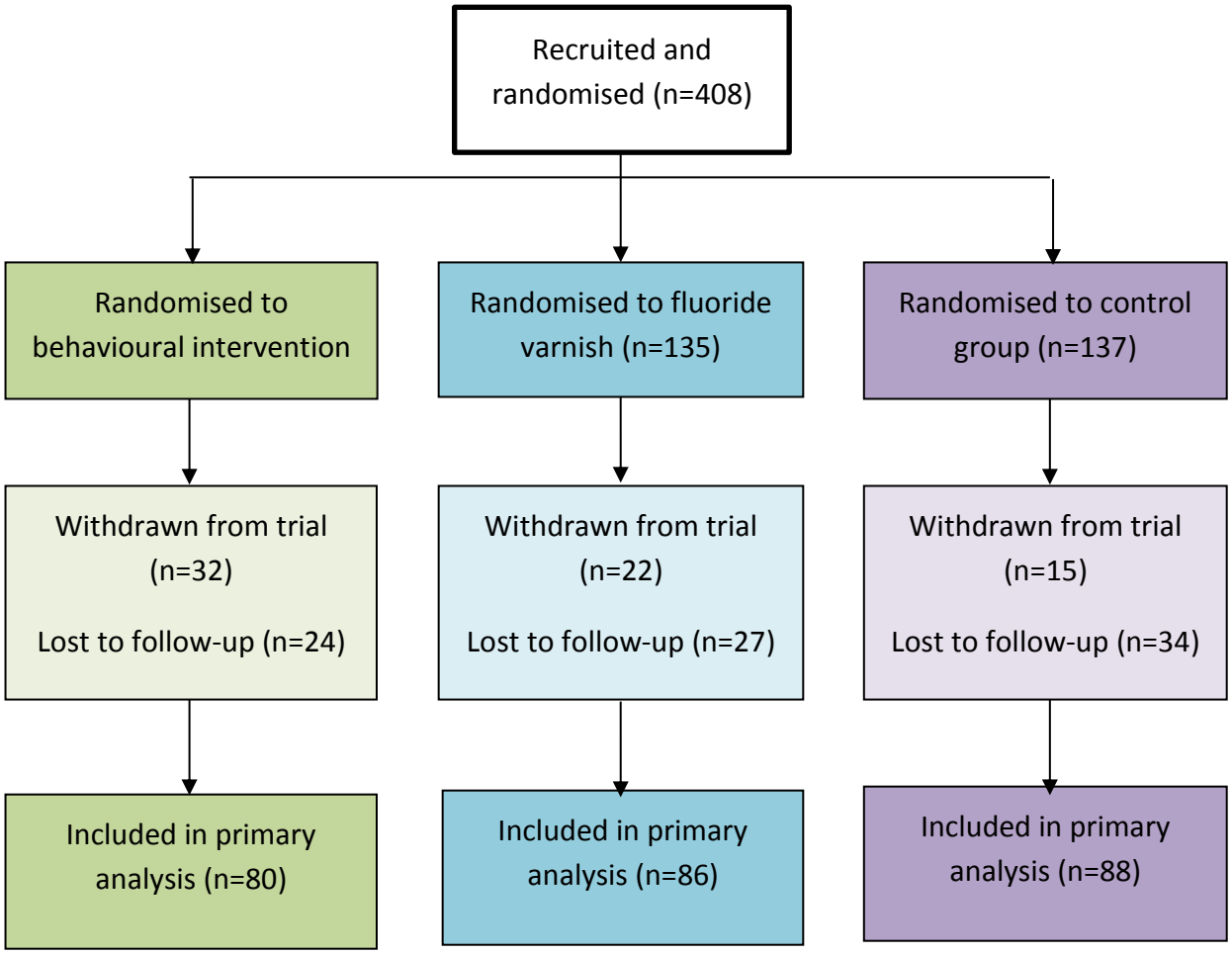
7.5.2 Ethics

Research ethics and governance approval for the trial and data analysis was gained through the IRAS system from NorthWest 8 REC GM East, Salford Royal NHS Foundation Trust R&D Department and the University of Salford Research Ethics Committee (appendix 13).

7.5.3 Participants

Parents enrolled on to the trial when their child was aged 0-13 months and remained on the trial until their child was 3 years old, when endpoint data collection was scheduled. A number of parents withdrew from the trial during the course of the two years. Participants were considered withdrawn if they notified the research team of their decision to withdraw from the study verbally or in writing. A further set of parents were lost to follow up. 'Loss to follow up' is defined here as participant not available to provide final primary outcome endpoint data, but did not formally withdraw – i.e. did not notify the research team of their intention to withdraw. The flow of participants in the trial is presented in figure 7.1.

Figure 7.1 - Salford Bright Smiles Baby Study Participant Flow



7.5.4 Measurements

Upon enrolment, parents of participants were asked to complete the Oral Health Behaviour Questionnaire (OHBQ) (Adair et al., 2004) (appendix 14). The OHBQ was developed to measure the attitudes and beliefs of parents around their children's health. The OHBQ includes 8 attitudinal factors categorised under three categories of attitudes 1) parental attitudes towards child toothbrushing behaviour, 2) parental attitudes towards child sugar snacking and 3) parental attitudes towards dental decay.

Responses to the 8 attitudinal factors (derived from multiple questions in the OHBQ) were given on a 5-point Likert scale from strongly disagree (1) to strongly agree (5). Higher scores

on this scale indicate higher levels of agreement with the statement. Negative items were reverse scored for the analysis (Adair et al., 2004).

The OHBQ also contains questions about sociodemographic items, including postcode, child gender, ethnicity, level of mothers' education, employment, marital status, parent age, number of children and child order. Additionally the questionnaire reports on the parents behaviours regarding twice daily toothbrushing, reasons for visiting the dentist and whether the parent has taken the child to the dentist.

Variables from the OHBQ were combined with additional data collected during the trial, including child's age at enrolment, method of informed consent (fact to face or postal) and whether parents returned the baseline OHBQ.

Two categorical measures of retention were used in the data analysis:

1) Retained – participants withdrew from the trial (coded 0) or remained (coded 1)
2) Availability of endpoint – participants withdrew or were lost to follow up (coded 0) or remained on the trial and provided endpoint data (coded 1)

7.5.5 Analysis

Baseline data collected from the OHBQ and trial dataset was entered into a trial database. Data from the database was extracted and imported into SPSS version 22 (IBM Corp, Released 2013), data was checked at data entry stage for data entry errors. Descriptive statistics, including frequencies for nominal or ordinal data and means for continuous data were generated to check for outliers. Where outliers were found, the source data was checked against the database.

Retention was quantified by the number of participants that formally withdrew from the trial. Analysis was also conducted on participants that withdrew or were lost to follow up against those who continued to the end of the trial.

All variables were examined for normality prior to analysis. Histograms for continuous data were examined, where continuous variables indicated skew data were transformed to categorical variables. Data was analysed using single-predictor logistic regression to test

association with sociodemographic, oral health behaviours and dental beliefs. Predictors with a p-value <0.2 were included in multiple logistic regression models.

A significance level of $\alpha = 0.05$ was adopted for all statistical analyses reported.

7.6 Results

In total 409 parents enrolled their child on to the Bright Smiles Baby Study. One parent withdrew prior to randomisation and will be excluded from this analysis. 69 participants formally withdrew from the trial (notifying the study team verbally or in writing of their intention to withdraw). A further 85 participants were lost to follow up and did not attend their final endpoint examination (as presented in figure 7.1). The characteristics of participants at baseline by participation status group are presented in table 7.1 ('enrolled', 'withdrawn' and 'did not withdraw') and table 7.2 ('enrolled', 'withdrawn or lost to follow up' and 'endpoint data available').

In summary, the majority of parents belonged to the most deprived (42.4%) or second most deprived (25.5%) Index of Multiple Deprivation (IMD) quintiles. 79.1% of parents were aged between 20 and 40 years, and 44.4% were married. Only 23% of parents described themselves as unemployed at baseline and parents were evenly divided between those who did and did not attend university. The majority of parents described their ethnicity as 'White British' (61.5%), the next most common ethnic grouping was 'Black' (7.4%). Most parents reported brushing at least twice a day (72.5%) and visited the dentist regularly for check-ups (80.4%).

Table 7.1 – Characteristics at baseline - Withdrawn

	All Enrolled	Withdrawn	Did not withdraw
Number of participants	408	69	339
Group			
Control	137 (33.6)	15 (21.7)	122
Behaviour	136 (33.3)	32 (46.4)	104
Fluoride	135 (33.1)	22 (31.9)	113
Child age at enrolment (mths)			
Mean (s.d.)	9.25 (3.36)	8.99 (3.10)	9.31 (3.41)
Child gender			
Male	205 (50.2)	37 (53.6)	168 (49.6)
Female	194 (47.5)	28 (40.6)	166 (49.0)
Missing	9	4	5
IMD			
most deprived 1	173 (42.4)	25 (36.2)	148 (43.7)
2	104 (25.5)	17 (24.6)	87 (25.7)
3	70 (17.2)	15 (21.7)	55 (16.2)
4	31 (7.6)	6 (8.7)	25 (7.4)
least deprived 5	25 (6.1)	5 (7.2)	20 (5.9)
Missing	5	1	4
Postal consent			
No	278 (68.1)	49 (71.0)	229 (67.6)
Yes	130 (31.9)	20 (29.0)	110 (32.4)
Baseline Q returned			
No	59 (14.5)	13 (18.8)	46 (13.6)
Yes	349 (85.5)	56 (81.2)	293 (86.4)
Parent brushes twice a day			
No	49 (12.0)	14 (20.3)	35 (10.3)
Yes	296 (72.5)	42 (60.9)	254 (74.9)
Missing	63	13	50
Baby has visited dentist			
No	276 (67.6)	48 (69.6)	228 (67.3)
Yes	70 (17.2)	8 (11.6)	62 (18.3)
Missing	62	13	49
Reason parent visits dentist			
Doesn't go	18 (4.4)	4 (5.8)	14 (4.1)
Goes regularly	328 (80.4)	52 (75.4)	276 (81.4)
Missing	62	13	49

	All Enrolled	Withdrawn	Did not withdraw
Age			
<20	8 (2.0)	0	8 (2.4)
20-30	158 (38.7)	26 (37.7)	132 (38.9)
31-40	165 (40.4)	26 (37.7)	139 (41.0)
>40	16 (3.9)	3 (4.3)	13 (3.8)
Missing	61	14	47
Marital status			
Married	181 (44.4)	27 (39.1)	154 (45.4)
Single	136 (33.3)	24 (34.8)	112 (33.0)
Divorced	8 (2.0)	1 (1.4)	7 (2.1)
Cohabiting	19 (4.7)	3 (4.3)	16 (4.7)
Missing	64	14	50
Employment			
Employed	244 (59.8)	37 (53.6)	207 (61.1)
Unemployed	94 (23.0)	15 (21.7)	79 (23.3)
Missing	70	17	53
University Educated			
No	172 (42.1)	27 (39.1)	145 (42.8)
Yes	173 (42.4)	27 (39.1)	146 (43.1)
Missing	63	15	48
Ethnicity			
White British	251 (61.5)	43 (61.4)	208 (61.4)
White other	25 (6.1)	0	25 (7.4)
Asian	18 (4.4)	5 (7.2)	13 (3.8)
Black	30 (7.4)	4 (5.8)	26 (7.7)
Chinese	4 (1.0)	0	4 (1.2)
Mixed	13 (3.2)	2 (2.9)	11 (3.2)
Missing	67	15	52
Number of children **Mean (s.d.)**	1.54 (0.911)	1.54 (1.008)	1.54 (0.893)
Birth order of child **Mean (s.d.)**	1.56 (0.898)	1.56 (0.977)	1.56 (0.884)
Number of visits	2.89 (2.514)	0.71 (1.426)	3.33 (2.456)
Self efficacy – toothbrushing **Mean (s.d.)**	4.18 (0.617)	4.16 (0.597)	4.18 (0.622)
Self efficacy – sugar control **Mean (s.d.)**	4.13 (0.676)	4.10 (0.749)	4.13 (0.663)

Table 7.2 – Characteristics at baseline – Withdrawn OR Lost to follow up

	All Enrolled	Withdrawn or lost to follow up	Final endpoint data available
Number of participants	408	154	254
Group			
Control	137 (33.6)	49 (31.8)	88 (34.6)
Behaviour	136 (33.3)	56 (36.4)	80 (31.5)
Fluoride	135 (33.1)	49 (31.8)	86 (33.9)
Child age at enrolment (mths)			
Mean (s.d.)	9.25 (3.36)	8.90 (3.28)	9.47 (3.40)
Child gender			
Male	205 (50.2)	81 (52.6)	124 (48.8)
Female	194 (47.5)	67 (43.5))	127 (50.0)
Missing	9	6	3
IMD			
most deprived 1	173 (42.4)	75 (48.7)	98 (38.6)
2	104 (25.5)	36 (23.4)	68 (26.8)
3	70 (17.2)	23 (14.9)	47 (18.5)
4	31 (7.6)	12 (7.8)	19 (7.5)
least deprived 5	25 (6.1)	6 (3.9)	19 (7.5)
Missing	5	2	3
Postal consent			
No	278 (68.1)	112 (72.7)	166 (65.4)
Yes	130 (31.9)	42 (27.3)	88 (34.6)
Baseline Q returned			
No	59 (14.5)	38 (24.7)	21 (8.3)
Yes	349 (85.5)	116 (75.3)	233 (91.7)
Parent brushes twice a day			
No	49 (12.0)	24 (15.6)	25 (9.8)
Yes	296 (72.5)	92 (59.7))	204 (80.3)
Missing	63	38	25
Baby has visited dentist			
No	276 (67.6)	95 (61.7)	181 (71.3)
Yes	70 (17.2)	21 (13.6)	49 (19.3)
Missing	62	38	24
Reason for parent dentist			
Doesn't go	18 (4.4)	7 (4.5)	11 (4.3)
Goes regularly	328 (80.4)	108 (70.1)	220 (86.6)
Missing	62	39	23

	All Enrolled	Withdrawn or Lost to follow up	Final endpoint data available
Age			
<20	8 (2.0)	5 (3.2)	3 (1.2)
20-30	158 (38.7)	61 (39.6)	97 (38.2)
31-40	165 (40.4)	45 (29.2)	120 (47.2)
>40	16 (3.9)	3 (1.9)	13 (5.1)
Missing	61	40	21
Marital status			
Married	181 (44.4)	45 (29.2)	136 (53.3)
Single	136 (33.3)	57 (37.0)	79 (31.1)
Divorced	8 (2.0)	3 (1.9)	5 (2.0)
Cohabiting	19 (4.7)	7 (4.5)	12 (4.7)
Missing	64	42	22
Employment			
Employed	244 (59.8)	44 (28.6)	177 (69.7)
Unemployed	94 (23.0)	67 (43.5)	50 (19.7)
Missing	70	43	27 (10.6)
University Educated			
No	172 (42.1)	40 (26.0)	99 (39.0)
Yes	173 (42.4)	73 (47.6)	133 (52.4)
Missing	63	41	22
Ethnicity			
White British	251 (61.5)	94 (61.0)	157 (61.8)
White other	25 (6.1)	1 (0.6)	24 (9.4)
Asian	18 (4.4)	6 (3.9)	12 (4.7)
Black	30 (7.4)	8 (5.2)	22 (8.7)
Chinese	4 (1.0)	0	4 (1.6)
Mixed	13 (3.2)	3 (1.9)	10 (3.9)
Missing	67	42	25
Number of children Mean (s.d.)	1.54 (0.911)	1.54 (1.040)	1.54 (0.843)
Birth order of child Mean (s.d.)	1.56 (0.898)	1.64 (1.018)	1.52 (0.831)
Number of visits	2.89 (2.514)	1.04 (1.652)	4.01 (2.273)
Self efficacy – toothbrushing Mean (s.d.)	4.18 (0.617)	4.20 (0.651)	4.16 (0.601)
Self efficacy – sugar control Mean (s.d.)	4.13 (0.676)	4.14 (0.693)	4.12 (0.669)

7.6.1 Analysis of retained and withdrawn participants

Single predictor logistic regression was conducted for the categorical dependant variable 'retained' (0 = no (participant withdrew), 1 = yes (participant did not withdraw)) and the independent sociodemographic and study related predictor variables shown in table 7.3.

Only one variable showed a significant relationship with retention. Participants in the behavioural intervention group were less likely to be retained (more likely to withdraw) than participants in the control group (odds ratio 0.40). There was no significant difference between the control and fluoride groups.

Table 7.3 – Sociodemographic and study related variables single predictor logistic regression results – withdrawn participants

							95% C.I. for OR	
	N	**df**	**B**	**Wald**	**P**	**OR**	**Lower**	**Upper**
IMD	403	1	-0.130	1.526	0.217	0.878	0.714	1.080
Group (Control)	408	2		7.493	0.024			
Group (Behavioural)		1	-0.917	7.271	0.007*	0.400	0.205	0.778
Group (Fluoride)		1	-0.460	1.636	0.201	0.632	0.312	1.277
Ethnic Group (non WB)	341	1	0.395	1.187	0.276	1.485	0.729	3.023
Marital Status (married)	344	1	0.168	0.326	0.568	1.183	0.664	2.106
Child gender (female)	399	1	0.267	0.952	0.329	1.306	0.764	2.231
Age at enrolment	408	1	0.028	0.493	0.482	1.028	0.952	1.110
No of children	345	1	0.009	0.003	0.955	1.009	0.735	1.385
Child order	341	1	-0.005	0.001	0.975	0.995	0.722	1.371
Parent age	347	1	-0.114	0.233	0.629	0.892	0.562	1.417
Parent employment (y)	338	1	0.060	0.033	0.856	1.062	0.553	2.042
Parent university educated (y)	345	1	0.007	0.001	0.981	1.007	0.563	1.800
Enrolled by postal consent (y)	408	1	0.163	0.316	0.574	1.177	0.667	2.076
Baseline Q're Complete (y)	408	1	0.391	1.276	0.259	1.479	0.750	2.915

*$p < 0.05$

Next, the oral health beliefs and behaviours of parents were tested for relationships between the retained and withdrawn participants using single predictor logistic regression (Table 7.4 below). Parents who brushed twice a day were more likely to be retained than parents who brushed less than twice a day (odds ratio 2.42). Parents who felt positive that their child's tooth decay was within their control were also more likely to be retained on the trial (odds ratio 1.55).

Table 7.4 – Oral health behaviours and beliefs – single predictor logistic regression results – retained and withdrawn participants

							95% C.I. for OR	
	N	df	B	Wald	P	OR	Lower	Upper
Parent brushes twice a day (y)	345	1	0.883	6.109	0.013*	2.419	1.201	4.874
Baby has visited dentist (y)	346	1	0.490	1.441	0.230	1.632	0.734	3.629
Tooth decay runs in families	343	1	0.038	0.071	0.790	1.039	0.785	1.374
People have naturally soft teeth	344	1	-0.072	0.226	0.635	0.930	0.690	1.254
Toothbrushing importance	346	1	0.359	2.171	0.141	1.432	0.888	2.308
Toothbrushing efficacy	347	1	0.038	0.025	0.873	1.039	0.652	1.653
Toothbrushing attitude	346	1	-0.040	0.025	0.874	0.96	0.591	1.564
Sugar Importance	347	1	-0.103	0.126	0.722	0.902	0.512	1.590
Sugar efficacy	347	1	0.077	0.128	0.720	1.080	0.709	1.644
Decay seriousness	345	1	-0.431	1.294	0.255	0.650	0.309	1.366
Decay chance control	344	1	0.205	0.873	0.350	1.227	0.799	1.886
Decay external control	344	1	0.439	3.924	0.048*	1.552	1.005	2.397
Reason for dentist (regular)	346	1	0.208	0.504	0.478	1.516	0.480	4.789

*p < 0.05

The four predictors with a p-value < 0.2 (group, parent brushing, toothbrushing importance and decay control) were included in a multiple logistic regression model (table 7.5.) The model included 339 participants. Three variables made a uniquely statistically significant contribution to the model when controlling for the other variables. The adjusted odds of withdrawal were 2.67 times higher in parents in the behavioural group than participants in the control group. Parents who brushed at least twice a day remained less likely to withdraw (adjusted odds ratio 2.78) and parents who saw their child's decay as within their control were also more likely to be retained (adjusted odds ratio 1.713).

Table 7.5 – Multiple logistic regression results – withdrawn participants

	df	B	Wald	P	OR	95% C.I. for OR Lower	Upper
Group (Control)	2		6.985	0.030*			
Group (Behavioural)	1	0.980	6.402	0.011*	2.665	1.247	5.644
Group (Fluoride)	1	0.339	0.699	0.403	1.404	0.634	3.109
Parent brushes twice a day (y)	1	-1.023	9.399	0.011*	0.359	0.163	0.794
Toothbrushing importance	1	-0.265	0.983	0.321	0.767	0.455	1.255
Decay external control	1	-0.538	5.271	0.028*	0.584	0.369	0.924

$X^2 = 18.937$, p = 0.002

*p< 0.05

7.6.2 Analysis of retained and withdrawn OR lost to follow up participants

Next, participants who did not attend the final endpoint dental examination (where final primary outcome data was collected) were combined with withdrawn participants to create a 'withdrawn OR lost to follow up' group. This group was compared to the group of participants that continued their involvement to the end. Single predictor logistic regression was conducted on the sociodemographic variables and is presented in table 7.6. Parents who were younger, non-married, unemployed and did not go to university were more likely to be unavailable for final outcome data collection (because they had withdrawn or were lost to follow up). Parents who described themselves as a group other than 'white British' were more likely to be retained on the trial than those who described themselves as 'white British'. Finally parents who returned their baseline OHBQ were significantly more likely to remain on the trial.

Table 7.6 – Sociodemographic and study design single predictor logistic regression results – retained and withdrawn OR lost to contact participants

							95% C.I. for OR	
	N	df	B	Wald	P	OR	Lower	Upper
IMD	403	1	0.171	3.727	0.054	1.186	0.997	1.410
Group (Control)	408	2		1.029	0.598			
Group (Behavioural)			0.229	0.843	0.359	0.795	0.448	1.297
Group (Fluoride)			0.253	0.008	0.927	0.977	0.596	1.603
Ethnic Group (non WB)	341	1	0.873	8.823	0.003*	2.395	1.346	4.262
Marital status (married)	344	1	0.746	10.143	0.001*	2.109	1.332	3.339
Child gender (female)	399	1	0.214	1.057	0.304	1.238	0.824	1.861
Age at enrolment	408	1	-0.050	2.719	0.099	1.052	0.991	1.116
No of children	345	1	0.003	0.001	0.979	0.997	0.779	1.275
Child order	341	1	0.139	1.236	0.266	0.871	0.682	1.112
Parent age	347	1	-0.561	8.558	0.003*	1.752	1.203	2.552
Parent employment (y)	338	1	-0.844	11.243	0.001*	2.325	1.420	3.807
Parent uni educated (y)	345	1	-0.897	14.281	<0.001*	2.452	1.540	3.904
Enrolled postal consent (y)	408	1	-0.346	2.391	0.122	1.414	0.912	2.192
Baseline Q're Complete (y)	408	1	-1.291	19.716	<0.001*	3.635	2.040	6.476

*p < 0.05

The oral health beliefs and behaviours of parents that withdrew or were lost to follow up were then compared to those who remained. Single predictor logistic regression results indicated that the odds of retention of parents who brushed at least twice a day were 2.13 higher than parents who brushed less than twice a day. Parents who saw decay as within their control were more likely to remain on the trial than parents who felt that decay was outside of their control (odds ratio 1.72) (Table 7.7).

Table 7.7 – Oral health behaviours and beliefs – single predictor logistic regression results – retained and withdrawn OR lost to contact participants

							95% C.I. for OR	
	N	Df	B	Wald	p	OR	Lower	Upper
Parent brushes x2 day (y)	345	1	0.756	5.858	0.016*	2.129	1.155	3.925
Baby has visited dentist (y)	346	1	0.203	0.489	0.485	1.225	0.694	2.162
Decay runs in families	343	1	-0.074	0.454	0.500	0.928	0.748	1.152
People have soft teeth	344	1	-0.038	0.105	0.746	0.962	0.764	1.213
Toothbrushing importance	346	1	-0.026	0.017	0.897	0.975	0.660	1.439
Toothbrushing efficacy	347	1	-0.096	0.265	0.607	0.909	0.631	1.309
Toothbrushing attitude	346	1	-0.163	0.706	0.401	0.850	0.581	1.243
Sugar importance	347	1	-0.173	0.594	0.441	0.841	0.542	1.306
Sugar efficacy	347	1	-0.053	0.096	0.757	0.949	0.680	1.323
Decay seriousness	345	1	-0.254	0.807	0.369	0.776	0.446	1.350
Decay chance control	344	1	0.183	1.112	0.292	1.201	0.855	1.687
Decay external control	344	1	0.541	9.471	0.002*	1.718	1.217	2.425
Reason dentist (regular)	345	1	0.260	0.272	0.602	1.296	0.489	3.437

p <0.05

The eight sociodemographic and two beliefs and behaviours variables with a p value < 0.2 in single predictor logistic regression were entered into a multiple logistic regression model (see Table 7.8 below). The model contained 320 participants. 'Baseline questionnaire returned' was excluded from the model as all the other variables in the model originate from the questionnaire so are missing in all cases where the questionnaire is missing. Five variables made a uniquely significant contribution to the final model when controlling for the other variables. Parents who were non 'white British' (categorised as 'other') were significantly more likely to be retained than white British parents (adjusted odds ratio 2.80). The adjusted odds of remaining were 2.49 times in employed parents than parents out of employment. Being educated to University level was also significantly linked to being retained on the trial (adjusted odds ratio 1.87). The adjusted odds of retention were 3.32 higher in parents who brushed at least twice a day compared to parents who brushed less than twice a day. Finally parents who saw decay within their own control were significantly more likely to be retained than parents who felt that their child's decay was outside of their control (adjusted odds ratio 1.72). The results are presented in table 7.8.

Table 7.8 – Multiple logistic regression results – retained and withdrawn OR lost to follow up

	df	B	Wald	P	OR	95% C.I. for OR Lower	Upper
IMD	1	0.083	0.536	0.464	1.086	0.870	1.356
Ethnic Group (non WB)	1	1.029	7.372	0.007*	2.798	1.331	5.881
Marital Status (married)	1	0.088	0.090	0.765	1.092	0.615	1.939
Parent Age	1	-0.001	0.001	0.981	0.099	0.914	1.092
Parent Employment (y)	1	0.904	8.636	0.003*	2.469	1.351	4.512
Parent University Educated (y)	1	0.624	4.891	0.027*	1.866	1.074	3.243
Postal consent (y)	1	0.113	0.118	0.732	1.120	0.586	2.142
Parent brushes twice a day (y)	1	1.172	10.996	0.001*	3.229	1.613	6.462
Decay external control	1	0.678	10.762	0.001*	1.971	1.314	2.936

$X^2 = 53.698$, $p = <0.001$

*$p<0.05$

7.7 Discussion

This study aimed to explore the relationships between sociodemographic and oral health beliefs and behaviours of participants that remained on or withdrew from the Salford Bright Smiles Baby Study. The qualitative findings of study three indicated that 'minority' parents were less likely to remain on the trial for fear of being judged. The focus groups and interviews also indicated that the parents' understanding of risk of poor oral health and their oral health beliefs and self-efficacy may also be linked to their decision to continue. This study allowed analysis of the full dataset for participants on the Salford Bright Smiles Baby Study to validate and expand on the findings of study three.

This study provides a unique contribution to the literature as it explores parental self-efficacy in relation to oral health behaviours as predictors of retention. It is also among a relatively small number of oral health and dentistry studies that analyse characteristics of dropouts and completers. A review of the current literature and examination of the 209 studies included in study 2 identified that very few oral health focussed studies compare characteristics of drop outs and completers, and those that do are most likely to compare levels of decay at baseline and are predominantly motivated by investigations of the external validity of findings due to sampling bias (Splieth et al., 2005, Davies et al., 2007). Very few studies have look at the parental beliefs and behaviours.

Parents who brushed their teeth in line with NHS recommendations (at least twice a day) (Department of Health, 2009) were less likely to withdraw or be lost to follow up than parents who brushed less than twice a day. Ramos-Gomez et al. (2008) also found that parents who brushed less than twice a day were less likely to enrol onto their trial; however this variable was not associated with retention in their study.

Analysis of the OHBQ indicated that parents who felt that their child's chances of getting tooth decay being within their control (and not controlled by external factors such as the dentist) were more likely to remain on the trial and attend the endpoint data collection appointment. This finding indicates that parents who had a better understanding of factors affecting their child's chances of getting tooth decay were more likely to remain on the trial to the end. These findings appear to correspond with the results of study 3. The interviews and focus groups indicated that parents who perceived their child to be at risk of poor oral health (by understanding the factors contributing to decay), were more likely to remain on the trial than parents who had less experience and knowledge of the causes of poor oral health. Understanding that decay does not occur by chance, and is within the parents control gives parents the understanding that their child is at risk of poor oral health if preventive action is not taken. Conversely, parents who feel that tooth decay is due to chance, or is not within their control are less likely to perceive their child as at risk of poor oral health, or see this as something that they could not prevent. Parents with less knowledge of the benefits of preventive action (such as the intervention offered on the Salford Bright Smiles Baby Study) were less likely to remain on the trial, as they were less likely to see the benefit of the preventive interventions.

Similar findings are evident in previous studies. Bryant et al. (2016) found that parents with a low external locus of control (i.e. parents did not see it as the responsibility of the dentist to prevent decay) were harder to retain on their community based oral health intervention in the Navajo Nation, USA. Two studies found that parents with less knowledge about dental decay were less likely to enrol than parents who had more dental knowledge (Ramos-Gomez et al., 2008, Vermaire et al., 2011). The findings also link to the suggestions of Splieth et al. (2005), who hypothesised that the children who required the intervention the most (i.e. those more at risk of poor oral health because of lack of knowledge by the parent) were those least likely to receive it. Previous studies have also suggested that parents who are

more aware of their 'power to prevent' will act differently to parents who see decay as inevitable, hereditary or out of their control (Vermaire et al., 2011). Previous studies in health inequalities have also linked locus of control and health beliefs to SES, with findings suggesting that low SES groups believe their health is determined more by chance (Wardle et al., 2010) and are more likely to engage in negative health behaviours (Pill et al., 1995).

Contrary to the findings of study 3, this study found no evidence to suggest that parental efficacy in relation to toothbrushing or sugar snacking predicted retention of participants. Overall, mean efficacy was high in all parents in relation to both toothbrushing and sugar snacking indicating that parents that enrolled on the trial had high self-efficacy in relation to oral health behaviours. It is possible that parents with lower self-efficacy scores did not enrol onto the trial. A comparison of eligible versus enrolled parents in respect of self-efficacy would be worthwhile, but data on participants who chose not to enrol was unfortunately not available on this trial. Furthermore, whilst a generic measure of parenting efficacy was not available for this study it would be worth investigating in future studies.

Several sociodemographic variables were identified to have a significant relationship with retention of participants. The analysis of ethnicity indicated that parents in ethnic minority groups were more likely to remain on the trial than parents who classified themselves as white British. This finding corresponds with the findings of study 1 of this thesis, in which two trials found that ethnic minorities were more likely to remain (Ramos-Gomez et al., 2008, Winslow et al., 2009). However, the findings around ethnicity in this current study should be analysed with caution as ethnicity was categorised into 'white-British' and 'other'. A more detailed analysis of ethnicity would therefore be warranted but outside of the scope of this study.

Other sociodemographic predictors corresponded with the findings of study 1. Namely, parents who were younger, un-married, unemployed and did not attend university were more likely to withdraw or be lost to follow up than parents who were older, married, employed and had been to University.

Study related factors also appeared to impact retention of participants on the trial. Firstly, logistic regression identified that participants randomised to the behavioural arm of the trial were more likely to formally withdraw than participants in the control arm of the trial.

Previous literature has indicated that group allocation can influence a participants' decision to remain or withdraw from a trial (Treweek et al., 2013a, Gross et al., 2001, Cui et al., 2015). However, in this study a likely explanation is that parents in the behavioural group received the most intensive contact from the research team compared to the other two groups. This increased amount of contact gave parents in the behavioural group more opportunity to express their wish to withdraw than parents in the other two groups. This idea is further confirmed by the lack of significance of the variable 'group' when the withdrawn parents were combined with those that were lost to follow up.

Parents who failed to return their baseline questionnaire were less likely to remain on the trial and provide primary outcome data at the end, correlating with the findings of Splieth et al. (2005) who identified that those who did not return their questionnaire were less likely to take part in their school based ECC trial. These results indicate that early compliance with the trial could be a predictor of later commitment to the study. Identification of participants who are non-compliant in the early stages could allow effective targeting of retention strategies to improve retention later in the trial.

7.8 Limitations

The Salford Bright Smiles Baby Study was not designed to empirically investigate retention of participants. It is therefore possible that different retention strategies were used on different groups or individuals that have not been accounted for. For example, the research team adopted a greater number of retention strategies as the trial progressed over time, when it became apparent that different strategies were required. Therefore participants who were younger when they enrolled onto the trial (and were therefore on the trial longer) may have been exposed to a greater number of retention strategies than participants who were older (and therefore on the study for a shorter period of time).

Participants who were 'lost to follow up' were grouped with participants who formally withdrew from the trial for the analysis. It is possible that parents did not intend to withdraw, but were simply unavailable for the endpoint examinations. However, in the context of the Salford Bright Smiles Baby Study it is reasonable to assume that 'lost to contact' indicated withdrawal, as parents were offered appointments in the home or at the

child's nursery and multiple attempts at contact were made to maximise attendance at the endpoint data collection exam.

Finally the measure used to analyse parents' brushing was obtained through self-report and is therefore at risk of bias. A clinical examination of the parents would allow a more reliable measure of brushing behaviour but was outside of the scope of this trial. Similarly, data for dental attendance would be more reliable if taken from dental practice attendance records. This is a drawback of secondary data analysis. Future studies that intend to analyse data for prediction of retention could collect a more comprehensive data set of oral health behaviours.

7.9 Conclusions

This study indicates that parents with a better understanding of their ability to control their own child's oral health are more likely to remain on a trial once enrolled. Parents who maintain optimal oral toothbrushing routines for themselves were also less likely to withdraw from the trial or be unavailable for follow up.

Sociodemographic factors also predicted retention with older, married, employed, university educated parents more likely to remain on the trial with their child to the end. Contrary to the findings of study 1, parents from ethnic minorities were more likely to remain on the trial than parents who described themselves as 'white British'.

Finally, early indicators of compliance could be used as predictors for retention as parents who did not return their baseline questionnaire at the start of the trial were more likely to withdraw from the trial.

Whilst there was no evidence to suggest that retention was related to parental self-efficacy in relation to oral health behaviours, the efficacy of parents that took part in the trial was high, and this would warrant further investigation in future recruitment and retention studies.

The results of this study can be used to effectively target retention interventions with parents most at risk of dropping out from a trial. An intervention to increase parents' knowledge on factors causing tooth decay and their influence over their child's oral health could be developed to increase the retention of participants in future oral health research.

Chapter 8
Discussion and Conclusions

8.1 Overview

RCTs are considered to be the gold standard in evaluating health care interventions (Treweek et al., 2013a). Despite the number of trials in children increasing over recent decades, a global need for paediatric trials still remains to ensure that recommendations for children are not extrapolated from the results of trials with adults (Caldwell et al., 2004). Recruitment and retention of participants is critical to the success of RCTs. The possibility of encountering a type II error (incorrectly concluding that there was no difference between two groups) is greater if the desired sample size is not achieved due to insufficient recruitment or retention of participants (Adamson et al., 2015). Being able to identify which children and families are most at risk of poor recruitment or retention could allow targeted use of strategies. Furthermore, research with these families could enable better understanding of how to improve research involvement and consequently wider health inequalities, particularly amongst vulnerable populations. Research to achieve this is therefore warranted.

Oral health trials, particularly with children, have the possibility of being far reaching due to the global burden of poor oral health (Gul and Ali, 2010). Research in this area could also address wider public health inequalities due to the global inequalities of oral health (Petersen et al., 2005). Despite this very little research has been conducted into recruitment and retention in this field. This thesis used mixed methods to investigate predictors and explore the barriers and facilitators to recruitment and retention of children and families to oral health trials. To achieve this aim a number of objectives were set out across four individual studies:

Study	Objective
1	1. What factors have been identified as significant participant predictors of recruitment and retention to RCTs involving children? 2. Are there any differences in predicting factors between community based and non-community based RCTs? 3. Are there any differences in predicting factors between 'healthy' and 'patient' (non-healthy) populations? 4. How do studies define participant drop-out?
2	1. Are study-level variables associated with recruitment and retention of children and families to oral health trials? 2. Do oral health trials involving children utilise the CONSORT guidelines for reporting of participant flow?
3	1. What motivated parents to enrol onto the Salford Bright Smiles Baby study? 2. What factors made it easier for the enrolled participants to continue on the trial to the end? 3. What factors made it difficult for the enrolled participants to continue on the trial to the end? 4. What do interviewed parents perceive to be barriers to recruitment for families that chose not to enrol on the trial?
4	1. Did sociodemographic variables predict which participants were more likely to be retained on the SBS? 2. Did oral health beliefs and behaviours predict which participants were more likely to be retained on the SBS?

8.2 Summary of main findings from this thesis

The first study of this thesis was a systematic review of RCTs that had examined participant predictors of recruitment or retention. The review was non-specific in its health focus and included trials with children aged 0-13 years. The findings of this study appeared to be synonymous with similar adult studies, in that minority, low SES, lesser educated younger parents were less likely to enrol and be retained on trials involving children. However, the evidence was often inconsistent as most variables that were found to be significant predictors were not significant in other studies.

Whist an original objective of the study was to investigate differences between health-based and community-based trials and 'healthy' and 'patient' participants it was not possible to conduct subgroup analyses due to the relatively small number of studies and heterogeneity in predictors between the included studies.

Heterogeneity, due to the wide range of studies involved, also made it difficult to draw conclusions that could be applied to specific fields of health or age groups. These limitations informed the design of study two, which took an oral health focus. Study two investigated study design predictors of recruitment and retention, through an analysis of oral health and dentistry trials identified from the Cochrane database. This allowed access to a large dataset of trials in various locations, with differing severities of illness and age ranges. To be as inclusive as possible the age range was increased to 0-16 years, including children in secondary education. The large number of included studies allowed analysis by setting (categorised into 'community' or 'healthcare' settings) and participant type (categorised into 'patients' and 'healthy' participants), whilst the two variables were confounding this was accounted for in the analysis. This study found that community based trials, over a year in length, with 'healthy' participants of pre-school age were most likely to be 'unsuccessful' in recruitment and retention of participants.

Whilst quantitative analysis of datasets such as studies one and two in this thesis are useful to identify groups and designs most at risk of poor recruitment and retention, they provide little understanding of the reasons for these difficulties. Furthermore, the variables identified as predictors are often immutable to change, so, whilst longitudinal studies with low SES groups are the most at risk of difficulties with recruitment and retention it is not feasible to remove the risk by decreasing the length of the study or working with different groups. Qualitative research involves in-depth exploration with participants, allowing exploration of the barriers and facilitators to recruitment and retention with hard to reach groups.

Study three gathered empirical evidence with a group of parents identified as 'at risk' based on the predictors identified in studies 1 and 2. The Salford Bright Smiles Baby Study was a community-based, early childhood caries trial with pre-school children. The setting of the study was deprived areas of Greater Manchester and it therefore targeted low SES parents and their children. Study three aimed to investigate the barriers and facilitators to participation on the trial over the two year period that families were involved. Both continuing and withdrawn parents were interviewed in 1:1 interviews or focus groups. This study provided unique insight into the factors affecting parents' decision to continue participation or withdraw from the trial. Emergent themes indicated that parents enrolled

on the trial because they perceived their child to be at risk of poor oral health and understood that they were able to do something to prevent this. Taking part in the trial made them feel like a better parent than those who withdrew or chose not to take part, particularly on the behavioural intervention arm of the trial. Parents appreciated the flexible approach to attending appointments, including home and nursery visits, multiple forms of contact and the friendly nature of the staff. Parents felt a commitment to the trial and this facilitated their decision to continue. Nevertheless, parents agreed that when the burden of taking part in the trial outweighed the benefit they chose to drop out. An interesting finding of this study was that parents clearly avoid situations in which they feel judged or like they don't fit in with the social norms. It also appeared that parental self-efficacy was higher in those that chose to continue than those that withdrew. Due to the relatively small numbers of parents interviewed, particularly in the withdrawn group it was not possible to draw firm conclusions.

Further analysis of the participants on the Bright Smiles trial was the focus of the fourth study which compared the sociodemographic variables, oral health beliefs and behaviours of the parents that continued or withdrew. This allowed exploration of some of the themes that emerged from study three and confirmed that parents who reported a greater understanding of optimum oral health routines (brushing twice a day and understanding that their child's oral health was within their control) were more likely to remain on the trial. Analysis of the sociodemographic variables also corroborated the results of study 1 as university educated, married, employed, older parents were more likely to remain on the trial to the end. Minority ethnic groups were more likely to retained than those reported to be 'white British'. Families on the behavioural arm of the trial were also less likely to attend the final data collection appointment than the control arm of the trial. Parental self-efficacy did not predict retention as hypothesised.

8.3 Summary of findings and the implications for oral health RCTs with children and families

The mixed methods analysis of participants on the Salford Bright Smiles Baby Study trial provided a unique opportunity to investigate a group of participants and a trial design that had been identified as potentially 'at risk' of poor recruitment and retention in the first two studies. These studies provided insight into why longitudinal, community based trials, with

'healthy', pre-school participants face recruitment and retention challenges. In addition, the studies also allowed exploration of motivations for participation.

Firstly, the focus group and interview study uncovered that parents' decision to take part in the trial was based on their perception of risk of their child having oral health problems. This was reinforced by the findings of the fourth study which confirmed that parents who felt that their child's chances of getting tooth decay was within their control (and was not controlled by external factors such as the dentist) were more likely to remain on the trial and attend the endpoint data collection appointment. These findings indicate that parents who chose to take part and remain on the trial had a better understanding of their influence over their child's oral health than parents who did not participate, or dropped out of the trial. Also related to this, study four confirmed that parents educated to university level were more likely to remain on the trial, than parents who completed their education earlier. The focus groups and interviews indicated that parents with higher education were more understanding of the difficulties of recruitment and retention and felt a greater commitment to the trial.

Secondly, the parents that remained on the trial and took part in the focus groups study put a high value on their child's oral health. The quantitative analysis also uncovered that parents who brushed twice a day (an indicator of the value that they placed on their own oral health) and felt that their child's oral health was within their control were more likely to remain on the trial than parents who brushed less than twice a day and saw oral health as beyond their control.

Understanding motivations for participation on the Salford Bright Smiles Baby Study trial can provide recommendations for recruitment and retention strategies for future community based oral health trials. If increased knowledge and understanding about oral health and the parents' ability to influence their own child's oral health, as well as the value of research in general, could increase recruitment and retention of participants it is feasible to consider interventions to increase understanding as part of the recruitment and retention process. Relatively few studies have used information giving about the condition as a strategy. Caldwell et al. (2010) identified three studies that gave information about the condition as part of the recruitment process in their systematic review of recruitment

strategies. They reported limited success. The first study was with pregnant mothers who were provided with a video to aid decision making (Weston et al., 1997). Women who watched the video containing information about the condition being studied and the information about the trial showed significantly more interest in taking part in the trial than women who did not receive the information video (Weston et al., 1997). However, as the women did not have the condition, the discussion and decision to take part was hypothetical and it was not possible to separate the impact of the information on the condition from information on the trial. Similarly Llewellyn-Thomas et al. (1995) used two approaches (video or audio tape) to present information about a hypothetical trial. Whilst patients showed more willingness to take part after watching the video presentation, it is not possible to conclude from their analysis whether receiving information about the condition was the reason for this. A third trial showed no increase in knowledge or willingness to participate in cancer trials following enhanced information (Berner et al., 1997).

Due to the limited evidence, further research into the impact of increasing knowledge is required. The value of increased knowledge in preventive trials (with healthy participants) appears to be unknown as research has focussed on particular conditions or with people at risk of a condition. Such strategies would benefit from testing in empirical studies to determine the effectiveness. This could be approached by nesting a trial of the recruitment and retention strategies within an ongoing oral health trial, as advised by Bower et al. (2014).

A major theme to emerge from the qualitative research in this thesis was that parents avoid situations in which they feel judged or marginalised. One parent withdrew from the trial because she felt that the trial dentist was judging her. Other parents admitted that they would generally avoid group sessions for fear of their child 'playing up', whilst another mum recalled how she felt marginalised around other mums in the area because of her oral health beliefs and behaviours. Very little research appears to have identified fear of judgement as a barrier to clinical trial participation, although previous studies have identified that minority ethnic groups avoid research for fear of being marginalised (Hussain-Gambles et al., 2004). Study four identified that parents in the behavioural intervention arm of the trial were more likely to drop out that parents in the control arm. It

is possible that the behavioural intervention sessions, which were held in group format and designed to deliver evidence on best practice techniques for caring for children' oral health, were off-putting for parents who were finding it difficult to conform to the best practice. Whereas those that were achieving the behaviours may have remained on the trial and felt like a better parent as a consequence. There was evidence of feelings of superiority and 'being a better parent' by those who remained on the trial.

Understanding fear of judgement as a barrier to recruitment and retention could allow targeted use of strategies. Health disparities research with ethnic minority groups has reported successful implementation of culturally sensitive recruitment and retention techniques including culturally sensitive staff, venues and materials (Garcia et al., 2016, Tiwari, 2014, Gibbs et al., 2015). Parents on the Salford Bright Smiles Baby Study also accredited friendly staff, child friendly appointments and home visits as reasons for staying on the trial. Therefore, ensuring that staff, settings and intervention content are as free from judgement as possible may be an effective strategy for involving minority groups.

Finally, this thesis provides some previously unidentified clarification on why longitudinal, community based oral health studies are less successful at recruitment and retention. Parents on the Bright Smiles Baby Study indicated that as the burden of taking part outweighed their perceived benefit, they chose to discontinue their involvement. Strategies to reduce the burden of taking part are therefore important for successful retention in longitudinal community based studies with parents. Furthermore, it is possible that trials involving 'healthy' participants, rather than 'patients' are more at risk, due to the perceived benefits of participation being less than those with sick children, or children requiring treatment. In these trials it is of great importance to reduce the burden of participation for parents and children.

On the Salford Bright Smiles Baby Study parents were grateful for home visits, appointments in nursery, reminders about questionnaires and appointments, multiple forms of contact and flexibility of staff when making appointments. Similar strategies have been reported as a success in previous, comparable trials (Chadwick and Treasure, 2005, Davies et al., 2007, Harrison et al., 2010, Marshman et al., 2012). Whilst expensive and resource intensive, such recruitment and retention techniques appear critical to the success of community based

oral health trials, particularly with 'healthy' participants. Offering these flexible approaches may be of particular benefit to parents at times of change (e.g. the birth of a second child or returning to work after maternity leave), to reduce the burden of participation.

In recommending intensive contact for participants on a research study it is important to recognise that enhanced contact could increase the risk of the 'Hawthorne Effect', i.e. a participants behaviour being changed due to the effect of being 'studied' (McCambridge et al., 2014). Huntington et al. (2017) also recognised the conflict between the importance of developing a good relationship with trial participants and the risk of the Hawthorne effect in parents recruited to their paediatric dental trial with children aged 5-7 years.

8.4 Quality of reporting

This thesis allowed rare exploration into the impact of the quality of reporting in oral health trials on recruitment and retention research. Study one investigated definitions of attrition. Of the 28 included papers, 17 included definitions with large variation (appendix 4). The findings of this thesis support the work of previous authors who suggest that standardised definitions of attrition be implemented in reporting (Marcellus, 2004, Zebracki et al., 2003, Yancey et al., 2006).

An effective platform for implementation of standardised definitions could be the CONSORT guidelines for reporting. However, the current guidelines appear to be misleading in their definitions and guidance on how to report attrition; this inexactness could contribute to the poor quality of reporting of recruitment and retention in RCTs. The current CONSORT flow diagram (Schulz et al., 2010) specifies 'lost to follow up' and 'discontinued intervention' as the two categories under which participants who are not followed up to the end should be reported. Whereas, under item 13b, the CONSORT checklist (Schulz et al., 2010) indicates that users should specify:

"For each group, losses and exclusions after randomisation, together with reasons".

Further guidance can be sought from the explanation/ elaboration document (Moher et al., 2012) which suggests that authors should distinguish between 'lost to follow up' and 'investigator determined exclusions', going on to list examples such as ineligibility, withdrawal from treatment and poor adherence to the trial protocol.

To be fully understood, it appears that researchers seeking guidance on how best to report participant flow need to read all three documents (the CONSORT diagram, CONSORT checklist and the explanation document). But even then, it could be argued that the three documents provide little clarification on what 'lost to follow' up actually means, and what categories of people who did not complete should be recorded where. None of the guidance documents refer to participants who chose to withdraw from the study. Previous authors have also highlighted the shortcoming of the CONSORT guidance in reporting of attrition. Toerien et al. (2009) suggested amendments to the CONSORT flow diagram in their review of reporting of recruitment and retention, where, similar to the findings of study one of this thesis, reporting and definitions of lost to follow up were inconsistent across the 133 included studies. They suggested greater clarity in relation to lost to follow up and the addition of a separate box to the flow diagram labelled 'discontinued intervention' to provide increased transparency (Toerien et al., 2009).

The quality of reporting has been the focus of several studies, including a study investigating cluster trials in oral health. Froud et al. (2012) assessed the quality of trials published between 2005 and 2009. In their review of 23 studies 65% reported a sample size calculation and 85% described lost to follow up. In study 2 of this thesis only 27.4% of included articles included a sample size calculation, however 94% included information about the number of retained participants. Evidence presented by Sjögren and Halling (2002) suggested that the quality of reporting in dentistry was less than medical trials, with 44% reporting withdrawals and dropouts in medicine compared to 35% of dental RCTs.

Study 2 of this thesis investigated use of the CONSORT flow diagram in the 201 included studies. Only 25% of the published studies included a CONSORT diagram. Studies in other fields have reported higher use of the recommended reporting tool. A study completed in 1998 (two years after the guidelines were published) reviewing CONSORT use in major medical journals reported a 51% uptake (Egger et al., 2001). Likewise, Toerien et al. (2009) reported that 79% of studies in their review included a CONSORT diagram. A more recent review reported 63% compliance with the CONSORT guidelines (Walters et al., 2017) (though they did not report on use of the diagram). This thesis therefore corroborates with studies that have suggested that the standard of reporting in the field of oral health of a lesser quality than other medical fields (Sjögren and Halling, 2002, Cioffi and Farella, 2011).

It is well recognised that the standards of reporting in journals that support the use of CONSORT is higher (Needleman et al., 2008, Egger et al., 2001), yet despite this a recent study with editors of dental journals and information collected from websites indicated that only 52% of journals mentioned use of CONSORT on their website and only 28% advise the use of the CONSORT flow diagram (Sarkis-Onofre et al., 2016). The findings of this thesis support the wider active implementation of reporting guidelines by dental journals (Sarkis-Onofre et al., 2016).

8.5 Limitations

The limitations of each individual study of this thesis have been discussed in corresponding chapters (4-7), the overall limitations of this thesis will be discussed hereon.

The conclusions and recommendations to come out of this thesis are based on a relatively limited sample size. Whilst studies one and two were systematic and quite considerable in size, studies three and four were based on a single trial with specific recruitment and retention difficulties. Whilst the recommendations are based on the findings of these studies they have been compared and critiqued alongside existing literature.

There are many other areas of recruitment and retention research that have not been within the scope of this thesis. For example, the opinion and actions of clinicians and study staff have a large impact on recruitment and retention of participants (Sullivan, 2004). Similarly, the conditions under which recruitment and informed consent are conducted have been shown to have a significant influence (Cartwright et al., 2011), as have incentives (Yancey et al., 2006). The opinions and understanding of the children who are the participants (when old enough to provide assent) is also an area impacting recruitment and retention that has been studied by authors in the field (Madden et al., 2016).

One study identified three areas that future research should focus upon for recruitment in primary care. These were developing a repository of effective recruitment techniques, developing infrastructure to support recruitment and improving public engagement with research (Bower et al., 2009). However, the literature reviews conducted as part of this thesis indicate that research in oral health trials with children is so limited that the field requires further evidence before arriving at this advanced stage.

The recommendations presented in this chapter are largely focussed on community based, oral health trials with 'healthy' pre-school children and their families. The generalisability of these recommendations to other areas of health is questionable. Furthermore, the specific age range (1-3 years) these recommendations were based on mean they may not be applicable to older age ranges where community based trials are often held in Schools (where other factors such as teacher involvement may be of more importance).

8.6 Conclusions

This thesis provides a unique contribution to the literature. There has not previously been a systematic review conducted on predictors of recruitment and retention to RCTs specifically with children and parents. Secondly, there have been very few studies investigating the impact of study design on recruitment and retention of children and families to oral health RCTs. Thirdly, the Salford Bright Smiles Baby Study provided a unique case study for qualitative and quantitative investigations of reasons for continuation and drop-out on a community based, pre-school oral health trial.

The work conducted in this thesis has identified several sociodemographic predictors of recruitment and retention to trials with children and families. Namely low SES, ethnic minority, lesser educated parents are less likely to take part in trials with their children. In addition, an analysis of oral health trials identified that studies over a year in length, based in the community with pre-school, 'healthy' participants are most likely to experience difficulties with recruitment and retention.

A detailed exploration of one such trial indicated that parents are motivated to take part in trials by a perception that their child is at risk of poor oral health and a belief that they are able to influence this. University educated parents who brush twice a day were more likely to be retained on a trial. Parents are put off by feeling judged and burdensome designs.

Recommendations for future community based, longitudinal oral health trials with pre-schoolers include flexible timing and location of appointments, including home visits, nursery visits, reminders about forthcoming appointments and multiple forms of contact. In addition friendly, culturally sensitive staff and child friendly environments could help to reduce the feeling of stigma for parents who often fear being judged. Interventions to

increase parents' knowledge of oral health and their ability to influence their childs' health could improve recruitment and retention in future trials but further evidence is required.

The quality of reporting of recruitment and retention in oral health trials is low. Only 25% of trials included in study three of this thesis included a CONSORT flow diagram. Amendments to the CONSORT guidelines could improve the reporting of recruitment and retention in trials involving children and families, as could a standardised definition of attrition.

8.7 Recommendations for practice

- Consideration should be made to allow for culturally sensitive recruitment and retention techniques for 'minority' communities (including ethnic minority and low SES groups) as they are more at risk from non-participation in RCTs with children and families.
- When conducting longitudinal, community based oral health trials (particularly with pre-schoolchildren), recruitment and retention techniques should be considered and incorporated at the design stage.
- Specific retention techniques for community based pre-school oral health trials:
    - Flexible timings and locations of appointments
    - Multiple forms of contact with participants and reminders about forthcoming appointments
    - Friendly staff and 'child-friendly' appointment locations
    - Culturally sensitive staff
- Trials should be designed to avoid situations in which parents will feel marginalised or judged.
- Trial reports should follow the CONSORT guidelines for reporting and include a CONSORT diagram.
- Reports should include a clear definition of participants who dropped out or were lost to follow up.

8.8 Recommendations for future research

- Further research into recruitment and retention strategies for infant ethnic minority populations is required, as this is not currently available. A randomised controlled

trial of different strategies within ethnic minority populations and SES categories would identify the most effective methods to overcome the obvious barriers.

- Study 1 identified that further investigation of the importance of clinical variables in predicting recruitment and retention to RCTs would be of value.
- As highlighted in the limitations of study 3, the design could have benefitted from interviewing participants who chose not to enrol on the trial at the time of refusal. Further qualitative investigation with parents who refuse to take part in oral health trials would therefore be warranted.
- Further research into the importance of fear of judgement, perception of risk of illness and also benefit of trial participation, in the decision making of parents of healthy children was identified as an area for further research in study 3.

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Appendices

Appendix 1 - Study 1 - Initial inclusion/ exclusion screening tool

Author:

Title:

Date of Screening:

Inclusion criteria	**YES**	**NO**	**UNCLEAR**
Study analyses participant data to predict participation recruitment/ retention			
Study based on measurements within real settings (not hypothetical)			
Study tests factors for significance of prediction ability of recruitment and/ or retention to clinical trials.			
Study based on data derived from RCTs			
Study investigates children aged 0-12 (or study finishes before child's 13th birthday).			
Study focused on health and wellbeing.			

INCLUDE / EXCLUDE

Further discussion required YES / NO

If yes – details for discussion

Appendix 2 - Study 1 - Data extraction form

Author:

Title:

General Study Details:		**Page No**
Study Year		
Study Length e.g. one off enrolment/ longitudinal		
Study design	☐ RCT individual ☐ RCT cluster ☐ RCT crossover	
What was the key aim and objective?		
Other aims and objectives?		
Predicting:	☐ recruitment/ enrolment ☐ retention ☐ other measure e.g. part completion	
Country of Principal Investigator/ where trial conducted		
Sample Size		
Setting		
Target Population		
Disease type		
Intensity of contact		
Predictors assessed for significance		
Data collection method		
Definition of recruit/ drop out		

Analysis conducted		
Significant predictors		
Insignificant predictors		
Recommendations		
Number of participants at start and end		
Other notes		

Date of Screening:

Further discussion required? YES / NO

Points for discussion:

Contact Authors for Information? YES / NO

Information required:

Appendix 3 - Study 1 - Quality assessment tool

		Score 0 inadequate description 1 fair description 2 adequate description
1	Does the paper explain the scientific background and rationale for the investigation being reported?	
2	Are specific objectives stated, including any pre-specified hypotheses?	
3	Are key elements of study design and original trial explained in enough detail?	
4	Are setting, locations, and the study sample described clearly in terms of sample size and characteristics?	
5	Are lengths of exposure/ intervention provided for applicable groups i.e. control and intervention or just intervention if only measuring this group?	
6	Is the study size large enough to test the hypotheses?	
7	If a longitudinal retention study are details given of the efforts to maintain the sample? i.e. payments, contacts made etc?	
8	Are the findings presented clearly, objectively and in sufficient detail to enable the reader to judge the results for himself/ herself?	
9	Are the findings internally consistent, i.e. do the numbers add up properly, can the different tables be reconciled etc?	
10	Were appropriate variables or factors controlled for or blocked during the analysis?	
11	Do the investigators present sufficient data in tables and in the text to adequately evaluate the results?	
12	Are limitations of the study discussed, taking into account sources of potential bias or imprecision?	
13	Do the authors discuss the generalisability (external validity) of the study results?	
14	Are recommendations for future research made?	

Total Score ____

Appendix 4 - Study 1 - Definitions of dropout

Author and year	Definition of drop out
Aylward, G.P., Hatcher, R.P., Stripp, B., Gustafson, N.F. and Leavitt, L., A. (1985)	*Withdrew from follow up.* (pg. 4)
Boggs, S.R., Eyberg, S.M., Edwards, D.L., Rayfield, A., Jacobs, J., Bagner, D. and Hood, K.K. (2004)	*Families who dropped out of the study before completing treatment. (*pg. 2)
Constantine, W.L., Haynes, C.W., Spiker, D., Kendall-Tackett, K. and Constantine, N.A. (1993)	*A subject for whom the 36-month data used in the major outcome article were missing. (*pg. 4)
Cunningham, C. E., Bremner, R. and Boyle, M. (1995)	*Failed to complete the 6 month follow up. (*pg. 1148)
Daniels, L, A; Wilson, J, L; Mallan, K, M; Mihrshahi, S; Perry, R; Nicholson, J, M; Magarey, A	*Could not be contacted and/ or did not provide any data at time 3. (*pg. 5)
Fernandez, M.A. and Eyberg, S.M. (2009)	(not) *participating in the 2 year final assessment. (*pg. 433)
Firestone, P. and Witt, J. E. (1982)	*Families that agreed to participate but terminated prior to the last session.* (pg. 212)
Gross, D., Julion, W. and Fogg, L. (2001)	*if they had completed baseline measures and enrolled in the parent training groups but were either unavailable for the immediate post intervention assessment or attended one or none of the parent group sessions. (*pg. 248)
Katz, K.S., El-Mohandes, P.A., Johnson, D.M., Jarrett, P.M., Rose, A. and Cober, M. (2001)	*mothers who could not be found despite multiple contact sources… the infant was placed with another caregiver either voluntarily by the mother or by foster care agencies for reasons of child protection or mother's incarceration… Repeatedly missing data collection visits and refusal of services.* (pg. 211)

Miller, G. E. and Prinz, R. J. (2003)	*Premature termination of dropout (excluded initial terminators i.e. dropping out before participating in treatment from analysis) operationalized as the parent specifically informing a staff member before completion that the family is stopping treatment, also in a small number of instances (less than 10%) some families repeatedly missed appointments without the parents articulating a desire to terminate. In these cases, therapists made repeated attempts to contact and schedule the next treatment session, if the family missed 3 consecutive appointments without extenuating circumstances therapists asked the parent permission to stop rescheduling.* (pg. 521)
Moser, D.K., Dracup, K. and Doering, J.V. (2000)	*Those who dropped out from trial from those who remained in the study until its completion. (*pg. 109)
Ramos-Gomez, F; Chung, LH; Beristain, RG; Santo, W; Jue, B; Weintraub, J; Gansky, S (2008)	*Retention was defined as the percentage of women who remained active participants in the study from enrolment (baseline) to randomization (4-month postpartum visit) or beyond; the complement of retention is attrition.* (pg. 340)
Roggman, L.A., Cook, G. A., Peterson, C. A. and Raikes, H.H. (2008)	*Dropped out before their child was 30 months old or before they had been enrolled for 18 months* (pg. 583)
Wagner, M. ; Spiker, D., Inman Linn, M. and Hernandez, F. (2003)	*the families who left the program prior to the child's first birthday.* (pg. 178)
Werba, B.E., Eyberg, S.M., Boggs, S.R. and Algina, J. (2006)	*Study dropouts included all families who dropped out of the study after signing, at their first assessment visit, the informed consent to participate in the study. The study dropouts included families who attended at least one assessment session, but dropped out before treatment actually started. (*pg. 624)
Winslow, EB; Bonds, D; Wolchik, S; Sandler, I; Braver, S (2009)	*Mother who enrolled but did not attend any sessions or dropped out before the programme was completed were considered not retained.* (pg. 162)
Zebracki, K., Drotar, D., Kirchner, H., Schluchter, M., Redline, S., Kercsmar, C. and Walders, N. (2003)	*attrition was categorized into pre-inclusion, dropout, and intermittent missing data. Pre-inclusion attrition consisted of the percentage of eligible subjects who (1) did not consent to participate and (2) were not randomized. Dropout attrition was composed of the percentage of randomized participants who (1) did not complete the intervention (intervention group only) and (2) did not complete the final follow-up visit (*pg. 522)

Appendix 5 – Study 2 Table of characteristics

Study ID	Authors	Study focus	Participants age	Healthy/ Patient	Length of intervention (days)	Total Study Length (Days)	Number of appointments	Number of arms	Sites	Recruitment Setting	Intervention Setting	World Bank Index classification (income)	Sample size calculation	No Eligible	No Randomised	No Analysed	No Dropouts	No Excluded	Participant blinding	Risk of bias	Consort diagram
1	Amir, et. al. 1997	Gingostomatitis	< 5 years	patient	7	14	6	2	2	health	health	high	60	-9	72	71	1	10	blind	high	no
2	Donly, et. al. 1999	caries treatment	5-11 years	patient	1	1095	4	2	-9	health	health	high	-9	-9	40	19	21	0	unclear	low	no
3	Fuks, et. al. 1999	caries treatment	5-11 years	patient	1	182	3	2	1	health	health	high	-9	-9	11	11	0	0	aware	high	no
4	Marks, et. al. 1999	caries treatment	5-11 years	patient	1	1095	7	2	-9	health	health	-9	-9	-9	30	24	6	0	unclear	high	no
5	Trimpeneers, et. al. 1997	toothbrush	12-16 years	patient	420	426	9	4	-9	health	community	high	-9	-9	36	35	0	1	unclear	low	no
6	Manning, et. al. 2006	orthodontics	12-16 years	patient	1	1157	1	2	1	health	health	high	32	-9	35	34	1	0	unclear	low	yes
7	Paschos, et. al. 2009	orthodontics	12-16 years	patient	365	365	13	2	1	health	health	high	23	168	24	24	0	0	unclear	high	yes
8	Baccetti, et. al. 2008	orthodontics	5-11 years	patient	1	547	3	3	1	health	health	high	-9	-9	75	69	5	1	aware	high	no
9	Leonardi, et. al. 2004	orthodontics	5-11 years	patient	1	547	2	3	2	health	health	high	-9	-9	53	46	7	0	aware	high	no
10	Masarei, et. al. 2007	cleft	< 5 years	patient	182	365	3	2	1	health	health	high	50	58	50	34	1	0	blind	high	no
11	Prahl, et. al. 2001	cleft	< 5 years	patient	365	547	5	2	2	health	health	high	46	-9	54	49	0	5	blind	high	yes
12	Shaw, et. al. 1999	cleft	< 5 years	patient	365	365	10	2	1	health	health	high	100	-9	101	99	0	2	blind	high	no
13	Petersson, et. al. 1998	caries prevention	12-16 years	healthy	1095	1095	2	2	-9	community	community	high	-9	-9	139	139	0	0	unclear	low	no
14	Stecksén-Blicks, et. al. 2007	caries prevention	12-16 years	patient	420	365	12	2	2	health	health	high	264	302	273	257	16	0	blind	low	yes
15	Øgaard, et. al. 2006	caries prevention	12-16 years	patient	547	548	2	2	2	health	community	high	-9	-9	115	97	18	0	unclear	low	no

Appendix 5 – Study 2 Table of characteristics

Study ID	Authors	Study focus	Participants age	Healthy/ Patient	Length of intervention (days)	Total Study Length (Days)	Number of appointments	Number of arms	Sites	Recruitment Setting	Intervention Setting	World Bank Index classification (income)	Sample size calculation	No Eligible	No Randomised	No Analysed	No Dropouts	No Excluded	Participant blinding	Risk of bias	Consort diagram
16	Källestål, 2005	caries prevention	12-16 years	healthy	365	1825	5	4	2	health	community	high	-9	4355	1134	925	209	0	unclear	high	no
17	Lin & Tsai 1999	caries prevention	< 5 years	Patient	730	730	9	3	1	health	community	high	-9	-9	140	115	25	0	unclear	low	no
18	Stecksén-Blicks, et. al. 2008	caries prevention	5-11 years	healthy	730	730	3	2	1	health	community	high	132	1300	160	115	45	0	blind	low	yes
19	Biesbrock, et. al. 2001	caries prevention	5-11 years	healthy	1095	1095	4	4	-9	community	community	high	-9	-9	5439	3395	2044	0.00 %	unclear	low	no
20	Chesters, et. al. 2002	caries prevention	12-16 years	healthy	365	730	3	2	2	community	community	high	3000	6670	2387	2011	335	41	unclear	low	yes
21	Davies, et. al. 2002	caries prevention	< 5 years	healthy	1825	1825	2	3	2	community	community	high	3750	7422	6781	3731	2078	0	blind	low	yes
22	Fan, et. al. 2008	caries prevention	< 5 years	healthy	730	730	3	3	-9	community	community	high	-9	-9	1200	998	202	0	unclear	low	no
23	Lima, et. al. 2007	caries prevention	< 5 years	healthy	365	365	2	2	1	community	community	upper middle	60	180	120	90	30	0	unclear	low	yes
24	O'Mullane, et. al. 1997	caries prevention	12-16 years	healthy	1095	1095	4	4	2	community	community	high	-9	11500	4196	3467	729	0	unclear	low	no
25	Stookey, et. al. 2004	caries prevention	5-11 years	healthy	730	730	3	4	-9	community	community	high	960	-9	955	683	272	0	unclear	low	no
26	Arruda, et. al. 2012	caries prevention	5-11 years	healthy	365	365	6	2	2	community	community	upper middle	340	379	379	210	169	0	aware	high	yes
27	Gugwad, et. al. 2011	caries prevention	5-11 years	healthy	7	365	5	2	-9	community	community	lower middle	-9	-9	250	211	39	0	blind	low	no
28	Liu, et. al. 2012	caries prevention	5-11 years	healthy	365	730	5	4	2	community	community	high	493	501	501	482	16	3	unclear	high	yes
29	Moberg Sköld, et. al. 2005	caries prevention	12-16 years	healthy	1095	1095	26	4	2	community	community	high	-9	-9	854	758	96	0	unclear	high	no
30	Weintraub, et. al. 2006	caries prevention	< 5 years	healthy	730	730	3	3	2	health	health	high	384	-9	376	202	123	51	blind	low	yes
31	Yang, et. al. 2008	caries prevention	< 5 years	healthy	730	730	5	4	-9	community	community	high	-9	-9	150	148	2	0	unclear	low	no

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Study ID	Authors	Study focus	Participants age	Healthy/ Patient	Length of intervention (days)	Total Study Length (Days)	Number of appointments	Number of arms	Sites	Recruitment Setting	Intervention Setting	World Bank Index classification (income)	Sample size calculation	No Eligible	No Randomised	No Analysed	No Dropouts	No Excluded	Participant blinding	Risk of bias	Consort diagram
32	Trakyali, et. al. 2008	anxiety	12-16 years	patient	182	182	6	2	1	health	health	upper middle	-9	37	30	30	0	0	unclear	high	no
33	Ysunza, et. al. 2008	cleft	5-11 years	patient	90	90	2	2	1	health	health	upper middle	64	72	72	72	0	0	unclear	low	no
34	Chen, et. al. 2000	trauma	5-11 years	patient	60	365	4	2	1	health	health	high	-9	-9	69	67	2	0	blind	high	no
35	Giannetti, & Murri, 2006	trauma	5-11 years	patient	365	365	6	2	1	health	health	high	-9	-9	20	19	1	0	blind	low	no
36	Garcia-Godoy, et. al. 2001	toothbrush	5-11 years	healthy	30	30	3	2	-9	99	99	high	-9	-9	70	66	4	0	blind	low	no
37	Hausen, et. al. 2007	diet	12-16 years	healthy	1241	1460	3	2	2	health	health	high	-9	706	577	497	80	0	unclear	low	yes
38	Innes, et. al. 2007	caries treatment	5-11 years	patient	1	700	3	2	2	health	health	high	120	-9	132	124	8	0	blind	high	yes
39	Lula, et. al. 2009	caries treatment	5-11 years	patient	1	182	3	2	1	health	health	upper middle	30	-9	30	26	1	3	blind	high	no
40	Orhan, et. al. 2010	caries treatment	5-11 years	patient	1	365	5	3	1	health	health	upper middle	-9	-9	123	123	0	0	unclear	high	no
41	Ribeiro, et. al. 1999	caries treatment	5-11 years	patient	1	365	6	2	-9	health	health	upper middle	-9	-9	38	38	0	0	unclear	low	no
42	Kusahara, et. al. 2012	pneumonia	< 5 years	patient	15	15	1	2	1	health	health	upper middle	-9	96	96	89	0	7	blind	low	yes
43	Sebastian, et. al. 2012	pneumonia	5-11 years	patient	21	21	63	2	1	health	health	lower middle	182	88	86	86	0	0	blind	low	yes
44	Acar, et. al. 2010	orthodontics	12-16 years	patient	84	84	5	2	-9	health	health	upper middle	-9	-9	30	30	0	0	unclear	high	no
45	Armi, et. al. 2011	orthodontics	5-11 years	patient	365	548	2	3	2	health	health	high	-9	-9	60	56	4	0	unclear	high	no
46	Bondemark & Karlsson, 2005	orthodontics	5-11 years	patient	198	198	6	2	1	health	health	high	40	44	40	40	0	0	unclear	low	yes
47	de Oliveira, et. al. 2007	orthodontics	5-11 years	patient	715	715	13	2	2	health	health	upper middle	-9	-9	75	75	0	0	blind	low	no

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48	Karacay, et. al. 2006	orthodontics	12-16 years	patient	198	198	9	3	1	health	health	upper middle	-9	-9	48	48	0	0	unclear	high	no
49	Papadopoulos, et. al. 2010	orthodontics	5-11 years	patient	120	198	2	2	1	health	health	high	26	27	27	26	0	1	unclear	low	yes
50	Paul, et. al. 2002	orthodontics	12-16 years	patient	183	183	2	2	1	health	health	high	22	27	27	23	1	3	unclear	high	yes
51	Toy & Enacar, 2011	orthodontics	5-11 years	patient	30	195	9	2	1	health	health	upper middle	-9	-9	30	30	0	0	unclear	low	no
52	Asanza, et. al. 1997	orthodontics	12-16 years	patient	1	91	2	2	-9	health	health	high	-9	-9	14	14	0	0	unclear	low	no
53	Sandikçioglu & Hazar, 1997	orthodontics	5-11 years	patient	210	210	3	3	-9	health	health	-9	-9	-9	30	30	0	0	aware	high	no
54	Abdelnaby & Nassar, 2010	orthodontics	5-11 years	patient	365	365	2	3	1	health	health	lower middle	-9	-9	50	50	0	0	unclear	high	no
55	Atalay & Tortop, 2010	orthodontics	5-11 years	patient	335	335	2	3	1	health	health	upper middle	-9	-9	45	45	0	0	aware	high	no
56	Keles, et. al. 2002	orthodontics	5-11 years	patient	183	183	2	2	1	health	health	upper middle	-9	-9	20	20	0	0	unclear	low	no
57	Mandall, et. al. 2010	orthodontics	5-11 years	patient	456	1095	3	2	2	health	health	high	46	73	73	69	4	0	blind	low	yes
58	Vaughn, et. al. 2005	orthodontics	5-11 years	patient	423	423	3	3	-9	health	health	high	-9	-9	46	46	0	0	unclear	low	no
59	Xu & Lin. 2001	orthodontics	5-11 years	patient	395	395	2	2	-9	health	health	high	-9	-9	40	40	0	0	unclear	low	
60	Banks, et. al. 2004	orthodontics	12-16 years	patient	243	243	2	2	2	health	health	high	160	-9	189	136	53	0	blind	high	yes
61	Bilgiç, et. al. 2011	orthodontics	12-16 yr	patient	183	183	7	2	1	health	health	upper middle	20	-9	24	24	0	0	unclear	high	no

Appendix 5 – Study 2 Table of characteristics

Study ID	Authors	Study focus	Participants age	Healthy/ Patient	Length of intervention (days)	Total Study Length (Days)	Number of appointments	Number of arms	Sites	Recruitment Setting	Intervention Setting	World Bank Index classification (income)	Sample size calculation	No Eligible	No Randomised	No Analysed	No Dropouts	No Excluded	Participant blinding	Risk of bias	Consort diagram
62	Cevidanes, et. al. 2003	orthodontics	5-11 years	patient	547	547	2	2	1	health	health	upper middle	-9	-9	84	84	0	0	unclear	low	no
63	Cura & Sarac. 1997	orthodontics	5-11 years	patient	183	183	2	2	1	health	health	upper middle	-9	-9	60	47	13	0	unclear	high	no
64	Chen, et. al. 2011	orthodontics	5-11 years	patient	913	3650	4	3	1	health	health	high	-9	1226	325	276	49	0	unclear	high	yes
65	Ghafaria, et.al. 1998	orthodontics	5-11 years	patient	730	730	13	2	1	health	health	high	-9	-9	84	63	21	0	unclear	high	no
66	Jamilian, et. al. 2010	orthodontics	5-11 years	patient	487	487	2	2	-9	health	health	upper middle	-9	-9	55	55	0	0	unclear	low	no
67	Lee, et. al. 2007	orthodontics	12-16 years	patient	274	365	2	2	1	health	health	high	62	-9	62	56	6	0	unclear	low	yes
68	Illing, et. al. 1998	orthodontics	5-11 years	patient	274	274	2	3	1	health	health	high	-9	-9	58	47	10	1	unclear	high	no
69	Jing & Hong. 1997	orthodontics	5-11 years	patient	-9	-9	-9	2	1	health	health	high	-9	-9	52	52	0	0	unclear	high	no
70	O'Neill et. al. 2000	orthodontics	12-16 years	patient	547	547	4	3	1	health	health	high	54	-9	54	42	2	6	aware	high	no
71	Tulloch et. al. 2004	orthodontics	5-11 years	patient	1049	1049	24	3	1	health	health	high	120	384	180	137	43	8	unclear	high	yes
72	Showkatbakhsh, et. al. 2011	orthodontics	5-11 years	patient	335	547	2	2	-9	health	health	high	-9	-9	50	50	0	0	blind	low	no
73	Thiruvenkatachari, et. al. 2010	orthodontics	12-16 years	patient	-9	547	6	2	2	health	health	high	64	65	64	54	9	1	blind	high	yes
74	O'Brien, et. al. 2003	orthodontics	12-16 years	patient	365	365	10	2	2	health	health	high	160	230	215	183	31	1	blind	high	yes
75	O'Brien K, et. al. 2009	orthodontics	5-11 years	patient	456	456	2	2	2	health	health	high	120	-9	174	127	47	0	blind	low	yes
76	Yaqoob, et. al. 2011	orthodontics	12-16 years	patient	365	365	2	2	1	health	health	high	64	76	64	60	4	0	blind	low	yes

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77	Florio, et. al. 2000	caries prevention	5-11 years	healthy	365	365	3	3	1	health	health	upper middle	-9	-9	34	31	3	0	unclear	high	no
78	Splieth, et. al. 2001	caries prevention	5-11 years	healthy	730	730	5	2	1	health	health	high	-9	-9	98	92	6	0	blind	high	no
79	Baygin, et. al. 2011	pain management	5-11 years	patient	1	1	4	3	1	health	community	upper middle	45	-9	45	45	0	0	unclear	low	no
80	Bernhardt, et. al. 2001	pain management	12-16 years	patient	1	1	7	3	1	health	community	high	-9	-9	41	22	0	22	unclear	high	no
81	Law, et. al. 2000	pain management	12-16 years	patient	1	1	6	3	1	health	community	high	-9	-9	115	63	0	52	unclear	high	no
82	Zanin, et. al. 2007	caries prevention	5-11 years	healthy	456	456	11	2	2	community	community	upper middle	60	-9	60	60	0	0	unclear	low	no
83	Amin. 2008	caries prevention	5-11 years	healthy	1	730	5	3	1	health	health	lower middle	-9	-9	45	39	6	0	unclear	low	no
84	Barja-Fidalgo, et. al. 2009	caries prevention	5-11 years	healthy	1	1825	3	2	1	health	health	upper middle	-9	-9	36	20	16	0	blind	high	no
85	Beiruti, et. al. 2006	caries prevention	5-11 years	healthy	1	1825	4	2	2	community	community	lower middle	-9	-9	103	-9	-9	-9	unclear	low	no
86	Chen, et. al. 2012	caries prevention	5-11 years	healthy	1	730	4	4	2	community	community	high	-9	-9	407	380	27	0	blind	low	yes
87	Dhar & Chen. 2012	caries prevention	5-11 years	healthy	1	730	5	4	1	health	health	lower middle	-9	-9	25	25	0	0	blind	low	no
88	Forss & Halme. 1998	caries prevention	5-11 years	healthy	1	2847	3	2	1	health	health	high	-9	-9	166	97	69	0	blind	low	no
89	Ganesh & Tandon. 2007	caries prevention	5-11 years	healthy	1	730	4	2	2	community	community	lower middle	-9	-9	100	100	0	0	blind	low	no
90	Güngör, et. al. 2004	caries prevention	5-11 years	healthy	1	730	5	2	1	health	health	upper middle	-9	-9	53	39	14	0	blind	high	no
91	Lampa, et. al. 2004	caries prevention	5-11 years	healthy	1	730	5	2	1	health	health	high	-9	-9	31	29	2	0	unclear	low	no

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92	Pardi, et. al. 2005	caries prevention	5-11 years	healthy	1	730	4	3	2	community	community	upper middle	-9	-9	113	-9	-9	-9	unclear	low	no
93	Poulsen, et. al. 2001	caries prevention	5-11 years	healthy	1	1095	4	2	1	health	health	lower middle	170	-9	170	116	54	0	blind	high	no
94	Tagliaferro, et. al. 2011	caries prevention	5-11 years	healthy	730	730	17	6	2	community	community	upper middle	-9	487	327	268	59	0	blind	low	no
95	Segura-Castillo, et. al. 2005	cleft	5-11 years	patient	90	760	7	2	1	health	health	upper middle	-9	-9	27	27	0	0	unclear	high	no
96	Al-Rakaf, et. al. 2001	sedation	< 5 years	patient	1	1	2	3	1	health	health	high	-9	-9	38	38	0	0	unclear	high	no
97	Avalos-Arenas, et. al. 1998	sedation	< 5 years	patient	1	1	1	2	-9	health	health	upper middle	-9	-9	40	40	0	0	unclear	high	no
98	Averley, et. al. 2004	sedation	5-11 years	patient	1	1	1	3	1	health	health	high	-9	-9	65	45	0	20	blind	high	no
99	Averley, et. al. 2004	sedation	5-11 years	patient	1	1	1	3	1	health	health	high	-9	848	848	697	66	85	blind	high	yes
100	Okcu, et. al. 2004	sedation	5-11 years	patient	1	1	1	2	1	health	health	upper middle	-9	-9	50	50	0	0	unclear	high	no
101	Baygin, et. al. 2010	sedation	5-11 years	patient	1	1	1	4	1	health	health	upper middle	60	-9	60	60	0	0	unclear	high	no
102	Bui, et. al. 2002	sedation	5-11 years	patient	1	1	2	2	1	health	health	high	-9	-9	22	22	0	0	unclear	low	no
103	Faytrouny, et. al. 2007	sedation	5-11 years	patient	1	1	1	2	1	health	health	upper middle	-9	-9	30	30	0	0	unclear	high	no
104	Isik, et. al. 2008	sedation	5-11 years	patient	1	1	1	4	-9	health	health	upper middle	60	-9	60	60	0	0	unclear	low	no
105	Isik, et.al. 2008	sedation	5-11 years	patient	1	1	2	4	1	health	health	upper middle	-9	-9	43	43	0	0	unclear	low	no
106	Jensen, et. al. 1999	sedation	< 5 years	patient	1	1	2	2	2	health	health	high	-9	-9	90	90	0	0	blind	high	no
107	Kapur, et. al. 2004	sedation	< 5 years	patient	1	1	1	2	1	health	health	lower middle	-9	-9	40	40	0	0	unclear	high	no
108	Koirala, et. al. 2006	sedation	5-11 years	patient	1	1	1	6	-9	health	health	low	-9	-9	120	120	0	0	unclear	high	no

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109	Lahoud & Averley. 2002	sedation	5-11 years	patient	1	1	1	2	1	health	health	high	-9	-9	411	-9	0	0	unclear	high	no
110	Lam, et. al. 2005	sedation	5-11 years	patient	1	1	1	2	1	health	health	high	-9	-9	23	23	0	0	unclear	high	no
111	Lee-Kim, et. al. 2004	sedation	< 5 years	patient	1	1	1	2	1	health	health	high	-9	-9	40	40	0	0	aware	high	no
112	Mortazavi, et. al. 2015	sedation	< 5 years	patient	1	1	1	2	1	health	health	upper middle	-9	-9	40	40	0	0	unclear	low	no
113	Rai, et. al. 2007	sedation	< 5 years	patient	1	1	1	3	1	health	health	lower middle	-9	-9	30	30	0	0	unclear	high	no
114	Roelofse, et. al. 1998	sedation	5-11 years	patient	1	1	1	2	1	health	health	upper middle	-9	-9	100	100	0	0	unclear	high	no
115	Shashikiran, et. al. 2006	sedation	< 5 years	patient	1	1	1	2	1	health	health	lower middle	-9	-9	40	40	0	0	unclear	high	no
116	Singh, et. al. 2003	sedation	5-11 years	patient	1	1	1	3	1	health	health	lower middle	-9	-9	90	90	0	0	unclear	high	no
117	Torres-Perez, et. al. 2007	sedation	5-11 years	patient	1	1	1	3	-9	health	health	upper middle	-9	-9	54	54	0	0	unclear	high	no
118	Wan, et. al. 2006	sedation	5-11 years	patient	1	1	1	2	1	health	health	high	-9	-9	40	40	0	0	unclear	low	no
119	Toumba & Curzon. 2005	caries prevention	5-11 years	healthy	730	730	7	2	2	community	community	high	-9	-9	174	132	42	0	blind	low	no
120	Tavener, et. al. 2005	fluorisis	< 5 years	healthy	1825	3650	3	2	2	community	community	high	-9	-9	4826	2716	2110	0	blind	high	no
121	Ellwood, et. al. 1998	caries treatment	12-16 years	healthy	1095	1095	3	2	2	community	community	high	-9	1042	641	480	71	90	blind	high	no
122	Bernardo, et. al. 2007	caries treatment	5-11 years	patient	1	2555	7	2		community	health	high	400	845	507	472	19	16	aware	high	yes
123	Maserejian, et. al. 2012	caries treatment	5-11 years	patient	1	1825	12	2	5	health	health	high	-9	598	534	449	50	10	aware	high	yes
124	AL-Bahlani, et. al. 2001	sedation	< 5 years	patient	1	1	1	2	1	health	health	high	-9	105	100	100	0	0	unclear	high	no

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125	Anand et. al. 2005	sedation	5-11 years	patient	1	3	3	2	1	health	health	high	30	-9	30	30	0	0	blind	low	no
126	Andrzejowski & Lamb. 2002	sedation	5-11 years	patient	1	1	1	2	1	health	health	high	120	-9	133	120	0	13	blind	low	no
127	Coulthard, et. al. 2006	sedation	5-11 years	patient	1	1	1	2	1	health	health	high	142	-9	142	139	0	3	blind	low	no
128	Gazal, et. al. 2004	sedation	5-11 years	patient	1	1	1	2	1	health	health	high	114	-9	139	135	4	0	blind	low	no
129	Leong, et. al. 2007	sedation	5-11 years	patient	1	3	1	3	1	health	health	high	-9	-9	87	54	4	29	blind	high	yes
130	McWilliams & Rutherford. 2007	sedation	< 5 years	patient	1	1	1	2	1	health	health	high	80	-9	85	76	0	9	blind	low	no
131	Quirke, et. al. 2005	sedation	5-11 years	patient	1	1	1	2	1	health	health	high	-9	-9	48	48	0	0	blind	low	no
132	Sammons, et. al. 2007	sedation	< 5 years	patient	1	1	1	2	1	health	health	high	116	-9	86	85	0	1	blind	low	no
133	Townsend, et. al. 2009	sedation	< 5 years	patient	1	1	1	2	1	health	health	high	-9	-9	27	20	7	0	blind	low	no
134	Watts, et. al. 2009	sedation	< 5 years	patient	1	1	1	2	1	health	health	high	46		48	48	0	0	blind	low	no
135	Pedrin, et. al. 2006	orthodontics	5-11 years	patient	365	365	2	2	-9	health	health	high	-9	-9	60	60	0	0	aware	low	no
136	Garib, et. al. 2005	orthodontics	12-16 years	patient	106	106	2	2	1	health	community	upper middle	-9	-9	8	8	-9	-9	aware	low	no
137	Godoy, et. al. 2011	orthodontics	5-11 years	patient	240	730	12	3	1	community	community	upper middle	99	-9	99	99	0	0	aware	low	no
138	Kilic, et. al. 2008	orthodontics	12-16 years	patient	-9	-9	2	2	1	health	community	upper middle	-9	-9	39	39	0	0	aware	low	no
139	Lagravere, et. al. 2010	orthodontics	12-16 years	patient	183	365	4	3	1	health	community	high	-9	-9	62	-9	-9	9	-9	low	no

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140	Lamparski, et. al. 2003	orthodontics	5-11 years	patient	-99	-99	-99	2	1	health	community	high	-9	-9	30	-9	-9	-9	-9	high	no
141	Lippold, et. al. 2013	orthodontics	5-11 years	patient	114	365	2	2	1	health	community	high	-9	82	82	66	16	0	-9	high	yes
142	Martina, et. al. 2012	orthodontics	5-11 years	patient	213	213	-9	2	1	health	community	high	24	-9	50	26	15	9	aware	high	yes
143	McNally, et. al. 2005	orthodontics	12-16 years	patient	84	84	4	2	2	health	health	high	46	60	60	52	8	0	aware	high	yes
144	Oliveira, et. al. 2004	orthodontics	5-11 years	patient	474	572	3	2	4	health	health	high	50	-9	38	38	0	0	unclear	low	no
145	Oshagh, et. al. 2012	orthodontics	5-11 years	patient	161	161	6	2	1	health	community	lower middle	-9	-9	36	35	-9	-9	unclear	high	no
146	Petrén & Bondemark. 2008	orthodontics	5-11 years	patient	365	365	12	4	3	health	community	high	48	61	60	60	0	0	blind	low	yes
147	Ramoglu & Sari. 2010	orthodontics	5-11 years	patient	79	79	4	2	1	health	community	upper middle	-9	-9	35	35	0	0	unclear	low	no
148	Biavati, et. al. 2010	toothbrush	12-16 years	patient	56	56	2	2	1	health	community	high	-9	-9	20	20	0	0	unclear	low	no
149	Kallar, et. al. 2011	toothbrush	5-11 years	healthy	84	84	5	2	-9	community	community	lower middle	-9	-9	200	200	0	0	unclear	high	no
150	Silverman, et. al. 2004	toothbrush	< 5 years	patient	42	42	3	3	1	community	community	high	51	-9	59	57	2	0	unclear	low	no
151	Aeinehchi, et. al. 2007	caries treatment	5-11 years	patient	1	183	3	2	1	health	health	upper middle	-9	148	126	100	26	0	unclear	high	yes
152	Agamy, et. al. 2004	caries treatment	5-11 years	patient	1	365	5	3	1	health	health	lower middle	-9	-9	24	20	4	0	unclear	high	no
153	Alaçam, et al. 2009	caries treatment	5-11 years	patient	1	365	5	3	1	health	health	upper middle	-9	-9	105	91	9	5	unclear	low	yes
154	Aminabadi, et. al. 2010	caries treatment	< 5 years	patient	1	730	5	2	1	health	health	upper middle	-9	-9	84	84	0	0	unclear	low	no
155	Ansari & Ranjpour. 2010	caries treatment	5-11 years	patient	2	730	5	2	1	health	health	upper middle	-9	-9	17	7	10	0	unclear	high	yes

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156	Bahrololoomi, et. al. 2008	caries treatment	5-11 years	patient	2	274	4	2	1	health	health	upper middle	-9	50	46	46	0	0	unclear	low	yes
157	Casas, et. al. 2004	caries treatment	< 5 years	patient	1	1095	4	2	1	health	health	high	-9	-9	130	29	101	0	unclear	high	no
158	Coser, et. al. 2008	caries treatment	5-11 years	patient	42	730	8	2	1	health	health	upper middle	-9	-9	29	29	0	0	unclear	-9	no
159	Dean, et. al. 2002	caries treatment	5-11 years	patient	1	365	2	2	-9	health	health	high	-9	-9	50	50	0	0	unclear	low	no
160	Demir & Cehreli, 2007	caries treatment	5-11 years	patient	1	730	9	5	-9	health	health	upper middle	-9	-9	67	67	0	0	unclear	low	no
161	Doyle, et. al. 2010	caries treatment	< 5 years	patient	1	548	5	4	1	health	health	high	-9	117	112	92	20	0	unclear	high	no
162	Eidelman, et. al. 2001	caries treatment	5-11 years	patient	1	912	5	2	1	health	health	high	-9	-9	26	18	3	4	unclear	high	no
163	Erdem, et. al. 2011	caries treatment	5-11 years	patient	1	730	4	4	-9	health	health	high	-9	-9	32	25	7	0	unclear	low	yes
164	Farsi, et. al. 2005	caries treatment	5-11 years	patient	1	730	5	2	-9	health	health	high	-9	-9	100	-9	-9	-9	unclear	high	no
165	Garrocho-Rangel, et. al. 2009	caries treatment	5-11 years	patient	1	365	4	2	1	health	health	upper middle	45	-9	45	45	0	0	blind	low	no
166	Holan, et. al. 2005	caries treatment	5-11 years	patient	1	1095	6	2	1	health	health	high	-9	-9	35	33	2	0	unclear	high	no
167	Huth, et. al. 2005	caries treatment	5-11 years	patient	1	728	5	4	1	health	health	high	100	-9	107	103	4	0	unclear	low	yes
168	Ibricevic & Al-Jame. 2000	caries treatment	< 5 years	patient	1	1460	16	2	-9	health	health	high	-9	-9	164	60	104	0	unclear	high	no
169	Malekafzali, et. al. 2011	caries treatment	5-11 years	patient	1	730	4	2	1	health	health	high	40	-9	40	35	5	0	unclear	high	no
170	Markovic, et. al. 2005	caries treatment	5-11 years	patient	1	548	5	2	1	health	health	upper middle	-9	-9	104	104	0	0	unclear	low	no
171	Moretti, et. al. 2008	caries treatment	5-11 years	patient	1	730	5	3	1	health	health	upper middle	-9	-9	23	21	2	0	unclear	low	yes

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172	Mortazavi & Mesbahi. 2004	caries treatment	5-11 years	patient	2	365	4	2	1	health	health	upper middle	-9	-9	58	52	6	0	unclear	high	no
173	Nadkarni & Damle. 2000	caries treatment	5-11 years	patient	2	274	6	2	1	health	health	lower middle	-9	-9	60	60	0	0	unclear	low	no
174	Naik & Hegde. 2005	caries treatment	Missing	patient	2	183	5	2	1	health	health	lower middle	-9	-9	38	-9	-9	-9	unclear	low	no
175	Nakornchai, et. al. 2010	caries treatment	5-11 years	patient	2	274	4	2	-9	health	health	upper middle	-9	-9	37	37	0	0	unclear	low	no
176	Noorollahian. 2008	caries treatment	5-11 years	patient	2	730	4	2	1	health	health	upper middle	-9	-9	24	20	4	0	unclear	high	no
177	Ozalp, et. al. 2005	caries treatment	5-11 years	patient	2	547	9	4	1	health	health	upper middle	-9	-9	76	79	0	0	unclear	low	no
178	Pinky, et. al. 2011	caries treatment	5-11 years	patient	30	365	3	2	1	health	health	lower middle	-9	-9	28	28	0	0	unclear	low	no
179	Prabhakar, et. al. 2008	caries treatment	5-11 years	patient	2	365	4	2	1	health	health	lower middle	-9	-9	41	41	0	0	unclear	low	no
180	Ramar & Mungara. 2010	caries treatment	5-11 years	patient	1	274	4	3	1	health	health	lower middle	-9	-9	77	-9	0	0	unclear	low	no
181	Sabbarini, et. al. 2008	caries treatment	5-11 years	patient	1	183	5	2	1	health	health	lower middle	-9	-9	15	15	0	0	unclear	low	no
182	Sakai, et. al. 2009	caries treatment	5-11 years	patient	1	730	5	2	1	health	health	upper middle	-9	30	30	24	1	5	unclear	high	yes
183	Saltzman, et. al. 2005	caries treatment	5-11 years	patient	1	478	5	2	1	health	health	high	-9	-9	15	15	0	0	unclear	high	no
184	Shumayrikh & Adenubi. 1999	caries treatment	5-11 years	patient	14	365	4	2	1	health	health	high	-9	-9	19	17	2	0	blind	low	no
185	Sonmez, et. al. 2008	caries treatment	5-11 years	patient	1	730	5	4	1	health	health	upper middle	-9	-9	16	11	0	5	unclear	low	yes
186	Subramaniam, et. al. 2009	caries treatment	5-11 years	patient	14	730	6	2	1	health	health	lower middle	-9	-9	19	19	0	0	aware	low	no

Appendix 5 – Study 2 Table of characteristics

Study ID	Authors	Study focus	Participants age	Healthy/ Patient	Length of intervention (days)	Total Study Length (Days)	Number of appointments	Number of arms	Sites	Recruitment Setting	Intervention Setting	World Bank Index classification (income)	Sample size calculation	No Eligible	No Randomised	No Analysed	No Dropouts	No Excluded	Participant blinding	Risk of bias	Consort diagram
187	Subramaniam, et. al. 2011	caries treatment	5-11 years	patient	7	548	6	3	1	health	health	lower middle	-9	-9	-9	-9	-9	-9	unclear	low	no
188	Trairatvorakul & Chunlasikaiwan. 2008	caries treatment	5-11 years	patient	1	365	3	2	1	health	health	upper middle	-9	-9	42	42	0	0	unclear	low	no
189	Tuna & Olmez. 2008	caries treatment	5-11 years	patient	1	730	6	2	1	health	health	upper middle	-9	-9	50	42	6	2	unclear	high	yes
190	Vargas, et. al. 2006	caries treatment	5-11 years	patient	1	365	3	2	1	health	health	high	-9	-9	23	-9	-9	-9	blind	high	no
191	Waterhouse, et. al. 2000	caries treatment	5-11 years	patient	1	365	2	2	1	health	health	high	-9	-9	52	-9	-9	-9	unclear	low	no
192	Zealand, et. al. 2010	caries treatment	5-11 years	patient	1	183	2	2	2	health	health	high	-9	-9	152	-9	-9	-9	unclear	high	no
193	Zurn & Seale. 2008	caries treatment	5-11 years	patient	1	730	4	2	1	health	health	high	-9	-9	23	20	3	0	unclear	high	no
194	Borsos, et. al. 2008	orthodontics	12-16 years	patient	-9	-9	-9	2	1	health	health	upper middle	-9	-9	16	16	0	0	unclear	high	no
195	Borsos, et. al. 2011	orthodontics	12-16 years	patient	860	860	40	2	1	health	health	upper middle	-9	-9	30	30	0	0	unclear	low	no
196	Feldmann. 2006	orthodontics	12-16 years	patient	-9	-9	10	4	1	health	health	high	-9	168	120	113	2	5	unclear	high	yes
197	Lehnen, et. al. 2011	orthodontics	12-16 years	patient	1	2	2	2	1	health	health	high	-9	-9	30	30	0	0	unclear	high	no
198	Milgrom, et. al. 2009	caries prevention	< 5 years	-9	365	365	52	3	-9	community	community	upper middle	96	-9	100	94	6	0	blind	low	yes
199	Oscarson, et. al. 2006	caries prevention	< 5 years	healthy	547	730	5	2	1	health	community	high	-9	-9	132	118	14	0	aware	high	no
200	Sintes, et. al. 2002	caries prevention	5-11 years	healthy	912	912	3	2	28	community	community	upper middle	-9	-9	3394	2593	-9	-9	blind	high	no
201	Taipale, et. al. 2013	caries prevention	< 5 years	healthy	730	1460	4	2	-9	health	health	high	-9	-9	106	94	12	0	blind	high	yes

Appendix 6 - Study 2 - List of included studies

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Appendix 7 – University of Salford Ethical Approval for Study 3

University of Salford MANCHESTER

Research, Innovation and Academic Engagement Ethical Approval Panel

College of Health & Social Care
AD 101 Allerton Building
University of Salford
M6 6PU

T +44(0)161 295 7016
r.shuttleworth@salford.ac.uk

www.salford.ac.uk/

13 March 2014

Dear Louise,

RE: ETHICS APPLICATION HSCR14/02 – A focus group study to explore experiences of participation in the Bright Smiles Baby Study - a Randomised Controlled Trial (RCT)

Based on the information you provided, I am pleased to inform you that application HSCR14/02 has now been approved. I would be grateful if you could forward a copy of the NHS approval letter once received.

If there are any changes to the project and/ or its methodology, please inform the Panel as soon as possible.

Yours sincerely,

Rachel Shuttleworth

Rachel Shuttleworth
College Support Officer (R&I)

Appendix 8 – NHS REC Approval for Study 3

NHS
Health Research Authority

National Research Ethics Service
NRES Committee North West - Greater Manchester East
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

Tel: 0161 625 7831
Fax: 0161 625 7299

01 April 2014

Ms R Armstrong
Clinical Trial Manager
WHO Collaborating Centre
School of Health Sciences
Room L817
Allerton Building
University of Salford
Salford

Dear Ms Armstrong

Study title:	**A comparison of community based preventive services to improve child dental health**
REC reference:	**10/H1013/8**
Amendment number:	**Modified Substantial Amendment 08**
Amendment date:	**20 March 2014**
IRAS project ID:	**31168**

Thank you for submitting the above amendment, which was received on 21 March 2014. It is noted that this is a modification of an amendment previously rejected by the Committee (our letter of 12 March 2014 refers).

The modified amendment has been considered on behalf of the Committee by the Chair.

Ethical opinion

There were no ethical issues found with this Modified Amendment.

I am pleased to confirm that the Committee has given a favourable ethical opinion of the modified amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved are:

Document	Version	Date
Modified Amendment	Modified Substantial Amendment 08	20 March 2014
Covering Letter	Email	21 March 2014
Participant Information Sheet: Focus Group PIL	1.1 (tracked)	14 March 2014

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

10/H1013/8:	**Please quote this number on all correspondence**

Yours sincerely

Signed on behalf of
Mr Francis Chan
Chair

E-mail: nrescommittee.northwest-gmeast@nhs.net

Copy to: Dr R Georgiou - Salford Royal Hospitals NHS Trust

Professor C Pine – University of Salford

Appendix 9 – Study 3 - Participant information leaflet

PIL V.1.0 06-12-13

Bright Smiles Baby Study

A **FOCUS GROUP STUDY** to explore experiences of participation in the Bright Smiles Baby Study – a Randomised Controlled Trial (RCT)

INFORMATION SHEET

Dear [INSERT PARENT NAME]

You are being invited to take part in a focus group to discuss your experiences of being on the Bright Smiles Baby Study at [INSERT VENUE] on [INSERT DAY] at [INSERT TIME]

All Parents will receive a £10 'Love2Shop' voucher as a thank you for taking part and to cover the cost of any expenses. Refreshments will also be provided.

To help you decide if you would like to take part we have answered some common questions on the back of this letter.

Thank you for your help!

Louise Robinson

Bright Smiles Baby Study

(Contact details overleaf)

1. **What are you doing?**

We are interested in understanding parents' experiences of taking part in the Bright Smiles Baby Study. To do this we are holding focus groups with parents who enrolled onto the Bright Smiles Baby Study. We are inviting 60-70 parents including those who chose to drop out of the main study.

2. **What is a focus group?**

A group of people coming together to discuss a certain topic. There will be 8-12 people in the group. The person running the group will ask questions and the participants will discuss their experiences and opinions as a group. There are no right or wrong answers, we are interested in everyone's views.

3. **How is this different to the Bright Smiles Study?**

The main study aims to evaluate methods for preventing tooth decay in children. This study is interested in understanding how we can involve more parents and children in future research projects, by finding out what it is like to take part in a study and how we can make it easier for people in future.

4. **What would I need to do?**

We are holding a focus group in your area at [INSERT VENUE] on [INSERT DAY] at [INSERT TIME]. We would like you to come along for roughly 1 hour and have a discussion about your experiences of being on the Bright Smiles Baby Study.

5. **Who will be there?**

The focus group will be run by Louise Robinson, a member of the Bright Smiles Team. Margaret Coffey, from the University of Salford may also come along to help run the session.

6. What will you do with the data?

We would like to tape record the session so that that the data can be analysed for results on how we can improve future studies. The data will all be anonymised so any quotes we use in the write up or publications will not identify you personally.

Please be advised that although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The researchers would like to remind participants to respect the privacy of your fellow participants and not repeat what is said in the focus group to others.

7. Do I have to take part?

No, as with the main Bright Smiles Baby Study your participation is voluntary and you can choose to withdraw at any time.

8. How can I take part?

If you would like to take part please complete the enclosed form and send it back to us in the freepost envelope. Or you can contact us using the details below.

9. Do I need to bring my child?

No, it would probably be easier if you came on your own so we can focus on the discussion. But if you would like to bring your child you are welcome to do so.

10. What if I have more questions?

If you have any questions about the project or you would like to book on the session, please contact:

Louise Robinson (Researcher - Bright Smiles Baby Study)
Telephone: 0161 295 2799
Email: l.robinson1@salford.ac.uk

(This research has received ethical approval from [INSERT UoS, NHS REC AND R&D DETAILS]

Appendix 10 – Study 3 - Enrolment form

Enrolment Form V.1.1. 03-03-14

If you would like to take part please complete this form and send it back in the pre-paid envelope provided. We will contact you on the contact telephone number provided to confirm the session.

'Yes!'

I would like to take part in the focus group at [INSERT VENUE] on [INSERT DAY] at [INSERT TIME]

- ✓ I have had the opportunity to ask further questions and time to reflect on the information provided.
- ✓ I have read and understood the Participant Information Sheet version 1.0, dated 06 December 2013. I understand that this is a research study, that it is voluntary and that I am free to withdraw at any time without providing a reason.
- ✓ I will allow the focus group to be audio recorded for research purposes
- ✓ I understand that all data will be anonymous in write up and publications.

Full Name:……

Contact Telephone Number:……

Signed:……

Date:……

Appendix 11 - Study 3 – Topic guide for focus groups

<u>Continuing</u> participants:

1. Why did you decide to take part on the Bright Smiles trial? [motivations etc.]
2. Tell me what is it like to be on the Bright Smiles Baby Study (or what was it like if you have got to the end of the study now)
3. How did you find the practicalities of taking part in the trial [booking in, attending appointments]
4. In terms of practicalities – what could the team have done differently to make your participation easier? [in respect of attendance/booking appointments/providing crèche facilities etc.]
5. In terms of sticking with the trial (retention) – can you tell me a bit about why you have stayed on the trial?
6. Have there been any factors which that have made it difficult or easy for you to stay on the trial (either positively or negatively)? [what factors are these… could you explain them? E.g. child going to nursery/mum going back to work/finishing work/having another baby etc.)
7. Have there been many changes like these since starting the trial? [have these changes shifted the importance taking part in the study in any way?)
8. What do you think are the pros and cons/ advantages and disadvantages of staying on the trial? [on your child's dental health; on your understanding of dental health etc.]
9. What would to say to one of your friends who has been asked to take part in a trial with their child? [would you recommend it/put them off etc.]
10. If we were starting a new trial, what do you think we could do to improve the number of people we get entering the study and making it easier for people to stay to the end?

<u>Withdrawn</u> participants:

1. Why did you originally decide to take part on the Bright Smiles trial? [motivations etc.]
2. Tell me what it was like being on the Bright Smiles Baby Study
3. How did you find the practicalities of taking part in the trial [booking in, attending appointments]
4. In terms of practicalities – what could the team could have done differently to make your participation easier? [in respect of attendance/booking appointments/providing crèche facilities etc.]
5. In terms of sticking with the trial (retention) – can you tell me a bit about why you haven't stayed on the trial?

6. Have there been any factors which have influenced you staying on the trial (either positively or negatively)? [what factors are these… could you explain them? E.g. child going to nursery/mum going back to work/finishing work/having another baby etc.)
7. Have there been many changes like these between starting the trial and withdrawing? [have these changes shifted the importance taking part in the study in any way?)
8. What were the pros and cons/ advantages and disadvantages of being on the trial? [on your child's dental health; on your understanding of dental health etc.]
9. What would to say to one of your friends who has asked to take part in a trial with their child? [would you recommend it/put them off etc.]
10. If we were starting a new trial, what do you think we could do to improve the number of people we get entering the study and making it easier for people to stay to the end?

Appendix 12 – Study 3 - Consent form

PIC at FG Form V.1.0. 07-03-2014

Thank you for attending the Focus Group session today.

Please complete this form by putting your initials in each box to confirm your consent to take part in this research study.

1) I have had the opportunity to ask further questions and time to reflect on the information provided. ☐

2) I have read and understood the Participant Information Sheet version 1.0, dated 06 December 2013. I understand that this is a research study, that it is voluntary and that I am free to withdraw at any time without providing a reason. ☐

3) I will allow the focus group to be audio recorded for research purposes ☐

4) I understand that all data will be anonymous in write up and publications. ☐

Full Name:……

Signed:……

Date:……

Appendix 13 - NHS REC Approval for Study 4

NHS

National Research Ethics Service

North West 8 Research Ethics Committee - Greater Manchester East
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7820

26 March 2010

RECEIVED
01 APR 2010

Private & Confidential
Prof C Pine, Professor in Public Health
Allerton Building
University of Salford
Salford
M6 6PU

Dear Prof Pine

Study Title:	**A comparison of community based preventive services to improve child dental health**
REC reference number:	**10/H1013/8**
Protocol number:	**1.0**

The Research Ethics Committee reviewed the above application at its meeting held on 16 March 2010. Thank you for attending the meeting with Rosy Armstrong to discuss the study.

Discussion

This was considered to be a very useful piece of work and you are commended on your application.

Queries arising related to the onus of completing the diary for the intervention group, the frequency of visits required, and whether participants will be re-consented at a second point. The anticipated drop-out rate seemed to be rather optimistic and some improvements were required to the information sheet. There was some concern about the return of the expression of interest in the study, which would contain personal details, from the point of view of confidentiality.

You were asked about recruitment into the study and you confirmed that this will be done on attendance at Children's Centres. On the question of completion of the diary, you said that you will require only brief notes and this will not be onerous. You said that visits will be spread evenly during the course of the study. Consent will be taken on one occasion only. With regard to the expected drop-out rate, you were confident on the basis of previous experience that this will be in the region of that stated in the application. You agreed to ensure that a specifically-addressed envelope is provided to potential participants for the return of the tear-off slip. Minor changes required to the study documentation were outlined.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, ***subject to*** the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Standard condition

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Sponsors are not required to notify the Committee of approvals from host organisations.

Additional conditions

1. Parts of the information sheet are written as though the sheet is addressed to the child, for example on page 3; the sheet needs to be proof-read for these occasions and the wording changed appropriately.

2. The information sheet needs to make it clear how long the study will last for, so that participants know the time period over which they will need to attend appointments for the fluoride varnish.

3. Under 'What happens when the research stops?', reference should be made to contacting participants again at a later date rather than asking for consent again.

4. Please confirm that the freepost envelope provided for the return of the tear-off slip on the flyer will be addressed to a specific researcher and advise who this will be.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering Letter		15 February 2010
REC application	2.5	17 February 2010
Protocol	1.0	10 February 2010
Investigator CV	1.0	02 October 2010
Investigator CV		02 October 2010
Participant Consent Form	1.0	10 February 2010

Letter of invitation to participant	4.0	02 February 2010
Evidence of insurance or indemnity		15 February 2010
Questionnaire: Validated	1.0	10 February 2010
Advertisement	4.0	02 February 2010

Membership of the Committee

The members of the Ethics Committee present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/H1013/8 **Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

p

Mr Francis Chan
Chair

Email: elaine.hutchings@northwest.nhs.uk

Enclosures: List of names and professions of members present at the meeting.

"After ethical review – guidance for researchers"

Copy to: Mrs Rosemary Armstrong, Faculty of Health & Social Care, University of Salford Allerton Building Salford M6 6PU

Appendix 14 – Study 4 - Oral Health Behaviours Questionnaire

Questionnaire to Parents/Carers

Thank you for agreeing to take part in this new dental study designed to give us an understanding of why some babies develop tooth decay. The study involves parents/carers and babies in Salford. We are trying to understand the wide range of dental beliefs and behaviours that families have and develop about their babies teeth. This questionnaire is divided into five sections. There are no right or wrong answers – we are just trying to understand what is usual for your family.

All information given in this questionnaire will be treated confidentially. Any results that are made public will not contain any information that can identify you personally.

General Information

We would like you to complete this questionnaire by providing us with information about your baby.

Baby's name …….

Baby's gender: male ☐ female ☐

The following questions are about the above named child.

Section A

The first set of questions is about visiting the dentist, toothache, and general questions about your baby's teeth and dental health.

1. Have you ever taken your baby to see a dentist? Yes ☐ No ☐

The next set of questions examines feelings and attitudes towards tooth decay and tooth-brushing. Please tick one box on each line.

	strongly disagree	**disagree**	**neither agree or disagree**	**agree**	**strongly agree**
2. As a parent/guardian, I am confident that I can reduce the chances of my baby getting tooth decay					
3. Tooth decay will not get better by itself					
4. Regular visits to the dentist stop my baby having tooth decay					
5. Tooth decay would affect my baby's general health					
6. Tooth decay is a serious problem in baby teeth					
7. As a parent/guardian, it is my responsibility to prevent my baby getting tooth decay.					
8. My baby losing a baby tooth due to tooth decay would be upsetting					
9. I feel it is important that I check my baby's teeth for decay					

	strongly disagree	disagree	neither agree or disagree	agree	strongly agree
10. If my baby does not want to have his/her teeth brushed every day I don't feel I should make them					
11. It is important to clean my baby's teeth every day so he/she has a nice smile					
12. It is the responsibility of the dentist to prevent my baby getting tooth decay					
13. No matter what I do, my baby is likely to get tooth decay					
14. I can prevent tooth decay in my baby by reducing sugary foods and drinks between meals					
15. It is just bad luck if my baby gets tooth decay					
16. I intend brushing my baby's teeth for him/her					
17. I intend brushing my baby's teeth for him/her twice a day					
18. The people in my family would feel it was important to brush my baby's teeth twice a day					
19. The people I know well would feel it was important to brush my baby's teeth twice a day					
20. I feel able to brush my baby's teeth for him/her					
21. I don't know how to brush my baby's teeth properly					
22. If we brush my baby's teeth twice a day, I can prevent my baby getting tooth decay in the future					

	strongly disagree	disagree	neither agree or disagree	agree	strongly agree
23. If I use a fluoride toothpaste on my baby's teeth, it will prevent tooth decay					
24. A toothpaste without fluoride will prevent tooth decay					
25. I can prevent tooth decay in my baby by helping with brushing once a day					
26. If I don't brush my baby's teeth at least once a day it would cause tooth decay					
27. If my baby gets tooth decay, it is by chance.					
28. It would not make any difference to my baby getting tooth decay, if I brushed their teeth every day					
29.I feel it is important to check if someone has brushed my baby's teeth					
30.I don't have time to brush my baby's teeth twice a day					
31.I cannot make my baby have his/her teeth brushed twice a day					
32.My baby's teeth are brushed as part of my baby's daily washing routine (washing hands and face)					
33. Buying toothbrushes and toothpaste for the whole family is expensive.					
34. Tooth decay runs in families.					
35. Some people just naturally have soft teeth.					

Section B

The next set of questions is about tooth-brushing / tooth cleaning.

What is used to clean your baby's teeth? (Please tick as many boxes as necessary)

Toothbrush ☐

I have not started brushing my baby's teeth yet ☐

Other ☐ (please specify) ……

What else do you use?

Toothpaste	☐	Nothing	☐
Water	☐	Other	☐ (please specify) ……

2. Who brushes/cleans your baby's teeth? (Please tick as many boxes as necessary)

parent ☐

someone else ☐

teeth are not brushed / cleaned ☐

3. How often are your baby's teeth brushed/cleaned? (Please tick one box)

Never	☐	Not every day	☐
Once a day	☐	Twice a day	☐
Three times a day	☐	Every other day	☐

4. When do you brush/clean your baby's teeth? (Please tick as many boxes as necessary)

Before breakfast	☐	After breakfast	☐
Before midday meal	☐	After midday meal	☐
Before evening meal	☐	After evening meal	☐
Before going to sleep at night	☐	Teeth are not brushed	☐

Other occasions ☐ please specify……

People start using toothpaste at different ages. Has your baby started using toothpaste?

Yes, always ☐ Yes, sometimes ☐ No ☐

If yes, which brand of toothpaste do you usually buy for your baby to use?

Brand name ……..

6. When your baby's teeth are brushed, do you use toothpaste or not?

Never use toothpaste ☐ Sometimes use toothpaste ☐

Always use toothpaste ☐

7. Does your baby use a toothbrush? Yes ☐ No ☐

If yes, does your baby:

have his/her own toothbrush? ☐ OR

do they share a toothbrush with someone else? ☐

8. Please tick the picture which most closely resembles the amount of toothpaste you put on your baby's brush.

1 ☐ 

2 ☐ 

3 ☐ 

4 ☐ do not use toothpaste yet

Section C

The next set of questions is related to eating and drinking.

1. Did you breast or bottle feed your baby?

Breast feed ☐ Bottle feed (with formula milk) ☐

Breast and bottle feed ☐

2. At what age did your baby start eating solid food?

Less than 2 months ☐ 2 to 3 months ☐ 4 to 5 months ☐

6 to 12 months ☐ over 12 months ☐ Cannot remember ☐

My baby does not eat solid food yet ☐

3. When your baby started eating solid food, did you ever taste your child's food first and then pass the food to your child?

Yes ☐ No ☐

4. Has your baby ever used?

A bottle Yes ☐ No ☐

A dummy Yes ☐ No ☐

5. To make the dummy taste nice, was it ever dipped in something sweet first?

Yes ☐ No ☐

If yes, what was it dipped into?

Honey ☐ Jam ☐ Other ☐ please specify…..……

6. If your baby's dummy dropped on the floor, do you usually put it in your mouth to clean it before giving it back to your baby?

Always ☐ Usually ☐ Occasionally ☐ Never ☐

7. Have you ever had advice about what your baby should or should not be eating or drinking to look after his/her teeth?

Yes ☐ No ☐

If yes, who has advised you?

Family ☐ Friend ☐ Dentist ☐ Doctor ☐ Health visitor ☐

Baby clinic ☐ Other ☐ please specify ……

Please tick one box on each line.

	Every day	**Most days**	**Once a week**	**Occasionally**	**Never**
8. How often does your baby eat sweets (including chocolates)?					
9. How often does your baby eat sugary foods between meals (for example, biscuits, cake, jam)?					
10. How often does your baby drink soft drinks containing sugar? (including squash, fizzy drinks, etc; not "diet" type drinks)					

11. What does your baby usually eat/drink within an hour before going to bed to sleep at night?

Eats ……..

Drinks ……..

Does not eat/drink before going to bed ☐

12. How often does your baby have something to drink in bed or during the night? (Please tick one box)

Every day	☐	Most days	☐
Occasionally	☐	Never	☐

13. When your baby has a drink in bed or during the night, what does he/she usually have? (Please tick as many boxes as necessary)

Milk	☐	Milk drinks (e.g. chocolate milk)	☐
Milk with sugar or honey	☐	Fruit juices	☐
Fruit squashes	☐	Fizzy drinks	☐
Tea with sugar	☐	Tea without sugar	☐
Coffee with sugar	☐	Coffee without sugar	☐
Water	☐	Never has a drink in bed	☐

Other ☐ (please specify) ……

14. Thinking about food, how often does your baby eat in bed or during the night? (Please tick one box)

Every day ☐ Most days ☐ Occasionally ☐ Never ☐

15. When your baby has something to eat when going to sleep or during the night, what does he/she usually have?

Sweet biscuits (including chocolate biscuits)	☐
Fruit	☐
Savoury and plain biscuits (including cheese biscuits)	☐
Sandwiches (sweet)	☐
Cakes	☐
Sweets or chocolate	☐
Crisps or savoury snacks	☐
Never eats in bed	☐
Other	☐

Please specify ……

16. If you sweeten your child's drinks, what do you add?

Sugar ☐ Honey ☐

Condensed milk ☐ Never sweeten child's drinks ☐

Other ☐ please specify ……..

17. Which drinks do you sweeten?

Milk ☐ Water ☐

Tea ☐ Other ☐ please specify …….

The next set of questions is about your baby as they get older and how you feel about your baby having sugary foods and drinks, both now and in the future.

Please tick one box on each line

	strongly disagree	**disagree**	**neither agree or disagree**	**agree**	**strongly agree**
18. I intend to limit how often my baby has sugary foods or drinks between meals					
19. The people in my family would feel it was important to limit how often my baby has sugary foods and drinks between meals					
20. I feel it could be difficult for me to stop my baby having sugary foods and drinks between meals					
21. I feel able to give my baby healthy alternatives to sugary foods between meals (e.g. like apples instead of sweets)					
22. In the future I will feel able to give my baby healthy alternatives to sugary drinks between meals (e.g. like water instead of a fizzy drink)					

	strongly disagree	disagree	neither agree or disagree	agree	strongly agree
23. It will be worthwhile to give my baby sweets/biscuits to behave well.					
24. If my baby eats sugary foods and drinks in between meals it will cause tooth decay					
25. The people I know well would feel it was important to control how often my baby has sugary foods and drinks					
26. In our family, it would be unfair not to give sweets to my baby every day					
27.It will be too stressful to say no to my baby when he/she wants sweet things					
28. When my baby is tired, it can be a struggle to brush his/her teeth					
29. Bringing my baby to the dentist on a regular basis is the best way to prevent tooth decay					
30. It is not worth it to battle with my baby to brush his/her teeth twice a day					
31. It is just bad luck if my baby gets tooth decay					
32. The dentist is the best person to prevent tooth decay in my baby					

Section D: This section is about YOU

The following questions are related to your experiences of visiting the dentist and oral care

1. What is your usual reason for going to see a dentist? (Please tick one box)

Regularly for a check up ☐

Regularly for treatment ☐

Only if I have problems with my teeth or gums ☐

I do not visit a dentist ☐

2. What brand of toothpaste do you usually use? **……**

3. When do you brush your teeth? ***(Please tick as many boxes as necessary)***

Before breakfast ☐ After breakfast ☐

Before mid-day meal ☐ After mid-day meal ☐

Before evening meal ☐ After evening meal ☐

Before going to bed ☐ Do not brush every day ☐

Other occasions ☐ please specify …….

Please tick one box on each line.

How often do you use the following?	**Every day**	**Most days**	**Occasionally**	**Never**
4. Dental floss				
5. Mouth rinses				
6. Sugar-free chewing gum				

Section E

Now to the final questions. People have different care arrangements for their babies. The following questions help us understand your baby care routines, and the section ends with a few routine questions on background information.

1. Who usually looks after your baby during the day? (*Please tick one box*)

Mother at home	☐	Father at home	☐
Sister/brother	☐	Child's grandparent	☐
Other relative	☐	Friend/neighbour	☐
Paid childminder	☐	Nursery school	☐
Day nursery	☐	Playgroup	☐
Other	☐ …….		

2. Who does your baby live with? (*Tick as many boxes that apply*)

Mother	☐	Father	☐
Mother and father	☐	Mother and stepfather	☐
Father and stepmother	☐	Grandparents	☐
Other relatives	☐	please specify ……	
Other	☐	please specify ……	

3. How many children are living in your house now? ……

4. Is your baby your first child, second child etc? ……..

5. Are you the baby's: Mother ☐ Father ☐

Other ☐ please specify …….

6. What is your age? Under 20 ☐ 20 – 30 ☐ 31 – 40 ☐ over 40 ☐

7. What is your marital status? Married ☐ Single ☐

Divorced / separated? ☐ Widowed ☐

8. What is your occupation? ……

9. What is the postcode, ward of your home address? ……

10. At what level did the baby's mother finish her full-time education?

Primary school ☐ Secondary school ☐

Further education (college) ☐ Higher education (university) ☐

No formal education ☐

Other ☐ please specify ……

11. At what level did the baby's father finish his full-time education?

Primary school ☐ Secondary school ☐

Further education (college) ☐ Higher education (university) ☐

No formal education ☐

Other ☐ please specify ……

Other ☐ please specify …….

12. What is your ethnic group? Please choose one section from (a) to (e), then place a cross in the appropriate box to indicate your cultural background

a. White

British ☐

Irish ☐

Other ☐ please specify……

Other ☐ please specify……

b. Mixed

White and Black Caribbean ☐

White and Black African ☐

White and Asian ☐

c. Asian or Asian British

Indian ☐

Pakistani ☐

Bangladeshi ☐

Other ☐ please specify……

d. Black or Black British

Caribbean ☐

African ☐

Other ☐ please specify……

e. Chinese or other Ethnic Group

Chinese ☐

Other ☐ please specify……

13. What is your religion?

Buddhist	☐	Christian	☐
Hindu	☐	Jewish	☐
Muslim	☐	Sikh	☐
No religion	☐	Prefer not to say	☐

Other ☐ please specify ……

Please take a moment to ensure that you have answered all the questions.

Appendix 15 – Peer reviewed Conference Poster – Study 1

L Robinson, P Adair, G Burnside, M Coffey, C Pine, Systematic Review of Participant-related Predictors of Recruitment and Retention in Randomised Controlled Trials (RCTs) Involving Children and Families. Presented at UKSBM, Oxford 2013

UK Society for Behavioural Medicine
UKSBM
Biology, Behaviour & Environment

ABSTRACT SUBMISSION

Title: Systematic Review of Participant-related Predictors of Recruitment and Retention in RCTs Involving Children and Families

Abstract No. 0085

Title Systematic Review of Participant-related Predictors of Recruitment and Retention in RCTs Involving Children and Families

Presentation Poster

Abstract

Background: There is little evidence of the synthesis of what influences participation in research involving parents and children.

Objectives: The aim of this review is to identify the significant predictors of recruitment and retention in RCTs involving parents/ children with a focus on definitions of retention.

Methods: All English language publications that reported participant predictors of recruitment and retention in RCTs involving children aged 0-12 years were identified. Data was extracted and synthesised qualitatively. Quality assessment was conducted using the STROBE.

Results: 28 studies were analysed. 144 predictors were reported across studies with little agreement as to their significance. Parent characteristics (ethnicity, age, education, SES) were the most commonly reported predictors of participation for both recruitment and retention. Being young, less educated, of an ethnic minority and low SES seemed to be barriers to participation in RCTs but again there was little agreement between studies. 17 different definitions of retention were identified across the studies. The quality of the studies varied greatly and ranged from 42-89%.

Conclusions: Parent characteristics may predict participation of children and their families to RCTs. However, given the lack of consensus, further studies that explore the actual barriers to non-participation in this group are warranted. Reporting of studies in this field need greater clarity as well as agreed definitions of what is meant by retention.

Approval Confirm

Permission Yes

Affiliations

(1) University of Salford, Salford, UK
(2) University of Strathclyde, Glasgow, UK
(3) University of Liverpool, Liverpool, UK
(4) Queen Mary University of London, London, UK
(5) Salford Royal NHS Foundation Trust, Salford, UK

Authors

Louise Robinson (1) Presenting
Pauline Adair (2)
Girvan Burnside (3)
Cynthia Pine (4) (5)

Appendix 16 – Peer reviewed Conference Poster – Study 3

L. Robinson, M. Coffey, R. Harris, G. Burnside, C. Pine, Factors Influencing Recruitment and Retention in a Community-Based Preschool RCT. Presented at IADR, Boston 11-14 March 2015

CONTROL ID: 2120785
TITLE: Factors Influencing Recruitment and Retention in a Community-Based Preschool RCT
PRESENTER: Louise Robinson
AUTHORS (FIRST NAME INITIAL LAST NAME): L. Robinson[1, 2], M. Coffey[3], R. Harris[4], G. Burnside[1], C. Pine[5, 2]
AUTHORS/INSTITUTIONS: L. Robinson, G. Burnside, Biostatistics, University of Liverpool, Liverpool, UNITED KINGDOM|L. Robinson, C. Pine, Salford Royal NHS Foundation Trust, Salford, UNITED KINGDOM|M. Coffey, School of Health Sciences, University of Salford, Salford, UNITED KINGDOM|R. Harris, Health Services Research, University of Liverpool, Liverpool, UNITED KINGDOM|C. Pine, Queen Mary University of London, London, UNITED KINGDOM|
Group Author Abstracts:
Objectives: Problems with the recruitment and retention of participants to RCTs are well documented. The majority of research in this area is focussed on adults. The Bright Smiles RCT is a community based three year RCT involving children ages 1-3 years and their families. **Aim:** To understand participants' reasons for continuing participation/withdrawal in a preschool trial of early childhood caries.
Methods: Focus groups and semi-structured interviews with a purposive sample (n=25) of completed participants (n=339) and withdrawn participants (n=70) on the Bright Smiles Baby Study, a RCT involving children and families in Salford and Manchester, UK. Analysis of transcripts was conducted using framework analysis.
Results: Participants' own dental experiences motivated their decision to take part. Flexibility of appointments and multiple contacts by the research team influenced parents' decision to continue their participation. Distance from home was an important factor; this is reflected in the main trial sample where 'moving out of the area' accounted for over a third of withdrawals (n=25, 36%). Parents who remained on the trial continued for the benefit of their child, citing additional check-ups and access to dental services as reasons to remain. The birth of a second child, returning to work after maternity leave and changing life priorities were barriers to continuing participation on the trial, this is reflected in the reasons given for withdrawal from the main trial (n=16, 23%). Parents advised greater flexibility, increased number of appointment times and venues and linking with existing groups and nurseries as possible recruitment and retention techniques for future studies.
Conclusions: Parents of preschool RCT participants identified flexible and convenient appointments as an important factor in participant retention. Retention techniques should target parents returning to work after maternity leave and following the birth of other children.
TABLE TITLE: (No Tables)
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TABLE FOOTER: (No Tables)
(No Image Selected)
PREFERRED PRESENTATION TYPE: Oral
KEYWORDS: Clinical trials, Recruitment.
AWARDS:
Student Status: PhD Student (no professional degree)
Session Chair Volunteers: Not Interested
Special Scheduling Needs:
Support Funding Agency/Grant Number: NIHR Research for Patient Benefit Grant number PB-PG-0808-17228

Appendix 17 – Peer reviewed Publication – Study 1 (attached as PDF)

Robinson, L., Adair, P., Coffey, M., Harris, R., & Burnside, G. (2016). Identifying the participant characteristics that predict recruitment and retention of participants to randomised controlled trials involving children: a systematic review. *Trials*, *17*(1), 294.