The Impact of Premature Extraction of Primary Teeth on Orthodontic Need in a Longitudinal Birth Cohort

Eman Hassan Yousuf Khalfan Alnuaimi

Submitted in accordance with the requirements for the degree of
Doctor of Philosophy

The University of Leeds
Faculty of Medicine and Health
School of Dentistry

May, 2023

The candidate confirms that the work submitted is her own and that appropriate credit has been given where reference has been made to the work of others.

Dedications

To my dearest parents, Fawzia and Hassan,
my beloved siblings Fatma, Amna, Buthaina,
Mohammad, Ahmad, and Omar,
my cherished nephews Saif, Bader, Ahmad, and Mohammad,
my dear aunts, Fatma and Hind,
the loving memory of my late grandparents, Yousef, and Salma,
and last but not lease, my sweet niece Maha, the cutest
member of the family,
I dedicate this project.

Acknowledgements

First and foremost, I express my thanks to the Almighty Allah for granting me the strength and perseverance throughout my PhD journey.

I would like to express my deep gratitude to:

my supervisor, Professor Peter Day, for being an exceptional mentor, for being such a great source of inspiration, and for creating opportunities that have enriched my professional development;

my co-supervisor, Professor Bernadette Drummond, for the wisdom and valuable advice, and for all the encouragement to explore new horizons and step outside my comfort zone, which have been an essential part of my growth;

and my co-supervisors, Professor Philip Benson, and Doctor Tiffany Yang for their kindness, invaluable support and guidance, which played a significant role in my progress.

Thank you all for helping me develop my academic and leadership skills, and for making my PhD journey truly exceptional.

A massive thank you goes to the data collection team, Annalea Staples, Louise Dell'Amico, and Anna Nielsen, for all the hard work, professionalism, and all the good memories during the school visits.

Special thanks go to the Born in Bradford team, primary schools and Born in Bradford parents and children who took part in the study. "Born in Bradford is only possible because of the enthusiasm and commitment of the Children and Parents in BiB. We are grateful to all the participants, health professionals and researchers who have made Born in Bradford happen."

Special thanks also go to the expert panel of specialist orthodontists Professor Philip Benson, Dr Sophy Barber, and Dr Simon Littlewood for conducting the orthodontic assessments.

I extend my thanks to:

the statistician, Dr Jianhua Wu, for performing the power calculation,

the recruitment team, Alison Barraclough, Elizabeth Nyamadzawo, Zubeda Khatoon, Julie Ara, Dhatshayini Devamanoharan, and Iftikhar Khan, for all their hard work during the recruitment phase,

Jenny Boards and Ayna Beden, for their help with ordering and purchasing the dental kit,

Professor Andrew Keeling, for guiding us through the digital software,

and Professor Gerry Richardson, for his guidance on health economics.

Last but not least, I would like to express my thanks to:
my employer, the Mohammed Bin Rashid University of Medicine and Health and Sciences, and my sponsor, the Ministry of Education-United Arab Emirates, for granting me this opportunity to pursue my PhD.
my friends Nadia, Kady, Jawaher, Rania, Moza, Marija, and Mona, who were there through thick and thin, I will always cherish our friendship.
the President of the UAE Society in Leeds 2022-23, Ali Alnuaimi, for his tireless efforts in supporting Emirati students during their studies.

Abstract

Background:

Extraction of primary teeth is common. The impact of premature extraction of primary teeth (PEPT) is uncertain on the future need for orthodontic treatment and oral health-related quality of life (OH-RQoL).

Aim:

To investigate the association between PEPT and orthodontic need based on the Index of Orthodontic Treatment Need (IOTN) and OH-RQoL based on the short form of the Child Oral Health Impact Profile (COHIP-SF 19).

Methods:

This was a cross-sectional study that recruited children aged 7-11 years participating in the Born in Bradford (BiB) birth cohort in England. An earlier dental data linkage study had identified BiB children who received PEPT under general anaesthetic (exposures). BiB children who had PEPT under local anaesthetic were identified during data collection. Trained examiners collected data from participants with and without PEPT (controls) in consented primary schools in Bradford. Data collected included dental examination, extra-oral and intra-oral photographs, and alginate impressions. Participants completed the COHIP-SF 19 questionnaire to assess OH-RQoL. A blinded expert panel, consisting of three specialist orthodontists, independently assessed the records for orthodontic need using the Dental Health Component of the IOTN (IOTN-DHC). Descriptive statistics using means, standard deviations or medians, interquartile ranges were calculated. The

proportion of participants assessed in need for orthodontic treatment and the odds ratio were calculated. Differences in COHIP-SF 19 scores by group were assessed using the Mann-Whitney U test.

Results:

Out of 374 participants who were recruited for the study, 322 (n=78/322 with PEPT) had sufficient records that enabled data analysis. The proportion of participants with PEPT who were assessed in need for orthodontic treatment was 69.2% (n=54/78) compared to 40.6% of participants without PEPT (n=99/244). PEPT was significantly associated with an increased need for orthodontic treatment (OR=3.3, 95% CI=1.91-5.68, *P*<0.001). The difference in the median total COHIP-SF 19 scores between participants with PEPT (57, IQR 52-60) and without PEPT (58, IQR 51-64) was not statistically significant.

Conclusion:

PEPT was strongly associated with an increased need for orthodontic treatment when assessed in the mixed dentition, using the IOTN-DHC. No impact of PEPT on the OH-RQoL was found.

Table of Contents

List of Tables

List of Figures

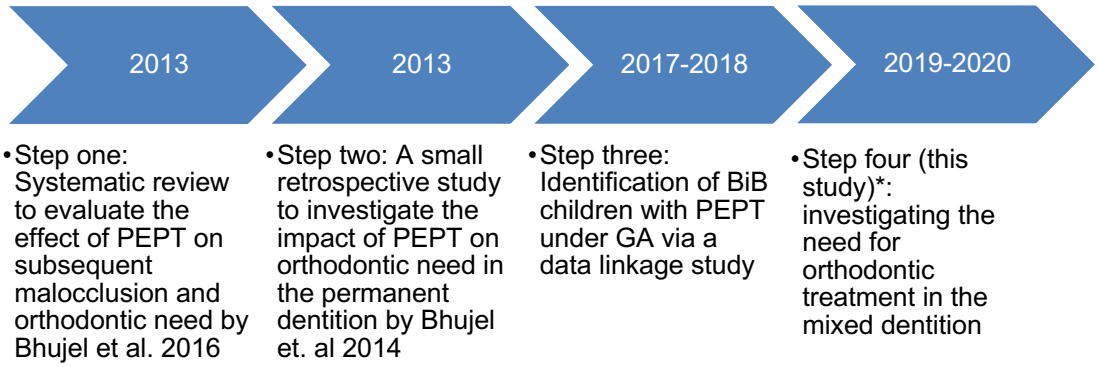
List of Appendices

Chapter One: Introduction

1.1 Introduction to the research

This study is part of a wider research project that aims at understanding the impact of premature extraction of primary teeth (PEPT) on the orthodontic need on a sub-sample of children from a longitudinal birth cohort, the Born in Bradford (BiB) cohort. A research group led by the Chief Investigator-Professor Peter Day, has 'undertaken four key steps to explore the impact of PEPT on orthodontic treatment need (Figure 1.1), namely: (1) completed a systematic review to evaluate the effect of PEPT on malocclusion (Bhujel et al., 2016); (2) undertaken a small retrospective study to explore the impact of PEPT on orthodontic need in the permanent dentition (Bhujel et al., 2014); (3) identified through data linkage around 1,150 children participating in BiB who have had the exposure, namely PEPT under general anaesthetic (GA) (Day, 2018); and (4) obtained funding and agreement to include a dental sub-study within the wider BiB birth cohort study (protocol paper (Brown et al., 2019) Appendix 1.1).

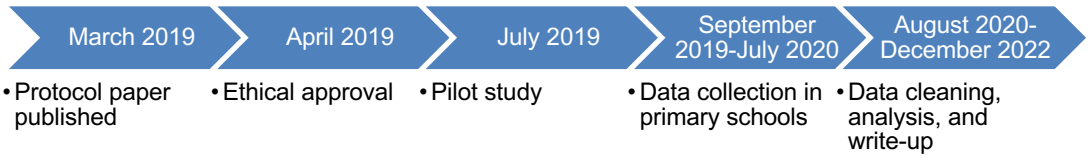
Figure 1.1 Key steps undertaken by the research group to explore the impact of PEPT on orthodontic treatment need



*Phase II: Further study to investigate need for orthodontic treatment in the permanent dentition for the same participants is discussed in section 6.7 Study limitations and further work

My thesis was focused entirely on step four. The planned timeline for the study is summarised in Figure 1.2.

Figure 1.2 The planned timeline for the study



1.2 Funding

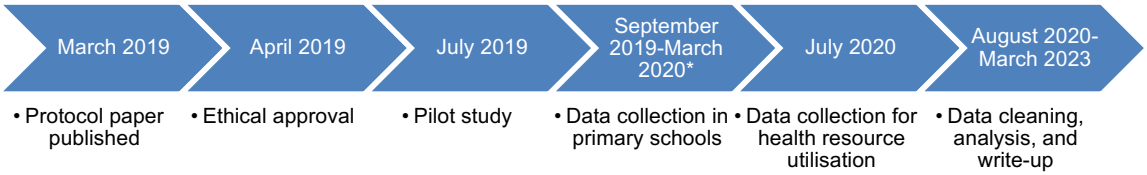
This study, step 4, was funded by a grant from the British Orthodontic Society Foundation (Appendix 1.2).

1.3 The impact of COVID-19 pandemic

On 11 March 2020, the World Health Organization declared coronavirus disease (COVID-19) outbreak caused by the novel coronavirus SARS-Cov-2 a pandemic. The BiB research group temporarily suspended data collection

taking place in primary schools in Bradford, including our study. Primary schools in Bradford that had consented to take part were contacted and informed that scheduled visits were postponed until further notice. My supervisory team made plans to work remotely on data cleaning and preliminary analysis. Permissions were sought from BiB to grant me remote access to data. The resumption of school-based data collection was not possible owing to the ongoing challenges during the pandemic, resulting in the disruption of data collection and participant recruitment. Figure 1.3 describes the timeline of this study after the disruption caused by the COVID-19 pandemic.

Figure 1.3 The timeline of this study after the disruption caused by the COVID-19 pandemic



*The hit of the COVID-19 pandemic

1.4 Notes to the reader

- Throughout the text, I will be referring to myself as 'the researcher'.
- For the sake of this research, parental consent includes other carers where they have legal authority to consent for the child.
- There are several reasons that could lead to PEPT, these are discussed in Chapter Two.

- This study investigates the impact of PEPT as a result of dental caries on the need for orthodontic treatment. Participants who had PEPT under local anaesthetic (LA) in the dental practice were identified during data collection. Those extractions will be referred to as PEPT under LA.
- Dental caries refers to dentinal caries which is used frequently in national oral health surveys.
- The research team consisted of the Chief Investigator/principal supervisor and co-supervisors, and occasionally the orthodontic panel and data collection team.
- The titles ‘Bradford Smile Study’ or ‘PLATOON’ (Premature Loss of primAry Teeth and its impact On the Orthodontic Need) were used to refer to this study

Chapter Two: Literature Review

2.1 Setting the scene

Dental caries is the main reason for extracting primary teeth, despite it being a preventable disease. Many young children are still being admitted to hospital for dental extractions of carious primary teeth. In England, among children aged 6-10 years, dental caries continues to be the leading cause of hospital admissions (OHID, 2023a). Findings from the National Dental Epidemiology's Oral Health Survey of five-year-old children in England showed that 23.4% of children had carious primary teeth, of these, 10% had undergone at least one tooth extraction (PHE, 2020). A more recent survey for the same age group showed similar figures, with 23.7% of children having dental caries, and an average of 3.5 carious primary teeth per child (OHID, 2023b). Out of these, 6.8% had experienced at least one tooth extraction. The survey also highlighted that in the most deprived areas, children were three times more likely to experience dental caries compared to those in the least deprived areas (35.1% vs 13.5%). Notably, hospital admissions for tooth extraction due to dental caries in children under 19 years had cost the National Health Service (NHS) £33 million between 2019 and 2020 (PHE, 2021).

The United Kingdom Government focuses on reducing oral health inequalities through initiatives that promote awareness of oral health and the implementation of effective prevention policies (PHE, 2018a). In England, the findings from the Children's Dental Health Survey indicate positive progress in reducing the prevalence of dental caries in primary teeth over the years.

However, children from deprived households did not show substantial improvements in their oral health (Masood et al., 2019). These children are more likely to require tooth extractions under general anaesthetic (GA) due to the increased dental needs and higher rates of dental caries. While GA is generally a safe procedure when administered by trained professionals in the proper clinical setting, it still carries some risks (SDCEP, 2018).

A statement from the British Dental Association highlights the ongoing issue concerning dental caries as a significant public health problem: "Tooth decay is still going unchallenged as the number one reason for hospital admissions among young children. Decay and deprivation are going hand in hand, and this inequality is set to widen. None of this is inevitable. This government needs to be willing to take off the gloves when it comes to fighting a wholly preventable disease" (BDA, 2023). This highlights the need for adopting a comprehensive and proactive approach to oral health, particularly for children coming from deprived backgrounds.

2.2 The importance of primary teeth for children's oral health and their well-being

Primary teeth play a major role in the oral health and well-being of children. They support essential functions such as mastication, which facilitates digestion, and they contribute to speech development. Furthermore, healthy primary teeth can have a positive impact on a child's self-esteem, enabling them to engage in social interactions with confidence. These primary teeth

also maintain the dental arch forms and dimensions until they are naturally replaced by their permanent successors (Rock, 2002).

2.3 Normal exfoliation times of primary teeth

Primary teeth begin to naturally exfoliate at approximately six years of age, starting with the primary mandibular central incisors, and continue until around 13 years of age for the primary second molars (Logan & Kronfeld, 1933). These timelines may exhibit slight variations among populations from different ethnic backgrounds. Following their exfoliation, primary teeth are replaced by their permanent successors. The period between primary teeth exfoliation and permanent successors emergence has been historically studied longitudinally (Nyström & Peck, 1989). It is believed that root development of permanent successors, along with alveolar bone remodelling, aid in facilitating tooth emergence of permanent successors (Marks & Schroeder, 1996). Table 2.1 provides a summary of exfoliation times for primary teeth and the period between primary teeth exfoliation and permanent teeth emergence.

Table 2.1 Exfoliation times for primary teeth and period between primary teeth exfoliation and permanent successor emergence

Tooth	Exfoliation time*		Mean length of toothless period**	
	Maxillary	Mandibular	Maxillary	Mandibular
Central incisors	7-8 years	6-7 years	6 weeks	2 weeks
Lateral incisors	8-9 years	7-8 years	4 months	6 weeks
Canines	11-12 years	9-11 years	4 months	6 weeks
First Molars	9-11 years	10-12 years	0-6 days	0-6 days
Second Molars	9-12 years	11-13 years	0-6 days	0-6 days

*(Logan & Kronfeld, 1933)

**(Nyström & Peck, 1989)

2.4 Deviation from normal exfoliation of primary teeth: early loss of primary teeth

Primary teeth can be lost prematurely due to extraction or other reasons. Premature extraction of primary teeth (PEPT) can be defined as the extraction of primary teeth before their physiological exfoliation time (Bhujel et al., 2016). When PEPT takes place several years ahead of the normal exfoliation time, it can disrupt the eruption pattern of their permanent successors. This is because permanent successors with immaturely developed roots require a longer time to erupt. Moreover, the permanent teeth adjacent to the extraction site, mainly the permanent first molars, can erupt ahead of the eruption time of permanent successors and subsequently drift into the space, resulting in space loss (Clinch, 1972; Rönnerman, 1977; Magnússon, 1979; Tunison et al., 2008; Kaklamanos et al., 2017). This is developed further in section 2.8.2.1 Space loss and malocclusion.

2.5 Dental caries in the primary dentition

Dental caries remains as the primary cause of PEPT in young children. Traditionally, risk factors were studied among populations from different ethnic backgrounds to understand the aetiology of dental caries. In the realm of oral health, this approach suggests that poor plaque control, poor dietary habits including high frequency of sugar intake, and lack of fluoride exposure, are the main risk factors for the development of dental caries (PHE, 2018a).

However, the life course approach suggest that the initiation and development of dental caries result from interconnected pathways that may have originated before conception (Fisher-Owens et al., 2007). These pathways are complex and can be associated with biological, environmental, behavioural, psychological, and socioeconomic risk factors (Fisher-Owens et al., 2007; Kim Seow, 2012). While dental caries in the primary dentition is a strong predictor for dental caries in the permanent dentition (Powell, 1998), the literature shows that risk factors tend to accumulate across the life course, resulting in carious teeth that are either unrestorable or have a poor prognosis, necessitating extraction (Fisher-Owens et al., 2007; Kim Seow, 2012). These risk factors can even be transmitted from one generation to another (Shearer & Thomson, 2010; Shearer et al., 2012).

Birth cohort studies serve as a valuable tool to understand the complex interactions of oral health determinants that contribute to the development of

dental caries across the life course. One of the largest birth cohort studies is the 1970 British Cohort Study, of more than 17,000 babies born in one week in April 1970 in the UK (Sullivan et al., 2022). This study found that parents with poor health literacy were less likely to utilise preventive dental services for their pre-school-aged children (Goodman, 1986). It is worth noting that baseline dental data for these children were not initially collected.

Another significant study, the Pelotas Birth Cohort, established in 1982 and based in Brazil, involved over 5,900 births from that year (Victora & Barros, 2006). Findings from this study showed an association between deprivation and the persistence of poor oral health from childhood into adulthood, and caries development in adulthood (Peres et al., 2011).

The Dunedin Study of more than 1,000 births in New Zealand between 1972 and 1973, has one of the highest retention rates reaching 95% of participants remaining engaged between 2010 and 2012 (Poulton et al., 2015). Results from this cohort showed that children of parents who had experienced permanent tooth extractions due to dental caries were more likely to have missing teeth due to dental caries (Shearer et al., 2012). Furthermore, the study found that deprivation was a major risk factor for developing dental caries in primary teeth and across the life course (Hong et al., 2020).

2.5.1 Impacts of dental caries in the primary dentition

Failure to look after primary teeth can result in dental caries at a very young age, known as early childhood caries (AAPD, 2008). Early childhood caries is more prevalent in children living in deprived areas and can have long-lasting effects on their oral and general health. Untreated carious primary teeth can cause dental pain and infection that may require hospitalisation. Dental pain can disrupt the child's ability to eat or drink, consequently resulting in dehydration, malnutrition, and impaired growth and development (Finucane, 2012). Moreover, dental pain can disturb sleep patterns (Goodwin et al., 2015; SDCEP, 2018) and concentration in children, thus affecting their performance at school (Guarnizo-Herreño & Wehby, 2012). Children with dental caries also tend to be more shy and unhappy, which can affect their self-esteem and social interactions (Guarnizo-Herreño & Wehby, 2012).

The impact of dental caries in primary teeth can extend to the child's family as well. In a questionnaire-based study involving 1,131 pairs of parents and their children aged 2-4 years old, 24% of parents reported feeling guilty about their child's dental problems (Carvalho et al., 2018). The same study found a significant association between the feeling of guilt and the presence of early childhood caries, along with the perception that dental caries is preventable. Similarly, a study based on 3,879 parental surveys from the Children's Dental Health Survey 2013 showed comparable results concerning the feeling of guilt among parents of children with severe dental caries (OR=5.4, 95% CI=2.9-9.9, P<0.001) (Abed et al., 2019).

2.6 Management options of dental caries in primary teeth

2.6.1 Restorative treatment

Dental guidelines urge clinicians to put in every effort to restore carious primary teeth where possible (Fayle et al., 2001; AAPD, 2016; SDCEP, 2018; Duggal et al., 2022). The choice of restorative techniques can vary widely in the literature. Early identification and treatment of dental caries allow for the use of less invasive techniques and make it easier to restore teeth rather than extract them. In certain cases, the biological management of dental caries in the primary dentition can be provided utilising the use of 38% Silver Diamine Fluoride (SDCEP, 2018; Duggal et al., 2022) or the Hall Technique (Innes et al., 2007; SDCEP, 2018; Duggal et al., 2022). Primary teeth with deep carious lesions and no signs and symptoms of infection can be managed by indirect pulp therapy or pulpotomy. In cases where signs and symptoms of infection are present, pulpectomy can be considered in primary teeth (SDCEP, 2018), particularly in cases where occlusion may be compromised due to space loss resulting from premature extraction (Duggal et al., 2022).

Dental treatment can be provided by utilising a combination of non-pharmacological and pharmacological behavioural management techniques. Non-pharmacological behavioural managemental techniques encompass a range of techniques that do not involve the use of drugs, such as tell-show-do, enhancing the child's sense of control, and positive reinforcement. Conversely, pharmacological behaviour management involve the use of drugs to facilitate dental treatment using local anaesthetic (LA), inhalation sedation, or general anaesthetic (GA) (SDCEP, 2018). It is crucial to evaluate the child's

cooperative ability and the number of carious teeth requiring treatment when deciding on the most suitable behavioural management technique for the child**.** Dental treatment under LA can be distressing for both the child and their parent, especially in young children with limited cooperative abilities. A questionnaire-based study involving 1,437 parents inquiring about their five-year-old child's anxiety towards dental treatment, found that 10.8% parents reported that their child had dental anxiety (Milsom et al., 2003). These anxious children had a higher number of carious teeth compared to their non-anxious peers (dmft 2.6 and 1.1 respectively). Pre-cooperative and anxious children with extensive dental needs may not cooperate for dental treatment under LA or inhalation sedation, necessitating dental treatment under GA (full mouth rehabilitation or extractions).

In the case of GA, a definitive treatment plan should be tailored to the child's best interest. Therefore, it has been recommended that teeth with dubious prognosis should be extracted to prevent relapse and the need for a second GA. One study showed that 29.4% (n=30/102) of children aged under six years developed at least one new carious lesion within 12 months following full mouth rehabilitation under GA (Amin et al., 2010). Hence, in some cases, extractions may be more sensible than full mouth rehabilitation, particularly for children with high rates of dental caries requiring dental GA.

2.6.2 PEPT

The primary cause of PEPT among young children is dental caries. As previously mentioned in section 2.6.1 Restorative treatment, carious primary teeth with signs and symptoms of infection that have a poor prognosis and cannot be restored are often extracted to prevent complications such as systemic spread of infection (SDCEP, 2018).

Other reasons for premature tooth loss may include dental traumatic injuries to anterior primary teeth which can result from immediate avulsion or delayed loss due to root resorption and tooth mobility as a result of trauma (Holan & Needleman, 2014). In rare cases, systemic diseases like Papillon–Lefèvre syndrome can lead to periodontal disease, causingthe loss of tooth attachment and early loss of affected primary teeth (Spodzieja & Olczak-Kowalczyk, 2022). Primary canines may be lost prematurely when the permanent lateral incisors begin to erupt (SDCEP, 2018). In situations with crowded dental arches, some dentists may consider balancing extraction of primary canines and primary first molars to avoid centreline shift (Rock, 2002). Primary second molars may also be lost prematurely in severe cases of ectopic eruption of permanent first molars (Bjerklin & Kurol, 1983). In such cases, the pressure excerted from the erupting permanent first molars can result in complete root resorption of the second primary molars, ultimately leading to their early loss.

2.6.3 Provision of space maintainers

The provision of space maintainers can help minimise the negative consequences of PEPT on the developing dentition, particularly when primary molars are extracted at an early age, several years before their natural exfoliation time (Rock, 2002; Fields & Proffit, 2019). However, several factors should be considered and the benefits of the space maintainer should outweigh the risks. When several teeth are prematurely lost in the same quadrant, especially primary molars, the options for space maintenance become limited, (Ahmad et al., 2018). In cases where space loss has occurred, treatment during the developing dentition may be necessary to control any unfavourable development and deviations from a normal occlusion (McNair & Morris, 2010; AAPD, 2022). However, in situations with excessive space loss, an intervention may complicate the existing occlusion.

The decision to place a space maintainer also necessitates meticulous oral hygiene maintenance. The median survival time of space maintainers was found to be 18 months (Rajab, 2002). Fixed space maintainers can fail for various reasons, including cement failure, solder failure, or gingival inflammation (Ramakrishnan et al., 2019). Furthermore, timely placement of space maintainers is critical since space loss can occur as early as eight weeks following PEPT (Tunison et al., 2008). In fact, in many instances, space had already been lost before the extractions due to the severe breakdown of carious primary teeth (Northway & Wainright, 1980).

2.7 Prevalence of PEPT

A study analysed data from the Hospital Episodes Statistics database (1997 to 2006) found that 80% of children aged up to the age of 17 years who were admitted for dental treatment (n=470,113) had dental extractions, with the highest occurrence of PEPT observed at the age of five years old (Moles & Ashley, 2009). The same study had also identified an annual increase in the number of hospital admissions for tooth extraction due to dental caries. In England, nearly 2.4% of five-year-old children have undergone PEPT, with the highest proportion (4.1%) found in Yorkshire and The Humber (PHE, 2018b). In Bradford, about 800 children undergo PEPT under GA every year, and on average, eight primary teeth are extracted (Bradford District Care NHS Foundation Trust, 2015).

More recent figures show that in England, 23.7% of five-year-olds have dental caries in their primary teeth, with 6.8% of these children having had at least one tooth extracted (OHID, 2023b). In Bradford, the proportion of five-year-old children with dental caries was 23.4%, and of these, 7.3% had undergone PEPT.

2.8 Impact of PEPT

PEPT can have significant impact on different aspects of the child's oral health and well-being in the short, intermediate, and longer term.

2.8.1 Short term impact (following dental care, either by full mouth rehabilitation or extractions)

Early childhood caries can have a negative impact on children and their parents. A systematic review and meta-analysis of 24 cross-sectional studies found that children aged under six years who experienced dental pain due to early childhood caries had poor oral health-related quality of life (OH-RQoL), as reported by their parents (Zaror et al., 2022). It is anticipated that eliminating the source of dental pain would have a positive impact on children's OH-RQoL and improve their ability to eat and sleep. In a prospective study of 29 participants aged three years, children with early childhood caries who received dental treatment under GA exhibited improvements in their eating and sleeping patterns and were able to catch up growth 16 months post-GA (Acs et al., 1999).

Another UK based prospective study, which included 51 participants aged under six years, who received dental treatment under GA, including PEPT (n=27), found a positive impact on oral health, functional, and emotional well-being of the child, as reported by their parent (Malden et al., 2008; de Souza et al., 2017). However, the sample size (n=78, 27 with PEPT) was not sufficient to detect differences in OH-RQoL between both treatment approaches, full mouth rehabilitation and PEPT. A systematic review aimed at reviewing the change in OH-RQoL in children following dental treatment, including PEPT, under GA, concluded that OH-RQoL improved in various aspects such as oral, socio-emotional, and functional well-being (Jankauskiene & Narbutaite, 2010). The studies included in the review, which

consisted of 10 clinical trials and one randomised controlled trial, did not specify which dentition was being treated. However, it was anticipated that studies involving participants under the age of six years received treatment for their primary dentition (Jankauskiene & Narbutaite, 2010).

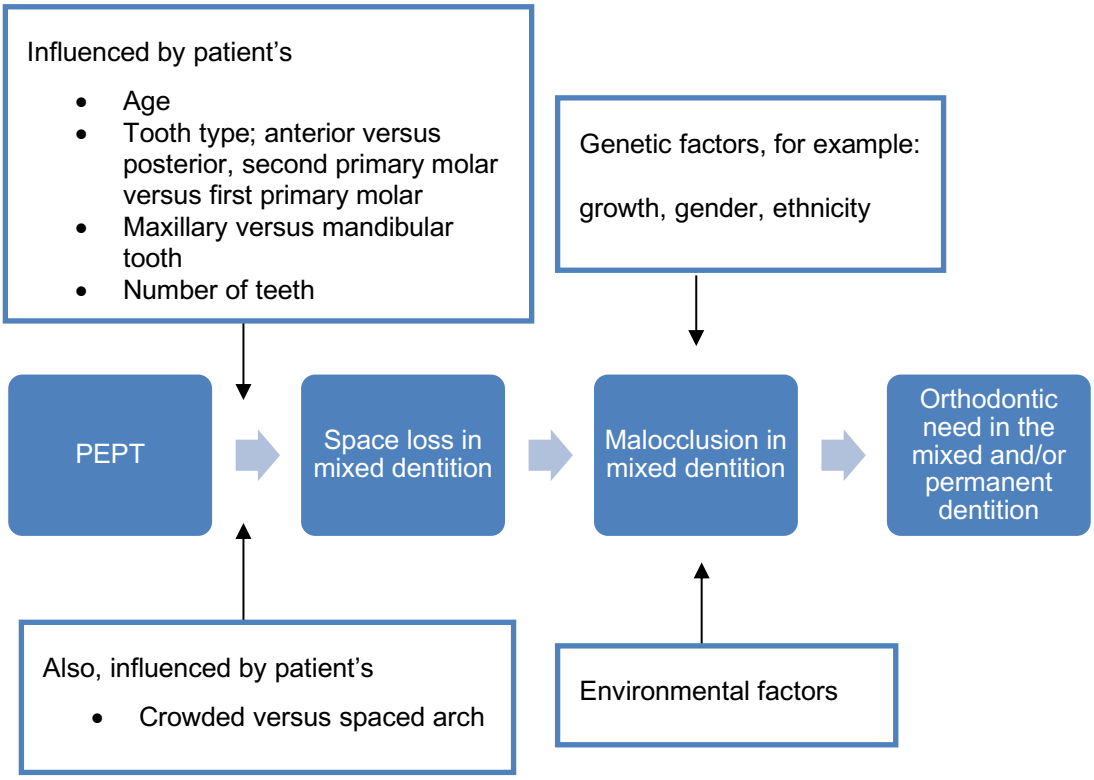
2.8.2 Intermediate and longer-term impact

In the intermediate or longer term, it is anticipated that PEPT could lead to unfavourable outcomes in various aspects, including space loss, malocclusion, OH-RQoL, and health economics (Bhujel et al., 2016; PHE, 2018).

2.8.2.1 Space loss and malocclusion

Understanding the impact of PEPT on space loss and malocclusion is crucial for clinical decision-making and the management of early childhood caries (AAPD, 2008). The aetiology of malocclusion is multifactorial, involving the complex interaction between both inherited genetic and environmental factors. Genetic factors include growth, gender, and ethnicity while environmental factors include PEPT (Mitchell, L., 2019). Figure 2.1 shows a schematic flowchart that illustrates how space loss following PEPT, and in conjunction with other factors, may influence the future need for orthodontic treatment.

Figure 2.1 A schematic flowchart illustrating how PEPT may lead to malocclusion *



*(Bhujel et al., 2016)

As previously mentioned in section 2.4 Deviation from normal exfoliation, when PEPT occurs at a very young age, several years before the natural exfoliation time, it increases the chances of adjacent teeth to drift and lose space. The severity of space loss is influenced by several factors, including the type of tooth extracted, the child's age, and the degree of crowding. Research indicates that space loss is more profound following premature extraction of primary second molars compared to primary canines and primary first molars (Clinch, 1972). The latter can lead to centreline shifts, mainly in crowded dentitions, while the premature extraction of primary incisors has little to no effect on space loss (Rock, 2002).

Moreover, extracting maxilllary primary teeth often result in greater space loss due to the mesial migration of posterior teeth relative to the extraction site, as compared to the mandibular primary teeth (Clinch, 1972; Northway et al., 1984). In the mandible, space loss primarily occurs because of the ‘lack of forward growth of teeth anterior to the extraction site’ (Clinch, 1972). Crowded dentitions tend to experience faster space loss (Rock, 2002), although the cuspal intelock of the upper and lower teeth can reduce the extent of space loss (Clinch, 1972).

A few studies have attempted to understand changes in malocclusion following PEPT, particularly during the transition from the primary to the mixed or permanent dentitions. However, these studies have often lacked long-term follow-up.

One longitudinal study followed-up 107 children aged six years, of these, 61% (n=71/107) had a history of PEPT (Northway et al., 1984). Yearly assessments showed that forward movement of permanenet first molars following PEPT was the primary cause of space loss. The rate of space loss was more profound in the first years following PEPT, and primary second molars had a detrimiental effect on permanent molar relationship. These findings align with those of other studies (Rönnerman, 1977).

Another longitudinal study, which collected baseline data from children aged 4.5-5.5 years (n=128), found that eight years later, 70% of those initially assessed with normal occlusion in their primary dentition developed malocclusion in their permanent dentition. Of these, 16.4% had a history of PEPT (Legovic & Mady, 1999).

2.8.2.2 Orthodontic treatment need

As mentioned in the previous section (2.2.2.1 Space loss and malocclusion), it is worth noting that following space loss in the developing dentition, teeth may exhibit varying degrees of malocclusion. Severe forms of malocclusion often benefit from orthodontic treatment (Gibas-Stanek & Loster, 2018). However, the existing literature lacks strong evidence regarding how PEPT impacts the need for orthodontic treatment.

Findings from the Pelotas 1993 birth cohort study in Brazil suggested that malocclusion in the primary dentition can increase the need for orthodontic treatment in the mixed dentiton (Peres, 2015). Malocclusion was assessed based on features such as the presence of any or all of the following: crossbite, open bite, and canine malocclusion. A retrospective study conducted by the research group at the University of Leeds aimed to investigate the impact of PEPT on the orthodontic need in the permanent dentition in 12-year-old children (Bhujel et al., 2014). They identified 66 participants out of 107 with a history of PEPT and found a positive association between the increased total number of prematurely extracted primary teeth

and the need for orthodontic treatment (Odds ratio=1.18, 95% confidence interval=1.01-1.37, *P*<0.001). However, the design of the study and limited number of participants may have limited the generalisability of the findings.

The same group conducted a systematic review on the impact of PEPT on the subsequent need for orthodontic treatment (Bhujel et al., 2016). This review included 15 studies, with 13 being cohort studies (either prospective or retrospective), and two controlled trials (one randomised). The authors concluded that malocclusion features contributing to the increased need for orthodontic treatment were more prevalent following PEPT and included features such as at least a 2mm space discrepancy, at least a 6mm increased overjets, and at least half a unit of Class II or III malocclusion. In addition, none of the studies included in their systematic review quantified the impact of PEPT on the orthodontic need using a validated index.

The number of children in need of orthodontic treatment in England is notably high. Data from the Child Dental Health Survey in 2013 showed that in England, 45% of 12-year-olds and 38% of 15-year-olds were assessed in need of orthodontic treatment or had already started orthodontic treatment (Holmes et al., 2015). In the Bradford and Airedale region, approximately one third of 12-year-olds, estimated at 2007 children, required orthodontic treatment annually (Godson et al., 2012).

2.8.2.2.1 Measure of the orthodontic need in the mixed dentition

Historically, the assessment of the need for orthodontic treatment was based on individual malocclusion characteristics, such as crowding or the sequence of permanent tooth eruption (Rönnerman, 1977; Pedersen et al., 1978). However, using these characteristics or any other occlusal index may be an unreliable method for determining orthodontic need, particularly in the mixed dentition. A cross-sectional study involving 915 Italian children aged 8-16 years, of whom 204 had a history of PEPT, found that participants with PEPT had an increased need for orthodontic treatment (60%) compared to participants with no-PEPT (42%) (Melsen & Terp, 1982). The authors of this study assessed the need for orthodontic treatment using three criteria: dental anomalies, occlusal anomalies, and deviations in space conditions.

Since the 1960s, researchers have proposed several indices to facilitate the screening of children and young adults and assess their eligibility for orthodontic treatment need. The provision of orthodontic treatment should aim at improving both function and aesthetics. It is worth noting that these indices do not diagnose malocclusion; instead, they record the severity of various malocclusion features to aid in decision-making and the provision of orthodontic treatment. Table 2.2 provides a summary of the various indices used to measure orthodontic need.

Table 2.2 Indices measuring the orthodontic need

Index	Year developed	Malocclusion features	Grades/scoring
Handicapping labio-lingual deviation index	1960	• Cleft palate • Traumatic deviation • Overjet • Overbite • Mandibular protrusion • Open bite • Labio-lingual spread	A score of 13 or over constitutes a physical handicap that requires orthodontic treatment
Swedish medical board index	1966	• Various characteristics of malocclusion, considers subjective views and patient's wishes	• 5 grades (4 very great need to 0 no need)
Dental Aesthetic Index	1986	• Overjet • negative overjet • tooth loss • diastema • anterior open bite • anterior crowding • anterior diastema • width of the anterior irregularities (mandible and maxilla) • antero-posterior spring relationship	• a score lower than or equal to 25 (no or slight treatment need) • a score between 26 and 30 (elective treatment) • a score between 31 and 35 (treatment highly desirable) • a score greater than 36 (treatment mandatory)
Index of Orthodontic Treatment Need (IOTN)	1989	• Aesthetic component (IOTN-AC): ○ Malocclusion of varying severity • Dental health component (IOTN-DHC): MOCDO ○ **M**issing teeth ○ **O**verjets ○ **C**rossbites ○ **D**isplacement of contact points ○ **O**verbites	• IOTN-AC: 10 coloured intra-oral photographs ranked based on attractiveness (grade 10 very great need to grade 1 no need) • IOTN-DHC: 5 grades and 30 subgrades (grade 5 very great need to grade 1 no need)
Index of Complexity, Outcome and Need	2000	• IOTN-AC • Upper arch crowding • Upper arch spacing • Incisor open bite • Incisor overbite • Buccal antero-posterior relationship	• 5 (greater need, more complex) to 0 (no need, less complex) to

*Adapted from (Farahani, 2011)

In England, the NHS utilises the Index of Orthodontic Treatment Need (IOTN) to determine the eligibility of orthodontic treatment for children under 18 years of age, based on the severity of malocclusion in the permanent dentition. The IOTN, initially developed by Brook and Shaw in 1989 (Brook & Shaw, 1989). consists of two components, the Dental Health Component (IOTN-DHC) and the Aesthetic Component (IOTN-AC).

Assessing the need for orthodontic treatment during the mixed dentition stage can be challenging due to variations in eruption patterns. Assessments made during this stage may not be as accurate as those conducted in the permanent dentition because the dynamic nature of the mixed dentition makes it difficult to assess aesthetics as the child continues to grow (Daniels & Richmond, 2000).

Earlier research has indicated that the use of the IOTN-AC tends to overestimate the need for orthodontic treatment during the mixed dentition stage. This overestimation is often linked to certain malocclusion features, such as an increased overjet, which tends to decrease as a child undergoes further growth, hence reducing the need for orthodontic treatment (Tarvit & Freer, 1998).

In a study that compared orthodontic treatment need using both the IOTN-DHC and IOTN-AC in participants aged nine, 12, and 15 years (Boronat-Catala et al., 2016), it was observed that participants aged nine years

exhibited lower agreement in IOTN-AC assessments (kappa 0.18) compared to those aged 12 (kappa 0.45) and 15 (kappa 0.41). The greatest diversity in IOTN-AC assessments was found in participants aged nine and 15 years. This variation was primarily due to the overestimation of orthodontic treatment need in relation to malocclusion features that tend to improve as the child grows, such as overbite and upper midline diastema.

An earlier study also reported higher kappa values for assessments using the IOTN-DHC (inter-examiner values of 0.73 to 0.80). However, these assessments were conducted in children aged 11-12 who were in the permanent dentition (Brook & Shaw, 1989). Therefore, it was suggested that IOTN-DHC is more stable over time and less influenced by changes during the child's transition from mixed to permanent dentition, especially when compared to the IOTN-AC (Boronat-Catala et al., 2016).

2.8.2.3 OH-RQoL

As mentioned previously in section 2.8.1 Short term impact, PEPT can improve the OH-RQoL of children in the short term. However, the literature lacks sound evidence that quantifies the long-term impact of PEPT on the OH-RQoL.

Tooth loss due to dental caries in the permanent dentition has been associated with poor OH-RQoL (Gerritsen et al., 2010). However, there is limited evidence to support the impact of PEPT on children's OH-RQoL. A

recent prospective observational cohort study, involving a relatively small number (n=163) of 6-8-year-old children, investigated the impact of PEPT on OH-RQoL (Feu et al., 2022). OH-RQoL was assessed at baseline and after 12 months for participants with and without PEPT. The study findings showed that OH-RQoL was poorer for children with PEPT at baseline but improved at the follow-up, with routine access to dental care potentially acting as a confounding factor. One systematic review assessed the change in OH-RQoL in children under 16 years who underwent dental GA for the management of dental caries, including PEPT (Knapp et al., 2017). The included studies (20 studies) had varying follow-up times, ranging from one to nine months, and used different instruments to measure OH-RQoL based on the child's and their parent's perceptions. The authors concluded that OH-RQoL was likely to improve in the several months following GA.

Malocclusion can have a negative impact on the OH-RQoL (Sun et al., 2018; Alrashed & Alqerban, 2021). The literature hints at an association between severe malocclusion and poor OH-RQoL (Sun et al., 2017). One study found that adolescents with malocclusion expressed concerns related to 'teeth appearance, social interaction, and oral health and function' (Patel et al., 2016), with more females wanting their teeth to be 'straightened' compared to males (Holmes et al., 2015). A comprehensive analysis of 4,217 participants in the 2013 Children Dental Health Survey showed that malocclusion was associated with poor OH-RQoL in 56.8% (n=1,967) of 15 year olds (OR=1.95, 95% CI=1.4-2.7, $P<0.05$) (Ravaghi et al., 2019). Consistent with these findings, other studies also indicated that malocclusion was found to

negatively impact OH-RQoL in participants aged 15-18 years (Masood et al., 2013; Alrashed & Alqerban, 2021).

In a systematic review on the impact of orthodontic treatment on OH-RQoL in children aged under 18 years, 13 studies were included, comprising eight cohort studies, three cross-sectional studies, and one case-control study (Javidi et al., 2017). The quality of the evidence was not strong enough to conclude that orthodontic treatment improves OH-RQoL in children.

2.8.2.3.1 Measure of OH-RQoL

Several tools that have been developed and validated for oral health research, aimed at measuring children's OH-RQoL (Genderson et al., 2013). These tools comprise a series of questions and domains to assess the overall well-being of children, covering their oral health, functional, and socioemotional well-being. Each tool may focus on specific areas such as OH-RQoL before and after dental care or treatment outcomes, providing a subjective perspective from the child or a perceived perspective from an observer like their parent. Different tools that measure OH-RQoL in children are summarised in Table 2.3.

Table 2.3 Tools for measuring OH-RQoL in children

Tool	Year developed	Age group	Number of items
Child Perceptions Questionnaire 11-14 (CPQ $_{11-14}$)	2002	11-14 years	37
Child Perceptions Questionnaire 8-10 (CPQ $_{8-10}$)	2004	8-10 years	25
Child Oral Impacts on Daily Performances (COIDP)	2004	10-12 years	8
Early Childhood Oral Health Impact Scale (ECOHIS)	2007	3-5 years	13
Child Oral Health Impact Profile (COHIP)	2007	7-18 years	34
Paediatric oral health-related quality of life (POQL)	2011	2-12 years	20
Short form of COHIP (COHIP-SF 19)	2012	7-18 years	19

The COHIP-SF 19, a shortened version derived from the COHIP questionnaire, has been validated for the use among children aged 7-18 years (Broder et al., 2012). Within this study involving 1,175 participants, 107 had increased orthodontic needs. Despite the reduced number of questionnaire items, this self-reported measure was found to be a sound measure for assessing OH-RQoL in school-age-children.

2.8.2.4 Health economics

Dental care, including procedures like PEPT under GA or LA, along with orthodontic treatment for malocclusion, can result in a substantial economic burden on both the child's family and health services. This economic burden includes direct and indirect costs. Direct costs can represent the total expenses associated with dental treatment, while indirect costs capture losses related to productivity due to oral diseases, such as dental caries in primary teeth (Listl et al., 2015). Examples of indirect costs include time off school,

time off work, and expenses related to traveling to healthcare facilities. In North West hospitals in England, approximately 26% of missed school days were linked to children who had PEPT (PHE, 2017a). Moreover, working parents might need time off from work to accompany their child to dental appointments or hospital visits.

According to the World Health Organization (WHO), more than 5% of the total health expenditure is spent on dental treatments (WHO, 2018). In England, the total funding for NHS primary care dentistry was £2,920 million between 2018 and 2019 (NAO, 2020).

2.8.2.4.1 Costs associated with PEPT in children

In England, tooth extraction in children under 19 years of age had cost the NHS over £50 million between 2015-2016 (PHE, 2018b). Between 2019 and 2020, hospital admissions for tooth extractions due to dental caries in children under 19 years of age had cost the NHS £33 million (PHE, 2021). This figure increased in financial year 2021-2022, costing the NHS more than £50 million (OHID, 2023a). Notably, a considerable number of children under five years of age (9,306) were admitted to hospital for tooth extractions, costing the NHS over £7.5 million (PHE, 2018b).

2.8.2.4.2 Costs associated with orthodontic need

In the financial year 2015-2016, orthodontic treatment accounted for approximately £3.4 billion of the NHS dental primary care budget in England

(NHS Digital, 2016). In Bradford and Airedale, the total cost of orthodontic treatment for patients seen in 2009 was £649,064, rising to £854,851 for patients seen in 2010 and 2011 (Godson et al., 2012).

2.9 The Born in Bradford (BiB) cohort

2.9.1 About BiB

The BiB is a population-based longitudinal, prospective study that was established in 2007, comprising a cohort of over 13,740 children born at Bradford Royal Infirmary between March 2007 and December 2010. (Wright et al., 2012). This longitudinal study aims at investigating the causes of health and disease of these children. The cohort comprises a considerable proportion of South Asian origin (50.1%) and exhibits high levels of deprivation, making it potentially representative of other similarly deprived communities in England.

2.9.2 What makes BiB a suitable cohort

The BiB offered a unique opportunity to investigate the impact of PEPT on the need for orthodontic treatment. As mentioned previously in section 2.1 Setting the scene, dental caries is strongly associated with deprivation. Bradford has a multiethnic population with high levels of deprivation (Conway et al., 2007). Therefore, it was anticipated that the levels dental caries in the primary dentition and PEPT would be high. Among five-year-olds, the proportion of dental caries in deprived children in England was more than twice that of less deprived children (34.3% and 13.7% respectively), with children in Bradford

showing the highest proportion of PEPT at a prevalence of 23.1% (PHE, 2020).

Prior to the commencement of the study, children in the cohort were between seven and 13 years old, representing diverse ethnic backgrounds. With the majority being in the mixed dentition, collecting data during this phase would provide a unique opportunity for future observational longitudinal studies as these children develop into their permanent dentitions. Longitudinal data collection will enable the assessment of the accuracy of IOTN-DHC predictions made during the mixed dentition and help quantify the impact of PEPT on the orthodontic need during this stage using a validated index such as the IOTN-DHC.

Chapter Three: Methods

3.1 Aim and objectives

3.1.1 Aim

The primary aim was to investigate the impact of premature extraction of primary teeth (PEPT) on the assessed orthodontic need based on the Index of Orthodontic Treatment Need (IOTN) in a cohort of children aged 7-11 years, participating in the Born in Bradford (BiB) birth cohort.

The secondary aims were:

a. to understand the association between PEPT and oral health-related quality of life (OH-RQoL) of BiB children in the mixed dentition
b. to estimate the cost difference between two different outcomes: the need and no need for orthodontic treatment among children with PEPT

3.1.2 Objectives

1. To compare a group of BiB children, aged 7-11 years, who have undergone PEPT with a similar cohort of children who have not undergone PEPT (no-PEPT) in regard to:
    a. The proportions assessed by specialist orthodontists to need orthodontic treatment based on the Dental Health Component of the IOTN (IOTN-DHC)
    b. The proportions predicted to need treatment now in the mixed or later in the permanent dentition

   c. To explore whether socio-demographic characteristics such as age, gender, ethnicity, and socioeconomic status influenced the need for orthodontic treatment

2. To compare OH-RQoL in a group of BiB children, aged 7-11 years:
   a. with and without PEPT
   b. who were assessed in need and no need of orthodontic treatment
   c. to explore whether socio-demographic characteristics such as age, gender, ethnicity, and socioeconomic status influenced the OH-RQoL
3. To estimate the cost associated with the two different outcomes, need and no need for orthodontic treatment

3.2 Null hypothesis

- Based on the Dental Health Component-Index for Orthodontic Treatment Need (IOTN-DHC) assessment, the proportions assessed to be in need of orthodontic treatment did not differ between PEPT and no-PEPT participants

3.3 Design and methods

3.3.1 Study design

This was an observational cross-sectional study embedded within a longitudinal birth cohort; the BiB cohort based in Bradford-England. Orthodontic need was assessed in participants with and without a previous

history of PEPT using the IOTN-DHC. Participants with PEPT were either identified via a previous data linkage study which linked participants who have undergone PEPT under general anaesthetic (GA) or verified during data collection by clinical evidence (further details are provided in section 3.3.3.1 Study Population).

3.3.2 Ethical approval

Research protocol V2 18.10.18 for this study was approved by the National Health Service (NHS) Health Research Authority Yorkshire and the Humber-Bradford Leeds Research Ethics Committee 18YH0440, Integrated Research Application System project ID 245132 and a protocol paper was published (Appendix 1.1). The study was funded by a grant from the British Orthodontic Society Foundation (Appendix 1.2). The study was eligible for portfolio adoption and National Institute for Health Research Clinical Research Network support through Bradford District Care Foundation Trust.

All research members had either completed or renewed the Good Clinical Practice training before commencement of the study. ‘The study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki (World Medical Association, 1964) and its later amendments or comparable ethical standards’.

3.3.3 Study setting, population and eligibility criteria

3.3.3.1 Study Setting

The data linkage study identified BiB children who had undergone PEPT under GA (further information is provided in section 3.3.3.2 Study population). The BiB data teams, were then able to collate a list of primary schools in Bradford by the numbers of BiB children and their study group (PEPT or no-PEPT) (Appendix 3.1). Those primary schools with the highest number of eligible BiB children were the first to be approached to take part in the study.

3.3.3.2 Study Population

BiB children aged 7-11 years who attended consented primary schools, were invited to take part in the study.

- The exposure group included BiB children who had undergone PEPT as a result of dental caries under GA or local anaesthetic (LA). BiB children who had PEPT under GA (n=1,139) were identified via an earlier data linkage study (Day, 2018). Data linkage also provided information on the age at the time of their operation, type and number of extracted primary teeth. BiB children who had PEPT under LA as a result of dental caries were identified via parental/child history collected as part of the consent form (Appendix 3.2) and verified by clinical evidence (clinical examination and/or photographs), where tooth loss did not correspond with the expected exfoliation patterns and dates and other carious teeth were present. In case the data team were unable to make a decision as to whether the participant had PEPT under LA, a meeting was held with the

Chief Investigator and uncertainties were resolved. If there was uncertainty the participant was considered as no-PEPT.

- The control group included BiB children who had not undergone PEPT (no-PEPT). To ensure participants in this group had not undergone PEPT under LA, parents and participants were asked about any history of primary tooth extractions with the information collected as part of the consent form (Appendix 3.2).

3.3.3.3 Eligibility criteria:

3.3.3.3.1 Inclusion criteria:

Inclusion criteria for the study population:

- An active participant in the BiB cohort, with parental consent to participate in the study and the child assenting at the study visit
- Aged 7-11 years

3.3.3.3.2 Exclusion criteria:

Exclusion criteria for study population:

1. Not an active participant in the BiB cohort or did not consent to participation in this embedded study within the wider BiB birth cohort
2. History or clinical evidence of extraction of any permanent tooth
3. History of orthodontic (brace) treatment
4. Currently undergoing orthodontic treatment
5. Cleft of the lip and/or palate

3.3.4 Recruitment

3.3.4.1 Data collection team

The data collection team comprised of a dental therapist, a research dental nurse, and the researcher/study coordinator. A dental therapist was recruited to perform the dental examinations and two research dental nurses were recruited to assist the dental therapist. Dental Core Trainees and a Clinical Research Network (CRN) Research Assistant joined the data collection team to help support the data collection process when required. Table 3.1 details the roles of the data collection team.

Table 3.1 Roles of the data collection team

Team member	Roles
Researcher/study coordinator	• Coordination between the data collection team members • Collection and return of consent forms from Bradford Institute for Health Research (BIHR) • Patient identification and reviewing consent • Overseeing data collection and quality assurance • Assisting participants with completion of the short form of the Child Oral Health Impact Profile (COHIP-SF 19) questionnaire • Issuing letter to parents/carers if urgent dental treatment was needed
Dental therapist	• Transfer of the dental research kit* • Set up space for dental examination • Infection prevention and control procedures • Dental examination, dental photography, and dental impression taking • Identification if there was an urgent dental need
Research dental nurse	• Transfer of the dental kit • Assisting the dental therapist • Communication with the dental laboratory for dental impression collection
Dental core trainee	• Patient identification and reviewing consent • Overseeing data collection and quality assurance • Dental examination • Assisting with COHIP-SF 19 questionnaire • Issuing a letter to parents if urgent dental treatment need was identified by the dental therapist during dental examination
CRN Clinical Study Officer	• Collection and return of consent forms from BIHR • Patient identification and reviewing consent

*Dental research kit (Appendix 3.3) comprised of all instruments and materials required for setting up a mobile dental clinic and data collection

3.3.4.2 School recruitment

The researcher used the list of primary schools by total number of exposures (Appendix 3.1), to identify and invite primary schools with the greatest numbers of BiB children with PEPT to take part in the study. Schools were contacted via email, over the phone, or by visiting the school. Schools interested in taking part were asked to sign a consent form (Appendix 3.4). School consent forms were stored on BiB warehouse (electronic copies) or in

a locked filing cabinet at BIHR (hard copies). The headteacher in each school assigned a point of contact (member of school staff) for future correspondence. The researcher liaised with the point of contact to meet up and discuss the logistics for the visit. This included Disclosure and Barring Service checks, examination room requirements, number of team members, school's policies (such as the use of electronic devices), preferred days for the visit, and duration of the visit. Also, the researcher discussed potential ways of giving back to the school as a way of saying thank you for taking part such as providing the school with a certificate of appreciation and taking part in careers week.

Following discussion of the logistics and agreement of study visit days, a follow-up email was sent to the point of contact for confirmation (Appendix 3.5). Before the day of the visit, a reminder email was sent to the point of contact to ensure that all preparations were made for the visit (Appendix 3.6).

3.3.4.3 Participant recruitment and consenting process

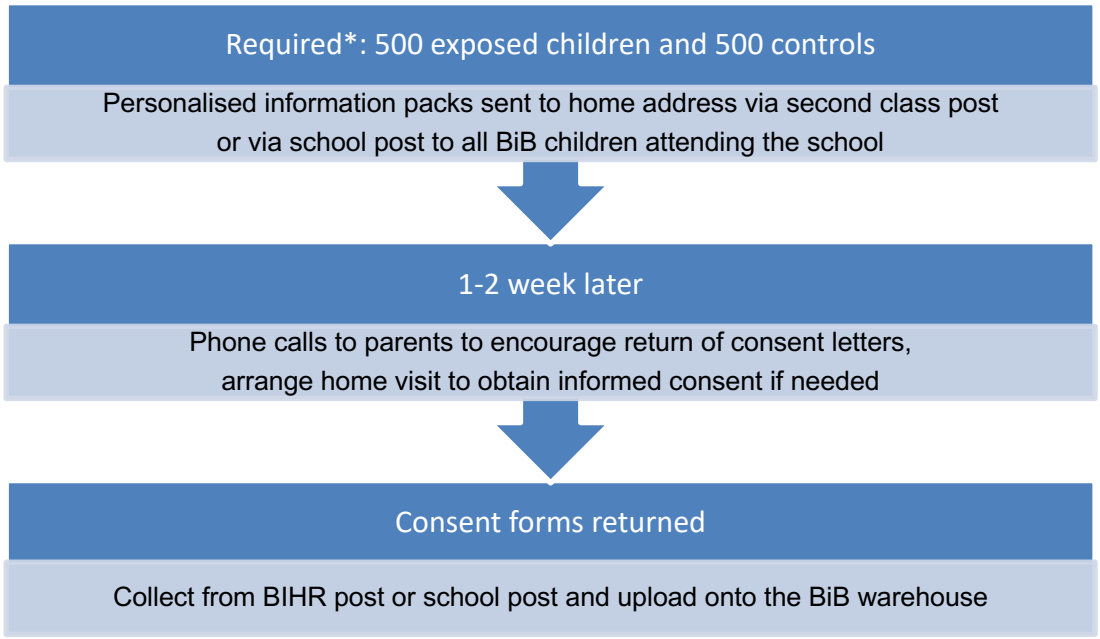
Information packs consisted of parent and child information sheets and consent forms that were developed and approved by the Chief Investigator. Following ethical approval and obtaining school consent, a password protected mail merge spreadsheet by consented school that includes BiB child's full name, date of birth, mother's name, school, home address, and contact number was requested from the BiB data team. This spreadsheet facilitated the print and preparation of personalised information packs (mail

merge). The information pack was printed on white A4 papers. Printing was undertaken at BIHR or at the approved print office within Bradford Teaching Hospital. Each pack comprised an A5 or A4 sealed envelope that was personalised with the BiB child's full name, date of birth, mother's name, school, and home address (BiB maintains a list of home addresses of all children who are participating in the study, the list is updated monthly with the NHS to ensure its accuracy). The envelope contained parent and child information sheets (Appendix 3.7 a-b), and two copies of consent forms (Appendix 3.2) (one to be sent back and the other one to be retained by the parent for their reference). Information packs were sent via second class post to the home addresses of all potential children in the identified and consented schools, or via the school post. Information packs that were sent via second class post contained prepaid postage for the parent to return the completed consent form to the study administration site, the BIHR. Information packs that were sent via the school post were transferred by the researcher or CRN Clinical Study Officer in a secure mailing pouch that was marked with 'If found, please return to BIHR' and handed to the point of contact. A tracking spreadsheet was created to assist the recruitment team chase-up parents and encourage them to take part.

The consenting was undertaken and supported by experienced CRN supported Clinical Study Officers. Those families who did not respond to the letter were contacted one to two weeks after sending the packs by CRN officers via phone and encouraged to send back the consent form or offered a home visit to discuss the study and consent if needed. Consent forms that

were returned by post were collected from BIHR by the BiB team and stored in a designated filing cabinet for the study. Consent forms that were returned to the school post were collected from the school by CRN officers and occasionally by the researcher and stored in the filing cabinet. CRN officers uploaded the consent forms to the web-based platform that was developed for the study by the BiB data team. Figure 3.1 outlines the process for recruitment of participants into the study.

Figure 3.1 Recruitment and consenting process



*Required: based on sample size calculation

A participant information YouTube video was produced to provide the BiB parent and their child with an overview of the data collection process at school. A consented child was filmed while their teeth were examined, and while intra and extra-oral photographs and dental impressions were taken. The video was dubbed into Urdu for parents with limited understanding of English. The

Uniform Resource Locators (URLs) as well as a Quick Response (QR) code for each URL were included in the parent and child information sheets (Appendix 3.7a-b).

YouTube URL English version:

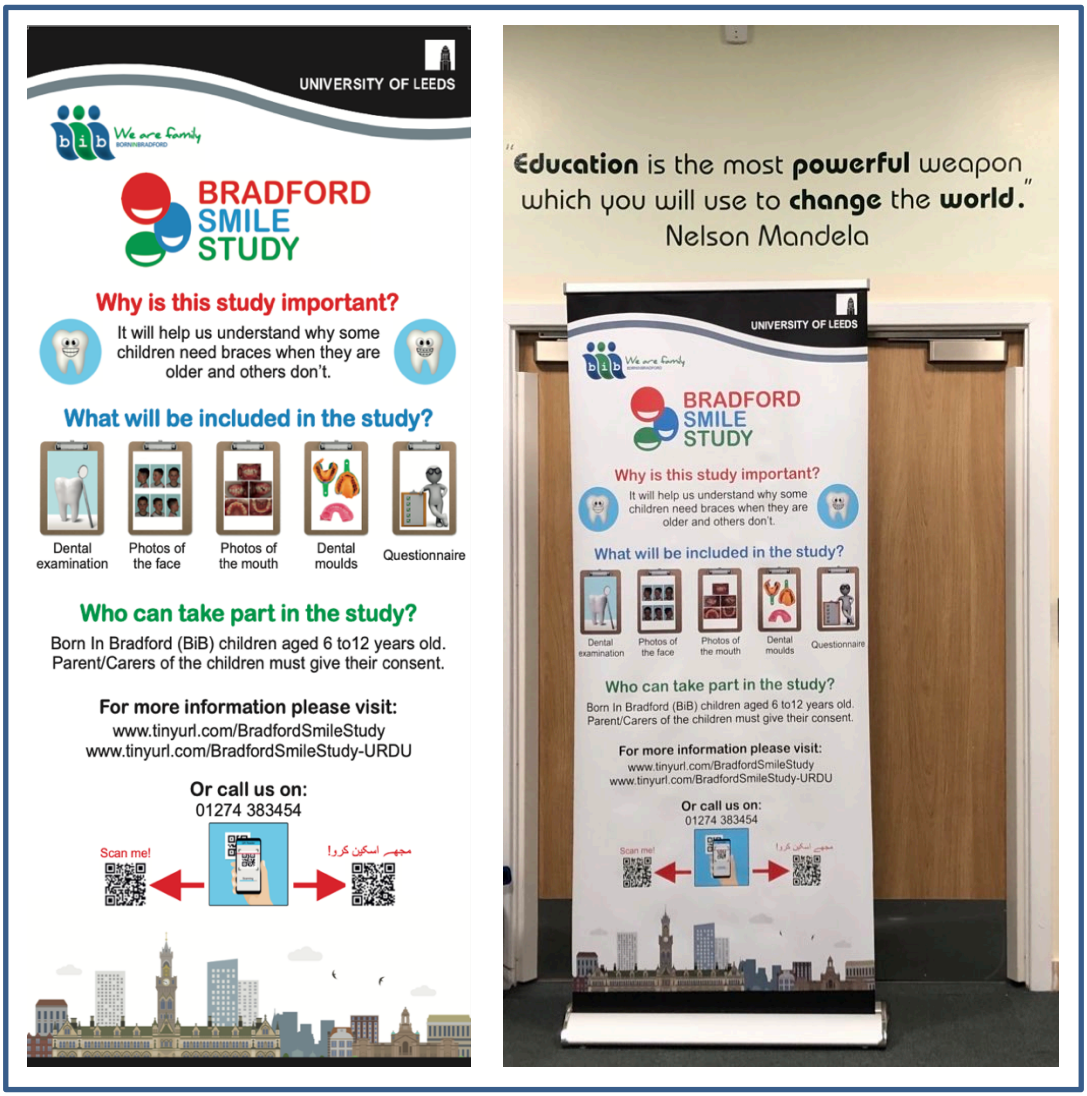
https://www.youtube.com/watch?v=SR0QASjTDz0

YouTube URL Urdu version:

https://www.youtube.com/watch?v=EwHQKqwQH9Q

A pull-up banner (Figure 3.2) was also used as an information tool at schools during parents' meetings and coffee mornings. It included brief information about the importance of the study and data collection, the YouTube URLs, and QR codes.

Figure 3.2 Bradford Smile Study pull-up banner artwork and at school

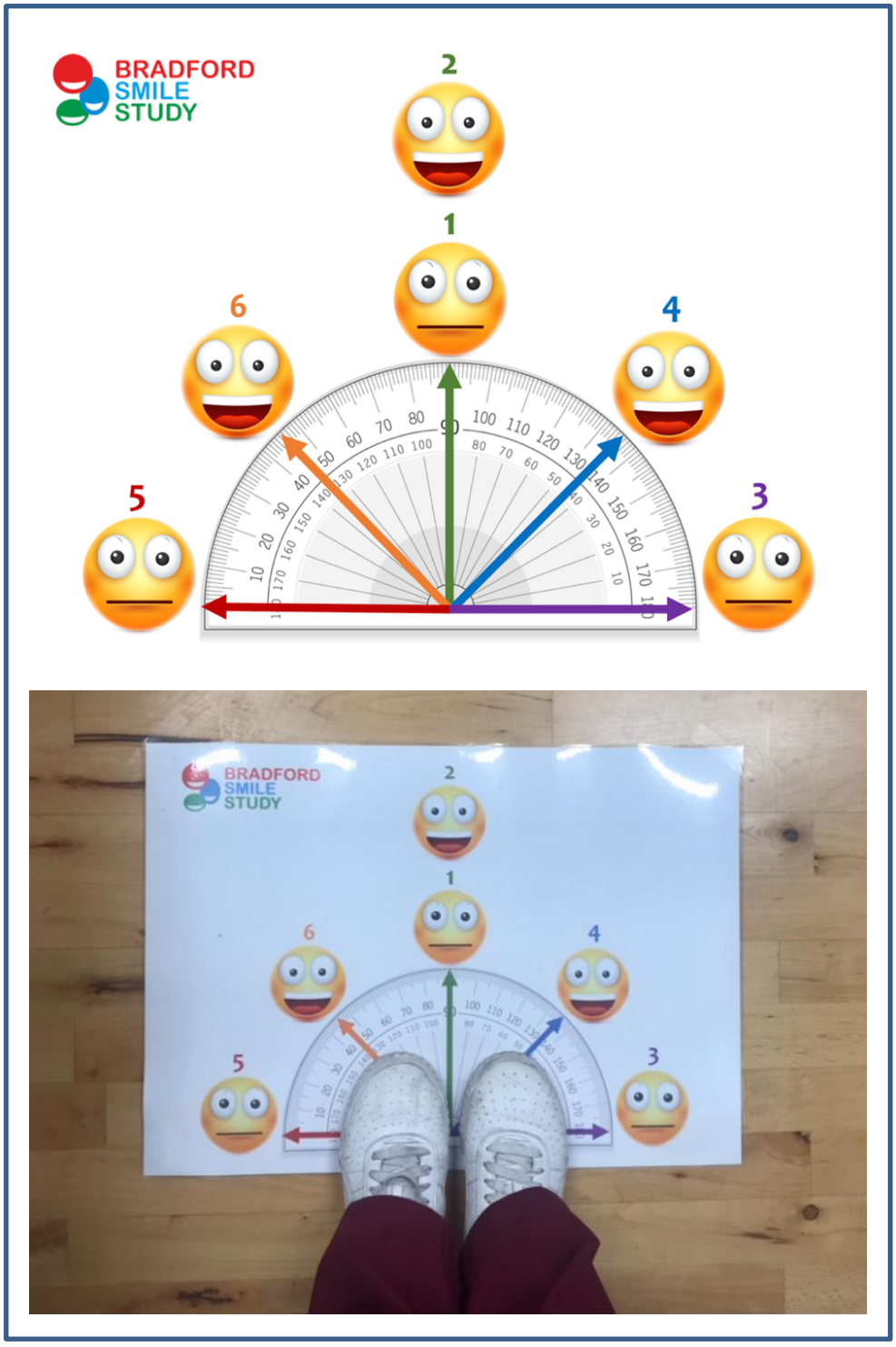


3.3.5 Training of data collection team and quality control

The researcher is a Specialist Paediatric Dentist who was responsible for overseeing the data collection process and quality assurance during the school visit. To standardise the process of data collection, the data collection team received a training session conducted by a Consultant Orthodontist on orthodontic photography, dental impression taking and bite registration before the study started. The bespoke training included exercises on how to use the equipment and positioning of the child to optimise data quality and minimise

any distress to the child. During the early stages of data collection, a Specialist Orthodontist accompanied the data collection team to ensure consistency in orthodontic photography and dental impression taking. Guiding the participants to stand on the desired direction for extra-oral photography was sometimes confusing. Therefore, a stand map was designed by the researcher to show participants where to stand for extra-oral photographs. Each angle on the map was marked with a smiley face either with the mouth closed and/or open to guide the participants whether to smile and show their teeth or not. The artwork was printed on an A3 poster and laminated. Figure 3.3 shows the stand map artwork and laminated poster.

Figure 3.3 Stand map artwork and laminated poster for extra-oral photography



Additionally, Standard Operating Procedures (Appendix 3.8 a-e) were developed by the researcher and reviewed by the Chief Investigator in accordance with the latest guidance. This was essential for quality assurance and consistency across all study activities such as data collection and data protection. Following final amendments and approval, the researcher circulated them to the data collection team.

3.3.6 Risk assessment

Data collection was based in a primary school setting; therefore, safety of participants and the data collection team was crucial. All study members had Disclosure and Barring Service checks prior to the commencement of the study. In addition, risk assessment was carried out following the University of Leeds Health and safety services-General Risk Assessment Form. This was reviewed and approved by the Chief Investigator and the Dental Translational and Clinical Research Unit team at Leeds Dental Institute at the University of Leeds (Appendix 3.9). The document covered different aspects of risks related to the transfer of the research kit, infection prevention and control, safety and how to minimise the risks. The final approved form was shared with all team members and with primary schools upon request.

3.3.7 Data collection and data entry:

3.3.7.1 Socio-demographic data

A Collaboration and Information Sharing Agreement with BiB was signed to access anonymised data and perform statistical analyseses. Socio-demographic data about participant age, gender, ethnicity, and

socioeconomic status were shared by the BiB data team on an Excel spreadsheet via a secure link. Age was provided in months and gender was categorised as female or male. Ethnicity was grouped into three main groups, South Asian (Pakistani, Indian, and Bangladeshi), White British, and Other to help assess whether the study group was representative of the BiB cohort or the wider community. Eligibility of free school meals (yes or no) was used as a marker for socioeconomic status to compare participants from lower income families as reported by the National Child Dental Health Survey 2013.

3.3.7.2 Clinical data

Clinical data that were collected during the school visit included a dental examination (recording the number of teeth present, obvious dental findings such as cavitated carious lesions into dentine) and an orthodontic assessment (recording malocclusion characteristics such as crossbites and molar classification), extra-oral and intra-oral photographs, upper and lower dental impressions and a bite registration.

3.3.7.3 Data collection tools and data entry

Overarching protocols from the National Child Dental Health Survey, which is conducted in primary school settings, were followed to collect clinical data (Health and Social Care Information Centre, 2015).

Data were recorded using a standardised data collection sheet that was developed prior to the commencement of the study. The data collection sheet

was reviewed and approved by the Chief Investigator and the orthodontic panel who would be assessing the orthodontic need using the IOTN-DHC. It consisted of two main charts, the dental chart and the orthodontic chart, and a section to record the file range of images and whether dental impressions and bite registration were taken or not (Appendix 3.10). The BiB data team developed a secure bespoke web-based application for live data entry during the school visit to ensure efficient entry and data confidentiality. For field data entry, a tablet (Lenovo, occasionally an iPad) to access the web application and a mobile phone (iPhone) with a tethering access point to act as a Wi-Fi dongle were used. Paper forms were available in case of any technical problems.

3.3.7.4 Dental research kit preparation and storage

Prior to the commencement of the study, a dental research kit comprising of a list including dental instruments, materials and other consumables (Appendix 3.3) was ordered and prepared for data collection. Dental examination and orthodontic assessment were performed using a disposable dental mirror and a headlight (SurgiTel Micro Light Emitting Diode). Gauze was used to wipe off any visible plaque and food debris. An overjet (the horizontal overlap between upper and lower anterior incisors when in centric occlusion) was measured using a disposable plastic ruler marked with centimetres and millimetres. The ruler was placed at a right angle to the labial surface of a lower central incisor and the incisal tip of an upper central incisor. An overbite (the vertical overlap between upper and lower incisors when in centric occlusion) was assessed visually and classified into three categories:

up to 1/3, more than 1/3 and up to 2/3, or more than 2/3 vertical overlap. For both overjets and overbites, the greatest score in the anterior segment was recorded. During the dental examination, participants who had dental caries and urgent dental needs were given a letter for their parent/carer to encourage them to visit a dentist in the near future (Appendix 3.11).

For orthodontic photography, sterile dental photography kits were used (dental photography mirror and cheek retractors) and a professional camera (Canon EOS 750D), ring flash (Canon macro ring lite MR-14EX II Ring Flash on ETTL) and a Macro lens (Canon 100 mm) were used. Upper and lower dental impressions were taken, using disposable dental impression trays of different sizes and a fast-setting alginate impression material that is dimensionally stable for five days (Hydrogum 5). Dental modelling wax (ANUTEX®) was used for bite registration. Each set of dental impressions and bite registration was identified using a unique barcode number that enabled anonymisation of study casts and digital models. Figures 3.4a-e show examples of setting up a mile dental clinic for data collection in different school settings.

Figures 3.4a-e Examples of the dental research kit before and after setting up a mobile dental clinic for data collection and giveaways at different primary schools in Bradford

Figure 3.4a

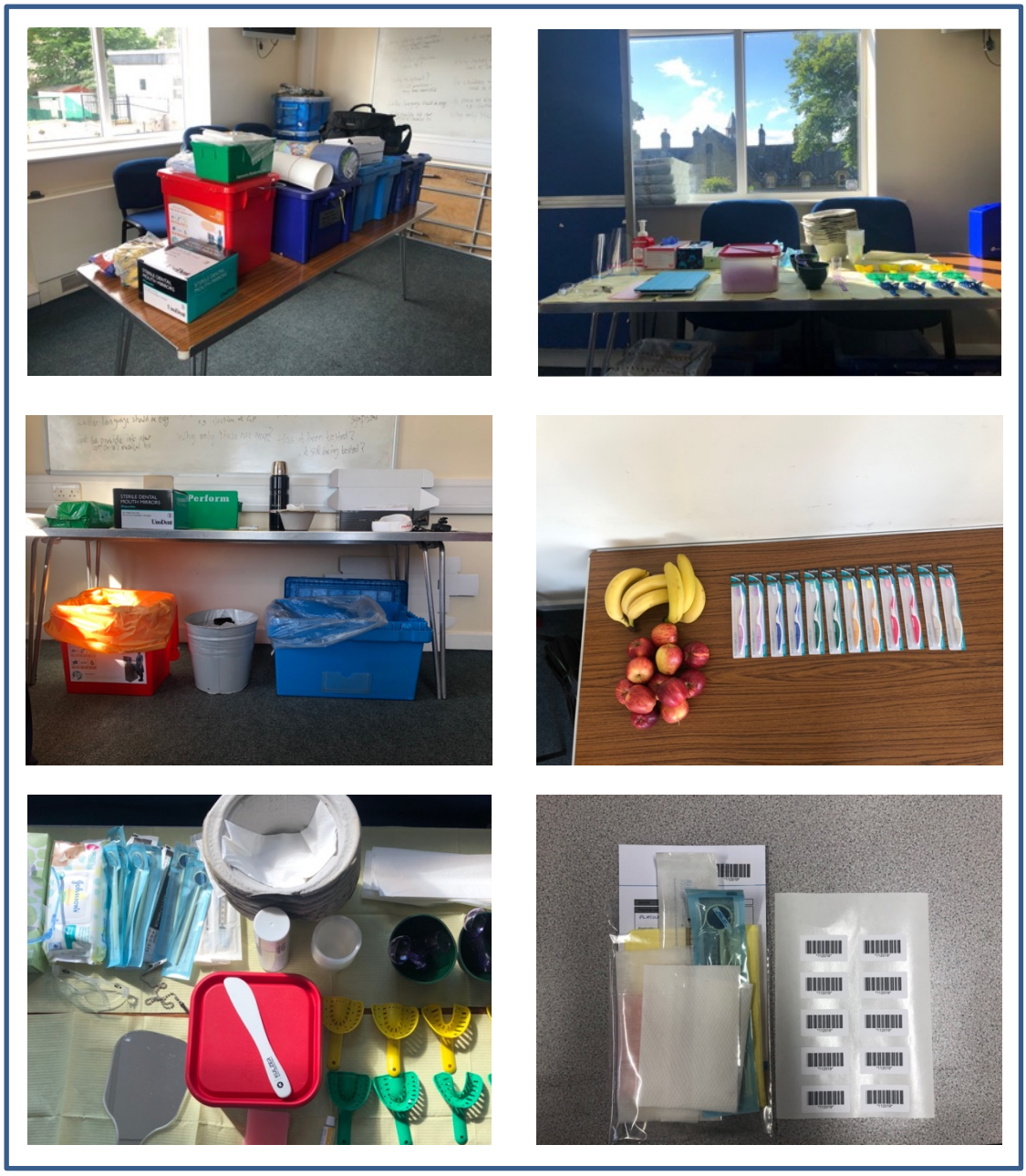


Figure 3.4b


"You don't choose your family
They are Gods gift to you,
as you are to them"
- Desmond Tutu
"WORRY less,
SMILE more,
LISTEN carefully,
TAKE responsibility,
ACCEPT what you can't change,
EMBRACE the lessons,
LOVE YOUR LIFE."

Figure 3.4c

Figure 3.4d

Figure 3.4e

The dental research kit was stored at the Dental Department at Westbourne Green Community Hospital in Bradford. The dental therapist and the research dental nurse were responsible for transferring the dental kit to and from the schools. The research dental nurse assisted the dental therapist during data collection in maintaining a high quality of infection prevention and control procedures at school and during the transfer of the research kit. The research dental nurse was also responsible for the sterilisation of the dental photography kit and disinfection of dental impressions and bite registration were performed in the Dental Department at Westbourne Green Community Hospital by. An external dental laboratory (ArKive Lab) collected the disinfected dental impressions and bite registrations the next working day from Westbourne Green Community Hospital, to obtain and scan dental study casts. Digital models were accessed online via the laboratory's warehouse and viewed via MeshLab software Version 3.0.

3.3.7.5 School visit for data collection

Before the school visit, the researcher prepared Team Guidance Notes (Appendix 3.12) for each school and shared them with the data collection team to provide an overview of the visit.

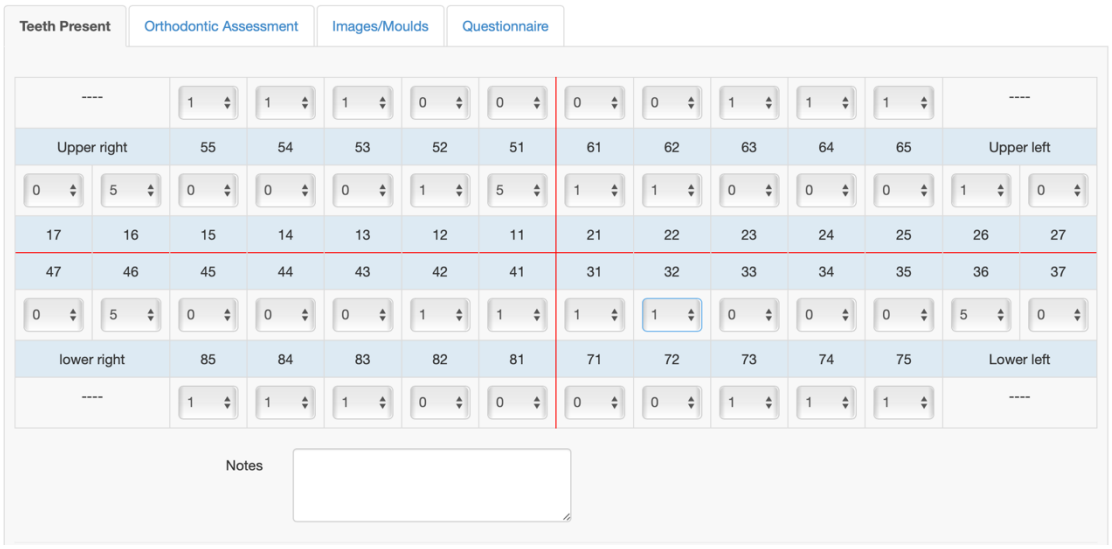
On the day of the school visit, the researcher collected the consent forms from BIHR to enable child identification and verification of some consented items such as extra-oral photographs. After the data collection team had arrived and checked in at the school, the point of contact provided the researcher with a

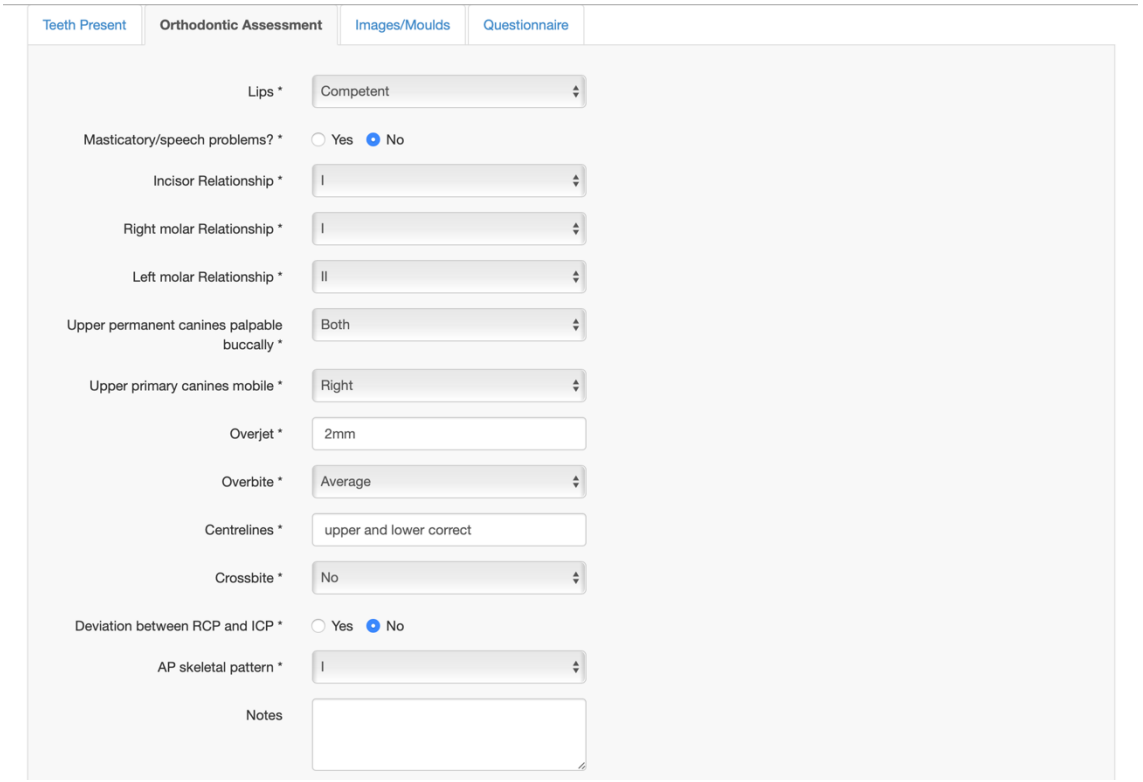
list of consented BiB children and their classrooms. The data collection team prepared the room for data collection. A child was fetched from their classroom by the researcher (if the DBS checks were required as part of the school's policy) or by a school staff (if the DBS checks were not required) to the designated room. The consent form was used to identify the child using two main identifiers, child's full name and date of birth. If the child did not remember their date of birth, a third identifier was used which was the child's mother's name. After showing the child the YouTube information video, verbal assent was obtained from the child prior to data collection and the child was informed that they could stop at any time. The data collection team ensured privacy during data collection by keeping the door always closed. After completing data collection, each child was offered a toothbrush, a smiley face sticker, and a piece of fruit (an apple or a banana) as a way of saying thank you.

After the end of the school visit, the researcher or the dental therapist returned the consent forms and transferred the images on the Secure Digital memory card to the secure BiB drive at BIHR. Figures 3.5a-d show an example of data collected for each participant.

Figures 3.5a-d An example of data collected for each participant

Figure 3.5a Example of dental chart, orthodontic chart and tracking of images/digital models





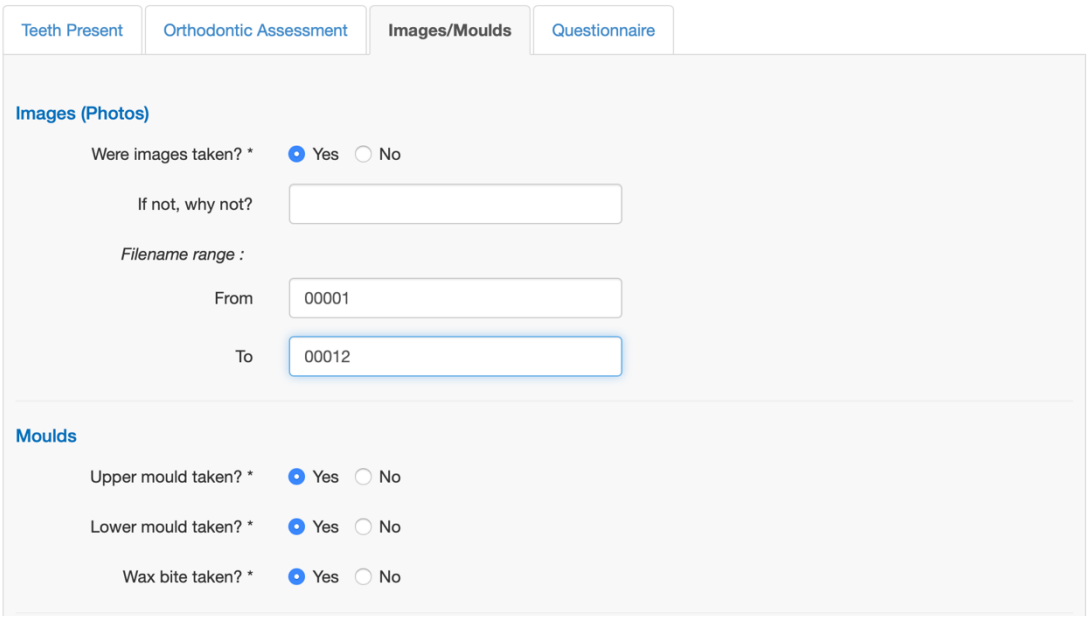
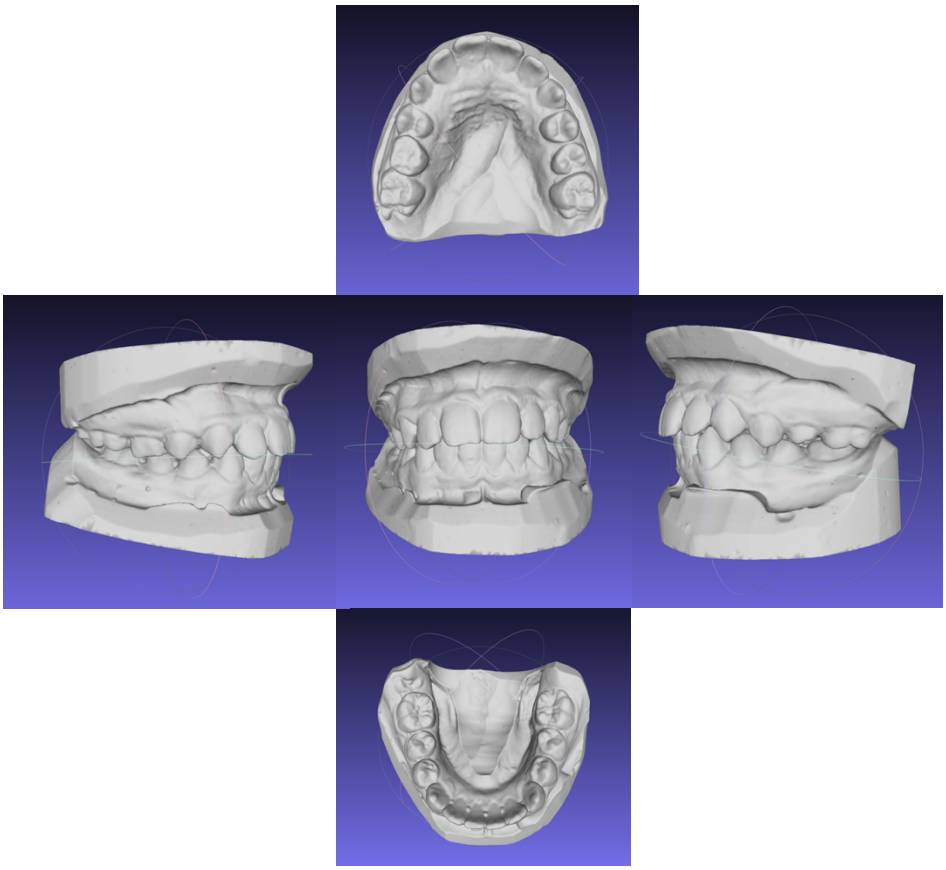

Teeth Present
Orthodontic Assessment
Images/Moulds
Questionnaire
Images (Photos)
Were images taken? * Yes No
If not, why not?
Filename range :
From 00001
To 00012
Moulds
Upper mould taken? * Yes No
Lower mould taken? * Yes No
Wax bite taken? * Yes No

Figure 3.5b Example of extra-oral photographs*

*Informed consent was obtained from the child's parent to use extra-oral photographs

Figure 3.5c Example of intra-oral photographs

Figure 3.5d Example of digitised models in different views*



*Digital models are from a different child to those shown in 3.5c

3.3.7.6 Data storage and manipulation

Data were handled and managed in accordance with the University of Leeds Data Protection-Code of practice and BIHR regulations in accordance with the BiB Collaboration and Information Sharing Agreement (Appendix 3.13). Scanned copies of parent and school consent forms were stored securely on the BiB data warehouse at BTHFT.

Physical data, such as the school and parental consent forms with identifiable data (including participant's name, date of birth, and mother's name), were stored securely in a designated locked filing cabinet at BIHR. Study casts produced from dental impressions were stored securely by ArKive Lab.

Digital data such as dental charts and questionnaires, were recorded direct onto a secure web-based application developed by BIHR and stored on the BiB data warehouse. In addition, extra-oral and intra-oral photographs, and digital models were stored securely on the BiB data warehouse. The BiB data warehouse can only be accessed by specific BiB staff. Spreadsheets produced for data analysis were anonymised using an unidentifiable ID and were stored securely on the University of Leeds OneDrive.

3.3.8 Project management

All documents pertaining to the study (such as information sheets, data standard operating procedures, and collection sheets) were reviewed and approved by the research team. This research project lies within the project

governance and management structures of the BiB research group and the University of Leeds as research sponsor. Responsibility for operational management of the project was overseen by the Chief Investigator. The research team arranged face-to-face and regular video conferences to discuss progress of the project.

3.3.9 Data set

Each participant had a data set comprised of socio-demographic and clinical data. Socio-demographic data were used for two main purposes: child identification and as potential confounders. Clinical data were used to assess the primary outcome, the need for orthodontic treatment using the IOTN-DHC and as potential confounders.

3.3.9.1 Socio-demographic data

Data obtained from the BiB database are presented in Table 3.2.

Table 3.2 Data obtained from BiB database

Data used for child identification	Data used as potential confounders
• BiB ID number • Name • Date of birth • Mother's name • Home address** • School	• Age* • Gender • Ethnicity • Eligibility for free school meals

*Calculating using date of birth

**This was used to send information packs via second class post

3.3.9.2 Clinical data

Data from the data linkage study were used as potential confounders and included age at PEPT under GA, number of primary teeth extracted, and type of primary teeth extracted were used as potential confounders. Data collected during school visit were used to assess the need for orthodontic treatment based on the IOTN-DHC. Clinical data included data from the data linkage study and data collected during school visits. These data are summarised in Table 3.3.

Table 3.3 Data obtained from the data linkage study and during school visits

Data from the data linkage study*	Data collected during the school visit
• Age at PEPT under General Anaesthetic • Number of primary teeth extracted • Type of primary teeth extracted	• Dental examination • Occlusal characteristics • Extra-oral and intra-oral photographs • Upper and lower dental impressions and a bite registration**

*(Day, 2018)

**Study casts were produced and digitised at an external dental laboratory (ArKive Lab)

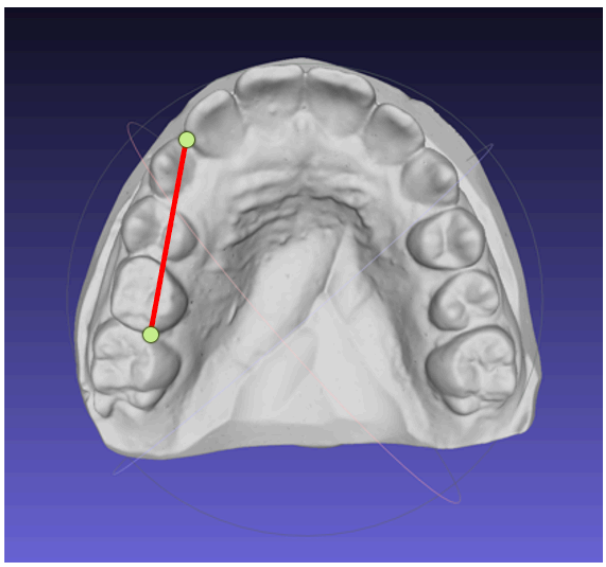
3.3.9.4 Assessing the primary outcome: need for orthodontic treatment based on the IOTN-DHC

The orthodontic panel were asked to make three decisions including the primary outcome: assessing sufficient space for permanent teeth, IOTN-DHC grading, and the need for orthodontic treatment.

Sufficient space for permanent canines and premolars was assessed for participants in the mixed dentition using measurements from the digital models. Following methodology outlined by Northway (Northway & Wainright,

1980) the space for the permanent canines and premolars was measured in each quadrant using the measurement tool within the Meshlab software. Measurements in millimetre were recorded on a master spreadsheet stored securely on the University of Leeds OneDrive. The reference points were identified as the most mesial contact point of the primary canine and the most distal contact point of the second primary molar. If any of these teeth were not present, then the most distal contact point on the permanent lateral incisor and the most distal point on the mesial surface of the permanent first molar were considered as reference points. The calibration targets used were accurate to <10 microns and were rounded to two decimal points. Figure 3.6 shows an example of the reference points on a digital model for the upper right quadrant.

Figure 3.6 An example of the reference points for the upper right quadrant on a digital model



If the space for the permanent canines and premolars was less than 18 mm per quadrant in the maxilla and 17 mm per quadrant in the mandible, this was regarded as insufficient space and an IOTN score of 5i was considered.

Using sufficient space assessments (based on the measurements from digital models), extra-oral and intra-oral photographs, and dental and occlusal findings, the orthodontic panel graded each participant's records using the IOTN-DHC (Table 3.4). The IOTN-DHC includes five categories that range from Grade 5 (great need for orthodontic treatment) to Grade 1 (no need for orthodontic treatment). The acronym MOCDO (Table 3.5) was used to help the assessor identify the most severe feature of the malocclusion (based on intra-oral photographs and clinical examination) and hence the IOTN-DHC grade. The assessed need for orthodontic treatment for each participant was dichotomised into either no need for orthodontic treatment for Grades 1-3, or a need for orthodontic treatment for Grades 4 and 5 (Table 3.4). When the need for orthodontic treatment was assessed as borderline or unclear, it was considered as no need.

Participants assessed in need for orthodontic treatment were also assessed whether they needed treatment in the mixed or permanent dentition. It was anticipated that there would be a small number of participants in their early permanent dentition. Those who were already in the permanent dentition and assessed to be in need for orthodontic treatment were included under the 'in need of orthodontic treatment in the permanent dentition stage' group.

Table 3.4 The Dental Health Component of the Index of Orthodontic Treatment Need

Grade	Subgrade	Characteristics
5 (Very great)	5i	Impeded eruption of teeth (with the exception of third molars) owing to crowding, displacement, the presence of supernumerary teeth, retained primary teeth and any pathological cause
	5h	Extensive hypodontia with restorative implications (more than one tooth missing in any quadrant) requiring pre-restorative orthodontics
	5a	Increased overjet >9 mm
	5m	Reverse overjet >3.5 mm with reported masticatory and speech difficulties
	5p	Defects of cleft lip and palate
	5s	Submerged primary teeth
4 (Great)	4h	Less extensive hypodontia, requiring pre-restorative orthodontics or orthodontic space closure to obviate the need for a prosthesis
	4a	Increased overjet >6 mm but ≤ 9 mm
	4b	Reverse overjet >3.5 mm with no masticatory or speech difficulties
	4m	Reverse overjet >1 mm but <3.5 mm, with recorded masticatory and speech difficulties
	4c	Anterior or posterior crossbites with >2 mm discrepancy between retruded position and intercuspal position
	4l	Posterior lingual crossbite with no functional occlusal contact in one or both buccal segments
	4d	Severe displacements of teeth >4 mm
	4e	Extreme lateral or anterior open bites >4 mm
	4f	Increased and complete overbite with gingival or palatal trauma
	4t	Partially erupted teeth, tipped and impacted against adjacent teeth
	4x	Supplemental teeth

3 (Moderate)	3a	Increased overjet >3.5 mm but ≤ 6 mm with incompetent lips
	3b	Reverse overjet >1 mm but ≤ 3.5 mm
	3c	Anterior or posterior crossbites with >1 mm but ≤ 2 mm discrepancy between retruded contact position and intercuspal position
	3d	Displacement of teeth >2 mm but ≤ 4 mm
	3e	Lateral or anterior open bite >2 mm but ≤ 4 mm
	3f	Increased and complete overbite without gingival or palatal trauma
2 (Little)	2a	Increased overjet >3.5 mm but ≤ 6 mm with competent lips
	2b	Reverse overjet >0 mm but ≤ 1 mm
	2c	Anterior or posterior crossbite with ≤ 1 mm discrepancy between retruded contact position and intercuspal position
	2d	Displacement of teeth >1 mm but ≤ 2 mm
	2e	Anterior or posterior open bite >1 mm but ≤ 2 mm
	2f	Increased overbite ≥3.5 mm without gingival contact
	2g	Pre-normal or post-normal occlusions with no other anomalies; includes up to half a unit discrepancy
1 (None)	Extremely minor malocclusions including displacements <1 mm	

Table 3.5 MOCDO acronym and IOTN-DHC subgrades

Initial	Features	Examples
M	Missing (including congenitally missing, impacted, and impacted teeth)	5i, 5h, 5s, 4h
O	Overjet (including reverse overjets)	5a, 5m, 4a, 4m, 3a, 3b, 2a, 2b
C	Crossbite	4c, 3c, 2c
D	Displacement of contact points	4d, 3d, 2d
O	Overbite (including open bite)	4f, 4e, 3e, 3f, 2e, 2f

The IOTN-DHC was designed to assess the need for orthodontic treatment in the permanent dentition. Therefore, a comprehensive toolkit of rules and assumptions was developed to ensure the consistency of scoring the IOTN-DHC (Table 3.6). Disagreements in IOTN-DHC scoring were resolved through discussion by the panel to achieve a consensus view.

Table 3.6 A toolkit of rules and assumptions to ensure the consistency of scoring the IOTN-DHC

Upper lateral incisor not present with complete loss of space	Scoring was based on the assumption that the tooth was unerupted, not missing
Increased overjet	Treatment should be offered in the permanent dentition, assuming that the child was not bullied
Reverse overjet and anterior crossbites involving one to three upper incisors	Treatment should be offered immediately
Contact point displacements	These were identified as part of the orthodontic clinical assessment
Contact point displacements between permanent and primary teeth	Displacements between permanent and primary teeth were not considered
Unclear cases	When it was unclear whether there is a need for treatment or not, opt for no treatment
Multiple crowding of anterior teeth	Enter the most severe overjet/overbite measurement

3.3.10 Data analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) software for Windows version 27.0 (SPSS Inc., Chicago, IL).

Socio-demographic characteristics (age, gender, ethnicity, and eligibility for free school meals), dental and malocclusion characteristics, and tooth level characteristics (age at extraction under GA, number and type of teeth extracted) for the study participants were reported using frequencies and proportions for categorical data. For continuous variables, results were reported using means and standard deviation if the data were normally distributed and median and inter-quartile ranges (IQR) if the data were skewed. A skewness value between -0.5 and 0.5 indicated a relatively

symmetrical distribution. Using the chi-square test, the study groups (PEPT and no-PEPT) were compared in terms of socio-demographic and malocclusion characteristics. A *P* value of <0.05 was considered statistically significant.

The proportions of participants assessed in need and no need for orthodontic treatment and whether the treatment should be provided now in the mixed dentition or later in the permanent dentition in each group were reported. An unadjusted Odds Ratio (OR) and 95% confidence interval were calculated using logistic regression to measure the association between PEPT (exposure) and the orthodontic need (primary outcome). Adjusted logistic regression analysis were carried out to examine the association between PEPT and orthodontic treatment need, taking into account socio-demographic variables such as participant's age, gender, ethnicity, and eligibility for free school meals.

3.3.11 Oral health-related quality of life (OH-RQoL) measure

3.3.11.1 Data collection

As described previously at the time of dental examination, participants were asked to compete the short form of the Child Oral Health Impact Profile (COHIP-SF 19) (Appendix 3.14) questionnaire to measure the OH-RQoL. It is comprised of 19 questions with three main domains: ''oral health well-being (5 questions), functional well-being (4 questions), and socio-emotional well-being (10 questions)'. Out of the 19 items, 17 were negatively worded. For example: 'Have you ever had difficulty eating foods you would like to because

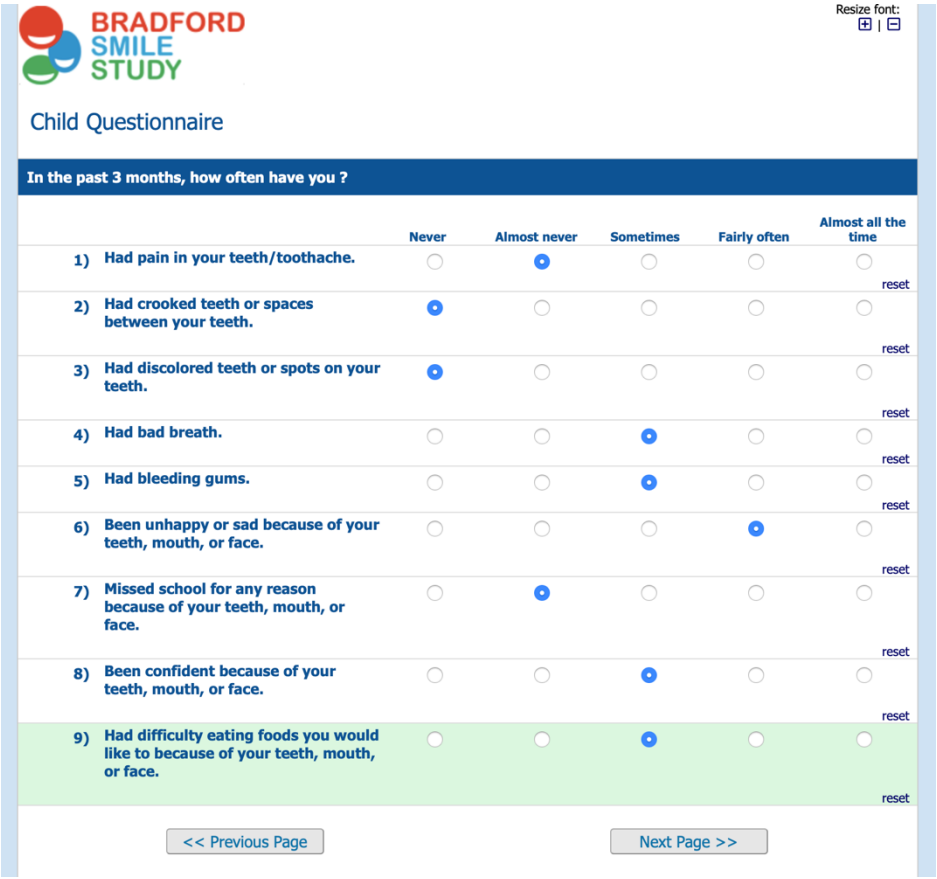
of your teeth, mouth, or face?'. In addition, the 'global self-rated oral health' question was included in the questionnaire (Table 3.7).

Table 3.7 COHIP-SF 19 questions and its three domains

Domain	Question	Wording (positive or negative)
Oral health well-being	Have you ever had pain in your teeth/toothache?	negative
	Have you ever had crooked teeth or spaces between your teeth?	negative
	Have you ever had discoloured teeth or spots on your teeth?	negative
	Have you ever had bad breath?	negative
	Have you ever had bleeding gums?	negative
Socio-emotional well-being	Have you ever been unhappy or sad because of your teeth, mouth, or face?	negative
	Have you ever missed school for any reason because of your teeth, mouth, or face?	negative
	Have you ever been confident because of your teeth, mouth, or face?	positive
	Have you ever felt worried or anxious because of your teeth, mouth, or face?	negative
	Have you ever not wanted to speak/read out loud in class?	negative
	Have you ever avoided smiling or laughing with other children because of your teeth, mouth, or face?	negative
	Have you ever been teased, bullied, or called names by other children because of your teeth, mouth, or face?	negative
	Have you ever felt that you were attractive (good looking) because of your teeth, mouth, or face?	positive
	Have you ever felt that you look different because of your teeth, mouth, or face?	negative
	Have you ever been worried about what other people think about your teeth, mouth, or face?	negative
Functional well-being	Have you ever had difficulty eating foods you would like to because of your teeth, mouth, or face?	negative
	Have you ever had trouble sleeping because of your teeth, mouth, or face?	negative
	Have you ever had difficulty saying certain words?	negative
	Have you ever had difficulty keeping your teeth clean?	negative
Global self-rated oral health: Overall, please rate your oral health.		

The questionnaire was included in the secure bespoke web-based application (that was developed by the BiB data team) along with the dental and orthodontic charts and completed by the participant on the day of the school visit. The researcher was available to support participants if they were unsure about the meaning of any of the words or questions. A tablet and a suitable Wi-Fi dongle were used to access and complete the questionnaire. All questions were marked as mandatory to ensure that there were no missing data. Spare hard copies were available in case of any technical problems. Figure 3.7 shows a screenshot example of a completed online-based COHIP-SF 19 questionnaire.

Figure 3.7 An example of a completed COHIP-SF 19 questionnaire



BRADFORD SMILE STUDY

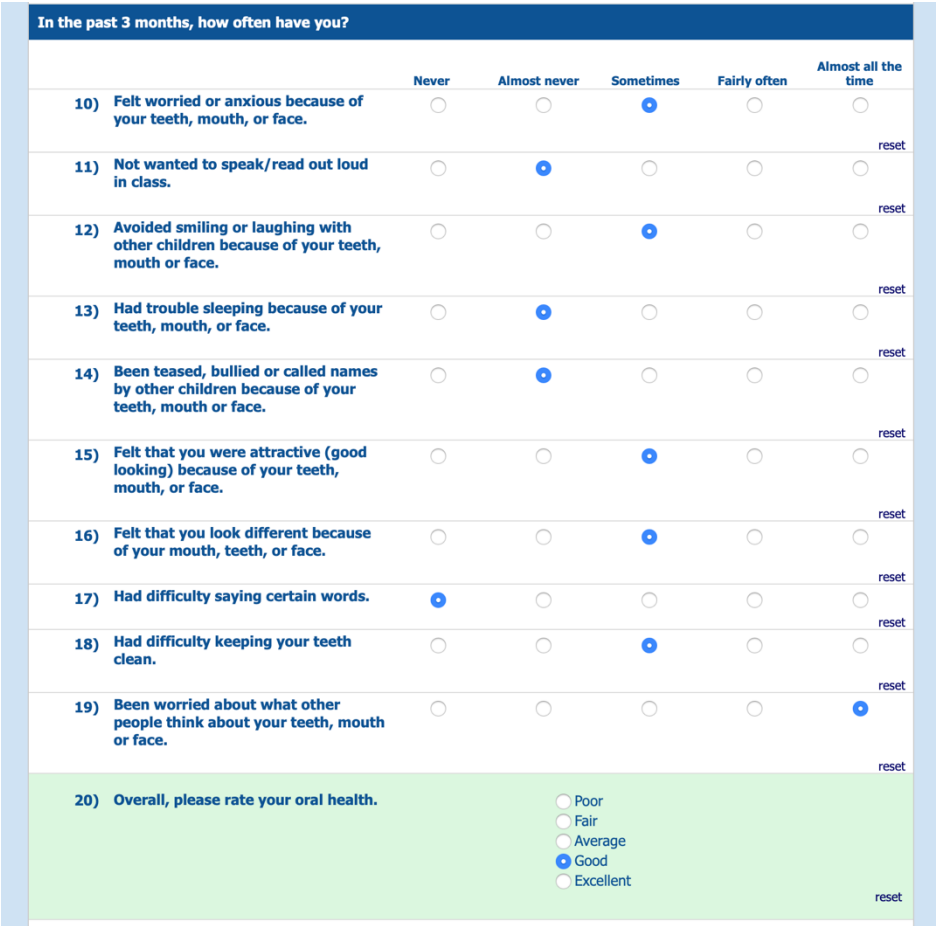
Resize font:

Child Questionnaire

In the past 3 months, how often have you ?

	Never	Almost never	Sometimes	Fairly often	Almost all the time
1) Had pain in your teeth/toothache.	○	●	○	○	○ reset
2) Had crooked teeth or spaces between your teeth.	●	○	○	○	○ reset
3) Had discolored teeth or spots on your teeth.	●	○	○	○	○ reset
4) Had bad breath.	○	○	●	○	○ reset
5) Had bleeding gums.	○	○	●	○	○ reset
6) Been unhappy or sad because of your teeth, mouth, or face.	○	○	○	●	○ reset
7) Missed school for any reason because of your teeth, mouth, or face.	○	●	○	○	○ reset
8) Been confident because of your teeth, mouth, or face.	○	○	●	○	○ reset
9) Had difficulty eating foods you would like to because of your teeth, mouth, or face.	○	○	●	○	○ reset

<< Previous Page Next Page >>



In the past 3 months, how often have you?

	Never	Almost never	Sometimes	Fairly often	Almost all the time
10) Felt worried or anxious because of your teeth, mouth, or face.	○	○	●	○	○
11) Not wanted to speak/read out loud in class.	○	●	○	○	○
12) Avoided smiling or laughing with other children because of your teeth, mouth or face.	○	○	●	○	○
13) Had trouble sleeping because of your teeth, mouth, or face.	○	●	○	○	○
14) Been teased, bullied or called names by other children because of your teeth, mouth or face.	○	●	○	○	○
15) Felt that you were attractive (good looking) because of your teeth, mouth, or face.	○	○	●	○	○
16) Felt that you look different because of your mouth, teeth, or face.	○	○	●	○	○
17) Had difficulty saying certain words.	●	○	○	○	○
18) Had difficulty keeping your teeth clean.	○	○	●	○	○
19) Been worried about what other people think about your teeth, mouth or face.	○	○	○	○	●

reset

20) Overall, please rate your oral health.

○ Poor
○ Fair
○ Average
● Good
○ Excellent

reset

3.3.12 Data analysis

The anonymised collected data were shared by the BiB data team on an Excel spreadsheet via a secure link. Data were transferred to IBM® SPSS® Statistics Version 27 software (SPSS Inc., Chicago, IL) to perform statistical analyseses. Responses to the questions were recorded on a five-point Likert scale as never (score=0), almost never (score=1), sometimes (score=2), fairly often (score=3), almost all time (score=4) for positively worded questions. For negatively questions, the scores were reversed from four (least) to zero (highest). A total score was calculated by summing the scores of the individual questions and this ranged from 0-76. The total scores for each domain range from 0-20 for the oral health domain, , 0-40 for the socio-emotional well-being

domain and 0-16 for the functional well-being domain. Higher scores using COHIP-SF 19 indicated better OH-RQoL, while lower scores indicated poorer OH-RQoL.

Descriptive statistics were calculated for the overall COHIP-SF 19 scores and each of the three domains. For continuous variables, the results were reported using means and standard deviations if the data were normally distributed and medians and inter-quartile ranges if the data were skewed.

Descriptive statistics for COHIP-SF 19 items were reported using frequencies and proportions. The differences in total and domain COHIP-SF 19 according to the study group, assessed need for orthodontic treatment, and socio-demographic variables were reported using the mean and standard deviation if the data were normally distributed or median and interquartile range if the data were skewed.

The minimally important difference (MID) in the mean or median total COHIP-SF 19 scores and its domains was used to determine any clinically significance differences between the groups. The MID is defined as ‘the smallest difference in score in the domain of interest which participants perceive as beneficial’ (Masood et al., 2014). The definitions of Masood and colleagues (2014) were used, whereby a difference in the total score of −1, 0 and 1 would be considered of ‘no clinical significance’, a difference in the total score of -3, -2, 2, and 3 would be considered of ‘minimal clinical significance’

and a difference in the total score of -7 to 4 or greater would be considered of 'clinical significance'.

Comparison between total and domain COHIP-SF 19 scores, orthodontic need, and other socio-demographic variables was reported using two-sided two-sample t-test if the data were normally distributed or the non-parametric Mann-Whitney U test (variables with two groups) if the data were skewed.

Unadjusted linear regression analysis was performed to explore the association between total COHIP-SF 19 scores and the study group, need for orthodontic treatment and socio-demographic variables. Significance for other sub-domains will be explored if statistical significance was found for PEPT. A probability value of $P<0.05$ was considered statistically significant.

3.3.13 Health economics: exploratory cost analysis of the primary outcome, the need for orthodontic treatment

3.3.13.1 Data collection

An exploratory cost analysis was performed by estimating the costs that can be associated with the primary outcome-the need for orthodontic treatment. An economic model was developed to explore the costs for three participant groups, PEPT under GA, PEPT under LA, and no-PEPT. Two main costs were estimated in the model for each group, family cost and health services cost.

Family cost was estimated by inviting parents of participants in the PEPT group via phone, to take part in a questionnaire about dental and non-dental health resource utilisation before PEPT. The BDCT recruitment team undertook these phone calls during the COVID-19 pandemic. A standardised questionnaire was developed to explore different health costs and services that parents had engaged with as a result of their child's carious and ultimately extracted teeth (Appendix 3.15). In addition, indirect non-dental cost such as the estimate time off work which was calculated based on a few assumptions (please see Tables 5.6c and e for further details).

Health services unit costs including the unit costs for GA, LA, and orthodontic treatment were obtained from different online resources (please see Tables 5.6a-e). A few assumptions were made and included as part of the health services costs such as permanent tooth extraction for orthodontic treatment and§ bi-annual dental check-ups.

Three timepoints were identified to understand the costs associated with the primary outcome (the need for orthodontic treatment):

- Timepoint 1: before conducting the study-this included direct and indirect dental and non-dental health resource utilisation as a result of dental caries by participants with PEPT and the assumed dental health resource utilisation by participants with no-PEPT. Within assumptions for these costs, wider research has been used to estimate the prevalence and costs of non-dental health resources (such as time

parents would take off work to facilitate this dental care). For the no-PEPT group, it was assumed that the cost would include bi-annual dental check-ups for a period equivalent to the child's mean age at PEPT under GA.

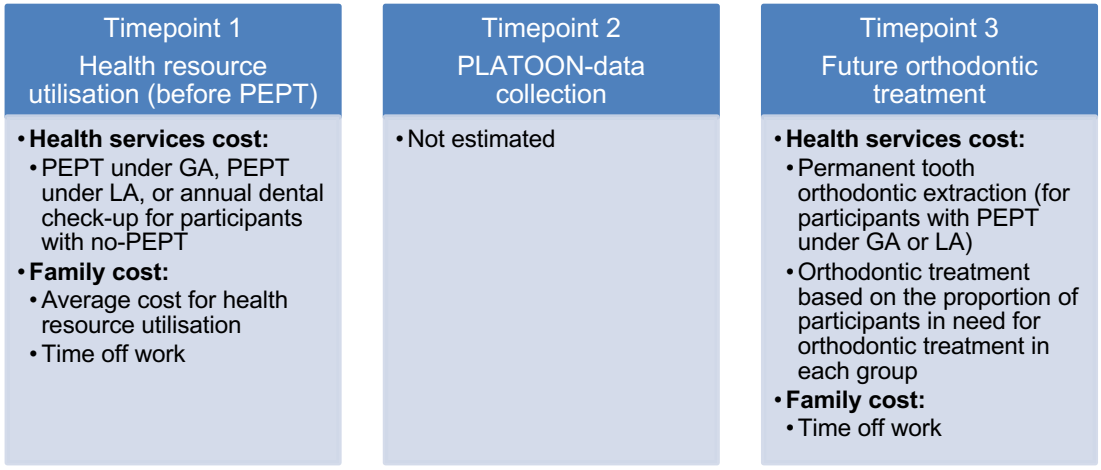
- Timepoint 2: data collection for this study-no applicable costs were assumed as it was uncertain how these costs may differ between the two groups.
- Timepoint 3: the future need for orthodontic treatment and possible permanent tooth orthodontic extractions-within the assumptions for these costs, wider research has been used to estimate the average number visits to delivering a course of orthodontic treatment. Based on the IOTN-DHC codes from this research (please see Table 4.3 in section 4.1.4.2 Dental and occlusal characteristics) extraction of one or more permanent teeth to facilitate orthodontic treatment has been assumed.

3.3.13.2 Data analysis

Based on the responses from the questionnaire, frequencies for different dental health resource utilisation pathways were calculated for participants with PEPT under GA and LA separately. The estimated average cost per participant for health resource utilisation was calculated by dividing the total cost of health resource utilisation by the total number of participants in each group (PEPT under GA and PEPT under LA).

After estimating the cost per participant for health resource utilisation, the estimated total unit cost per participant were calculated to facilitate the estimation of the total cost per participant based on the primary outcome results, the proportion of participants in need for orthodontic treatment, in each group (PEPT under GA, PEPT under LA, and no-PEPT). The estimated cost per participant for orthodontic treatment was calculated by multiplying the unit cost of orthodontic treatment by the proportion of participants assessed in need for orthodontic treatment in each group (PEPT under GA, PEPT under LA, and no-PEPT). Figure 3.8 describes the costs included in the model.

Figure 3.8 Costs included in the economic model to explore the cost associated with the primary outcome



3.4 Estimation of sample size power

The estimated sample size was calculated on a binary outcome of orthodontic need using the current NHS threshold (need, no need), using the raw data from the 2008 Dental Epidemiology Survey for Bradford. Prior to the Stephens' correction, orthodontic need was 53% (Bhujel et al., 2014). A multiple logistic regression was used to model the relationship between the orthodontic need and the exposure (with versus without PEPT) and adjusted for other

independent variables. The power was calculated for a given number of PEPT cases (500) and allocation ratio between PEPT and no-PEPT cases to detect a clinically relevant difference of at least 10% in the orthodontic need. An adjustment was made for multiple correlation between the exposure and the other independent variables. Table 3.8 shows the power calculation for a given combination of parameters, and it shows a sample size of 1,000 subjects (of which 50% are PEPT cases) could achieve at least 81% of power at a 5% significance level to detect a change of 10% in orthodontic need.

Table 3.8 Power calculation for a combination of parameters

Power	PEPT cases	Total sample size	Allocation ratio	Clinically relevant difference in orthodontic need	Multiple correlation between PEPT and other independent variables	Alpha
85%	500	1,000	1	10%	0.1	0.05
81%	500	1,000	1	10%	0.2	0.05
91%	500	1,000	1	11%	0.1	0.05
88%	500	1,000	1	11%	0.2	0.05
95%	500	1,000	1	12%	0.1	0.05
93%	500	1,000	1	12%	0.2	0.05
91%	600	1,200	1	10%	0.1	0.05
87%	600	1,200	1	10%	0.2	0.05
95%	600	1,200	1	11%	0.1	0.05
93%	600	1,200	1	11%	0.2	0.05
91%	500	1,250	1.5	10%	0.1	0.05
87%	500	1,250	1.5	10%	0.2	0.05
95%	500	1,250	1.5	11%	0.1	0.05
93%	500	1,250	1.5	11%	0.2	0.05
93%	500	1,500	2	10%	0.1	0.05
90%	500	1,500	2	10%	0.2	0.05

Chapter Four: Results-primary outcomes

Logistical challenges relating to operationalisation of the protocol and the preliminary results of the impact of premature extraction of primary teeth (PEPT) on the orthodontic need were presented at several dental meetings. These were entitled:

- PLATOON: Logistical Challenges, Limitations, and Solutions (Appendix 4.1)
    - Oral presentation at the British Society for Oral and Dental Research Annual Meeting 2019 in Leeds
- Infection Prevention and Control in a School-Based Dental Project in Bradford (PLATOON) (Appendix 4.2)
    - Poster presentation at the International Association of Paediatric Dentistry 2020 Virtual Congress
- Premature Loss of Primary Teeth Increases Future Orthodontic Need (Appendix 4.3)
    - Oral presentation at the International Association of Dental Research General Session (Virtual Experience) 2021

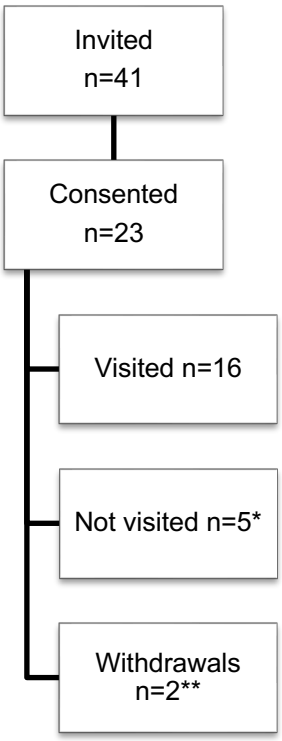
4.1 Recruitment and characteristics of study participants

4.1.1 Recruitment of primary schools

Following ethical approval, 41 primary schools in Bradford were invited to take part in the study. Initially, 23 primary schools consented to take part with a response rate of 56.1%. Two schools withdrew from the study prior to data collection and five schools were not visited owing to the coronavirus disease

2019 (COVID-19) pandemic. Figure 4.1 shows the recruitment flowchart of primary schools.

Figure 4.1 Flowchart of the recruitment of primary schools in Bradford



*Not visited owing to the challenges during the COVID-19 pandemic

**Schools did not have the capacity to fit in the study within their schedule

4.1.2 Recruitment of study participants

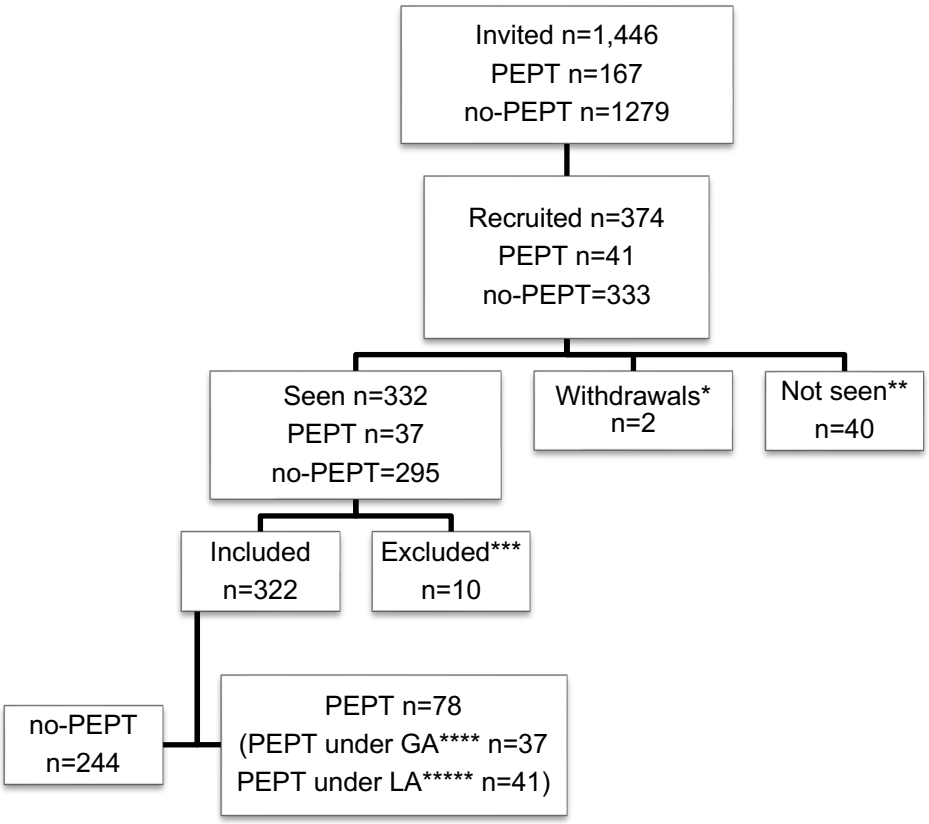
Participants were recruited between May 2019 and March 2020. Recruitment stopped at this time due to the first national lockdown during the COVID-19 pandemic where all schools were closed except to children of key workers.

A pilot study was carried out in July 2019 to finalise and test different methods for recruitment and data collection, and to capture Year Six pupils before they transitioned to Year Seven. During the pilot study, six primary schools in Bradford consented to take part. Out of 207 letters that were sent to home

addresses of Born in Bradford (BiB) children via post or school bag, informed consent was obtained from 52 BiB parents, with a response rate of 25%. Only 50 participants were seen (the rest were absent) and their data were included as part of the whole data set. Following the pilot study, amendments were made to enhance recruitment (Appendix 4.4).

In total, 1,446 BiB children (including those invited for the pilot study) were invited to take part in the study. Parental informed consent for 374 BiB children aged 8-11 years was obtained, with a response rate of 25.9%. Participants with PEPT were comprised of children with PEPT under general anaesthetic (GA) and local anaesthetic (LA). Out of 374 participants, 332 were examined, of these, 322 were included. The proportion of participants with PEPT under GA was 11.5% (n=37/322), these children were pre-identified in the data linkage study (Day, 2018). The proportion of participants who had PEPT under LA was 12.7% (n=41/322), these were identified during data collection with a conversion rate of 16.8%. Figure 4.2 shows the flowchart of recruited participants.

Figure 4.2 Flowchart of the recruitment of study participants



*Children did not want to take part

**Not seen owing to the COVID-19 pandemic

***Excluded due to insufficient data to enable data analysis

****Participants who had PEPT under GA and were identified via a previous data linkage study (Day, 2018)

*****Participants who had a history and clinical evidence of dental extraction under LA during their examination and were therefore included in the PEPT group

4.1.3 Dental records

Data sets were collected from 332 participants of whom 78 were in the exposure group (PEPT under GA and LA). Dental examinations were performed for all participants. Only 297 (89.5%) participants had parental consent to have their extra-oral photographs taken. Intra-oral photographs and dental impressions were taken for 309 (93.1%) and 305 (91.9%) participants respectively. The reasons why participants did not have their

intra-oral photographs (all or some), or dental impressions taken was that they struggled with an exaggerated gag reflex. Table 4.1 shows the total number of records taken. Complete records were collected for 281 participants.

Table 4.1 The total number of dental records taken for study participants

Dental record	PEPT n=78	No-PEPT n=254	Total n=332
	n (%)	n (%)	n (%)
Dental examination	78 (100%)	254 (100%)	332 (100%)
Extra-oral photographs	76 (97.4%)	221 (87%)	297 (89.5%)
Intra-oral photographs*	76 (97.4%)	233 (91.7%)	309 (93.1%)
Dental impressions**	72 (92.3%)	233 (91.71%)	305 (91.9%)

*Complete sets of frontal in occlusion, upper and lower occlusal, right and left buccal in occlusion

**Complete upper and lower sets

4.1.4 Characteristics of study participants

4.1.4.1 Socio-demographic characteristics

The mean age of participants in both PEPT and no-PEPT groups was 10.0 (standard deviation (SD)=0.78) and 10.3 (SD=0.79) years respectively, with the majority being females in both groups (n=49/78, 62.8% and n=141, 57.8% respectively). Most participants were from South Asian (Pakistani, Indian, and Bangladeshi) origin (PEPT n=71/78, 82.8% and no-PEPT n=202/244, 91%). Around a quarter of participants in both groups were eligible for free school meals (PEPT n=18/78, 23.1% and no-PEPT n=66/244, 27%).

When comparing the study groups (PEPT and no-PEPT), no significant difference was found between the groups with regards to socio-demographic characteristics including age, gender, ethnicity and eligibility for free school meals. The descriptive of participant groups by socio-demographic characteristics are summarised in Table 4.2.

Table 4.2 Descriptive of participant study groups (PEPT and no-PEPT) by socio-demographic characteristics

		PEPT	**No-PEPT**	***P* value***
		n=78	**n=244**	
		Mean (SD)**	Mean (SD)**	
Age		10.04 (0.78)	10.26 (0.79)	0.05
		n=78	**n=244**	***P* value***
		n (%)	n (%)	
Gender	Female	49 (62.8%)	141 (57.8%)	0.40
	Male	29 (37.2%)	103 (42.2%)	
Ethnicity	South Asian	71 (82.8%)	202 (91%)	0.20
	White British	5 (6.4%)	29 (11.9%)	
	Other	2 (2.6%)	13 (5.3%)	
Eligibility for free meals	Yes	18 (23.1%)	66 (27%)	0.50
	No	60 (76.9%)	178 (73%)	

*Chi-square test except for age, Mann-Whitney U test was used, a *P* value of <0.05 was considered statistically significant

**Mean and standard deviation (SD) were reported because age was normally distributed based on Skewness (-0.08)

4.1.4.2 Dental and occlusal characteristics

Most participants in the PEPT group (n=77/78, 98.7%) and no-PEPT group (n=203/244, 83.2%) were in the mixed dentition. At the time of examination, more than one third of PEPT participants (n=31/78, 39.7%) and no-PEPT participants (n=86/244, 35.2%) had at least one carious/restored primary

tooth. The proportion of PEPT participants who had at least one carious/restored permanent tooth (n=17/78, 21.8%) was almost twice as high as no-PEPT participants (n=28/244, 11.5%). The proportion of participants with hypomineralisation in the primary teeth was also higher among PEPT participants (n=10/78, 12.8%) when compared to no PEPT participants (n=13/244, 5.3%). Hypomineralisation in permanent teeth was reported in n=28/78 (35.9%) and n=86/244 (35.2%) in the PEPT and no-PEPT groups respectively.

The majority of participants had competent lips (PEPT n=69/78, 88.5%, no-PEPT n=219/244, 89.8%), Class I incisor relationship (PEPT n=33/78, 42.3%, no-PEPT n=114/244, 46.7%), Class I molar relationship in both right and left molars (PEPT n=39/78, 50%, no-PEPT n=132/244, 54.1%), and Class I skeletal pattern (PEPT n=41/78, 52.6%, no-PEPT n=158/244, 64.3%). Most PEPT participants had an average overbite (n=34/78, 43.6%) but an increased overjet (n=29/78, 37.2%), while no-PEPT participants had an average overbite and overjet (n=133/244, 54.5% and n=128/244, 52.5% respectively). Other malocclusion characteristics were also recorded such as palpability of upper permanent canines, mobility of upper primary canines, and mandibular deviation.

When comparing the study groups (PEPT and no-PEPT), type of dentition (mixed or permanent) was significantly different between groups ($P<0.01$). The presence of caries/restorations in permanent teeth and

hypomineralisation in primary teeth was also significantly different (*P*=0.02 and 0.03 respectively). Moreover, the differences in the overjet and palpability of upper canines were significant (*P*=0.01, 0.02 respectively). The descriptive of participant groups by dental and malocclusion characteristics are summarised in Table 4.3.

Table 4.3 Descriptive of participant study groups (PEPT and no-PEPT) by dental and malocclusion characteristics

		PEPT n=78	No-PEPT n=244	*P* value*
		n (%)	n (%)	
Dentition	Mixed	77 (98.7%)	203 (83.2%)	**<0.01**
	Permanent	1 (1.3%)	41 (16.8%)	
Caries/restorations in primary teeth	Yes	31 (39.7%)	86 (35.2%)	0.5
	No	47 (60.3%)	158 (64.8%)	
Caries/restorations in permanent teeth	Yes	17 (21.8%)	28 (11.5%)	**0.02**
	No	61 (78.2%)	216 (88.5%)	
Hypomineralisation in primary teeth	Yes	10 (12.8%)	13 (5.3%)	**0.03**
	No	68 (87.2%)	231 (94.7%)	
Hypomineralisation in permanent teeth	Yes	28 (35.9%)	86 (35.2%)	0.9
	No	50 (64.1%)	158 (64.8%)	
Lip competence	Incompetent	9 (11.5%)	25 (10.2%)	0.7
	Competent	69 (88.5%)	219 (89.8%)	
Permanent incisor relationship	Class I	33 (42.3%)	114 (46.7%)	0.7
	Class II division I	30 (38.5%)	93 (38.1%)	
	Class II division II	6 (7.7%)	19 (7.8%)	
	Class III	9 (11.5%)	18 (7.4%)	
Permanent molar relationship (right)	Class I	39 (50%)	132 (54.1%)	0.7
	Class II	28 (35.9%)	82 (33.6%)	
	Class III	11 (14.1%)	28 (11.5%)	
	Not applicable	0 (0%)	2 (0.8%)	
Permanent molar relationship (left)	Class I	41(52.6%)	158 (64.8%)	0.1
	Class II	30 (38.5%)	73 (29.9%)	
	Class III	7(9%)	11 (4.5%)	
	Not applicable	0(0%)	2 (0.8%)	
Skeletal pattern	Class I	41 (52.6%)	152 (62.3%)	0.3
	Class II	29 (37.2%)	71 (29.1%)	
	Class III	8 (10.3%)	21 (8.6%)	
Overbite	Average	34 (43.6%)	133 (54.5%)	0.1
	Increased	28 (35.9%)	80 (32.8%)	
	Decreased	16 (20.5%)	31 (12.7%)	
Overjet	Average	28 (35.9%)	128 (52.5%)	**0.01**
	Increased	29 (37.2%)	85 (34.8%)	
	Decreased	21 (26.9%)	31 (12.7%)	
Palpability of upper permanent canines	Right	2 (2.6%)	15 (6.1%)	**0.02**
	Left	2 (2.6%)	9 (3.7%)	

	Both	60 (76.9%)	145 (59.4%)	
	No	2 (2.6%)	1 (0.4%)	
	Not applicable	12 (15.4%)	74 (30.3%)	
Mobility of upper primary canines	Right	2 (2.6%)	15 (6.1%)	0.3
	Left	7 (9%)	11 (4.5%)	
	Both	8 (10.3%)	17 (7%)	
	No	34 (43.6%)	121 (49.6%)	
	Not applicable	27 (34.6%)	80 (32.8%)	
Mandibular deviation	Yes	8 (10.3%)	40 (16.4%)	0.2
	No	70 (89.7%)	204 (83.6%)	

*Chi-square test, a *P* value of <0.05 was considered statistically significant

4.1.4.3 Tooth level characteristics of participants with PEPT under GA

Data related to tooth level characteristics were only available for participants with PEPT under GA. The mean age for PEPT under GA was 5.3 years (SD=1.25). The mean age when participants were examined as part of this study was 10.1 (SD=0.75), with a time gap of approximately five years since the extraction under GA. The total number of primary teeth extracted under GA ranged from 1-16, median=10, IQR=7.5-12 (Skewness=2.62). The number of participants according to the total number of extracted primary teeth under GA are reported in Table 4.4.

Table 4.4 The number of participants according to total number of extracted teeth per participant and the total number of extracted teeth

Total number of extracted teeth per participant	Number of participants n=37
	n (%)
1	1 (2.7%)
5	1 (2.7%)
6	5 (13.5%)
7	2 (5.4%)
8	4 (10.8%)
9	4 (10.8%)
10	3 (8.1%)
11	2 (5.4%)
12	8 (21.6%)
13	2 (5.4%)
14	3 (8.1%)
16	2 (5.4%)

The type of primary teeth extracted included central incisors and first and second molars. The most commonly extracted primary tooth under GA in the PEPT group was the primary first molar in 97.3% (n=36/37) of the participants followed by the primary second molar in 94.6% (35/37) of the participants. The frequency of participants with PEPT under GA according to the type of primary teeth extracted is reported in Table 4.5.

Table 4.5 The number of participants with PEPT under GA according to the type of primary teeth extracted

Type of teeth extracted* **(in at least one quadrant)**	**Number of participants n=37**
	n (%)
E	1 (2.7%)
ADE	25 (67.6%)
AD	2 (5.4%)
DE	9 (24.3%)

*A=primary central incisor, D=primary first molar, E=primary second molar

4.1.4.4 Assessing sufficient space for permanent teeth (canines and premolars) utilising the Leeway space

Measurements were performed on digital models in millimetres for the CDE space of each quadrant. These were performed using Meshlab software Version 3.0 in which measurements were accurate to <10 microns on calibrated scans. Less than half (n=35/78, 44.9%) of the participants with PEPT were assessed as likely to have an impaction within the arch, compared to the no-PEPT participants (n=21/244, 8.6%). The results of whether space loss or crowding in the arch was likely to cause permanent tooth impaction or not are summarised in Table 4.6.

Table 4.6 Assessment of whether space loss or crowding within the arch is likely to cause permanent tooth impaction

	PEPT n=78	No-PEPT n=244
	n (%)	n (%)
Yes*	35 (44.9%)	21 (8.6%)
No	43 (55.1%)	223 (91.4%)

* A 'yes' relates to at least one quadrant in the mouth being assessed with a likelihood of impaction due to space loss or crowding.

4.1.5 Primary outcome: the assessed need for orthodontic treatment using the dental health component of the Index of Orthodontic Treatment Need (IOTN-DHC)

The proportion of participants with PEPT who were assessed in need of orthodontic treatment was 69.2% (n=54/78) compared to 40.6% (n=99/244) participants with no-PEPT. PEPT was strongly associated with an increased need for orthodontic treatment, OR=3.3, 95% CI=1.9-5.7, *P*<0.001 (unadjusted and adjusted OR are presented later in Table 4.13). The proportions of participants, with and without PEPT, who were assessed for the need of orthodontic treatment (need or no need) are summarised in Table 4.7.

Table 4.7 The need for orthodontic treatment in PEPT and no-PEPT participants

	PEPT n=78	No-PEPT n=244
	n (%)	n (%)
In need of orthodontic treatment	54 (69.2%)	99 (40.6%)
No need for orthodontic treatment	24 (30.8%)	145 (59.4%)

The proportion of participants with PEPT under GA, who were assessed in need for orthodontic treatment was 83.8% (n=31/37) compared to 56.1%

(n=23/41) participants with PEPT under LA. PEPT under GA was associated with an increased need for orthodontic treatment, OR=7.6, 95% CI=3.0-18.8, *P*<0.001 (unadjusted and adjusted OR are presented later in Table 4.15). The proportions of participants, with PEPT under GA, LA and without PEPT, who were assessed for the need of orthodontic treatment (need or no need) are summarised in Table 4.8.

Table 4.8 The need for orthodontic treatment in PEPT under GA, LA and no-PEPT participants

	PEPT under GA n=37	**PEPT under LA n=41**	**No-PEPT n=244**
	n (%)	n (%)	n (%)
In need of orthodontic treatment	31 (83.8%)	23 (56.1%)	99 (40.6%)
No need for orthodontic treatment	6 (16.2%)	18 (43.9%)	145 (59.4%)

The IOTN-DHC grades ranged from 2 to 5 with 17 malocclusion categories. Half of the participants in the PEPT exposure group (50%) were graded IOTN-DHC 5 with the majority falling under the category 5i (n=37/78, 47.4%). In contrast, most participants in the no-PEPT control group were graded 2 with the majority falling under 2d (n=54/244, 22.1%). The proportion of different IOTN-DHC grades for the PEPT and no-PEPT participants are presented in Table 4.9.

Table 4.9 IOTN-DHC grades* and frequency for all 322 participants

IOTN-DHC Grade**	Subgrades**	PEPT n=78	No-PEPT n=244
		n (%)	n (%)
Grade 5	5i	37 (47.4%)	14 (5.7%)
	5a	4 (5.1%)	4 (1.6%)
Grade 4	4a	8 (10.3%)	25 (10.2%)
	4d	3 (3.8%)	42 (17.2%)
	4c	1 (1.3%)	12 (4.9%)
	4t	0 (0%)	2 (0.8%)
Grade 3	3d	4 (5.1%)	41 (16.8%)
	3b	1 (1.3%)	0 (0%)
	3a	1 (1.3%)	9 (3.7%)
	3c	1 (1.3%)	3 (1.2%)
	3e	0 (0%)	2 (0.8%)
	3f	0 (0%)	1 (0.4%)
Grade 2	2d	11 (14.1%)	54 (22.1%)
	2a	5 (6.4%)	27 (11.1%)
	2c	2 (2.6%)	4 (1.6%)
	2g	0 (0%)	3 (1.2%)
	2b	0 (0%)	1 (0.4%)

*Please refer to Table 3.3 in Chapter 3 for detailed description of each grade

**Grades and subgrades were reported in descending order according to the number of participants in the PEPT group

4.1.5.1 Assessing the proportions who would benefit from treatment now in the mixed dentition rather than waiting until the permanent dentition for their orthodontic treatment

The assessments about the most appropriate time for treatment (soon or in the permanent dentition) were also reported. For the majority of participants assessed in need for orthodontic treatment, the optimal time for treatment was assessed to be performed in the permanent dentition (PEPT n=53/78, 67.9%, no-PEPT n=94/244, 38.5%).

The proportions of PEPT and no-PEPT participants who were assessed to be treated in the mixed or permanent dentition was reported in Table 4.10.

Table 4.10 The proportions of participants who were assessed to be treated in the mixed or permanent dentition

	PEPT n=78	**no-PEPT n=244**
	n (%)	n (%)
In need of orthodontic treatment in the permanent dentition*	53 (67.9%)	94 (38.5%)
In need of orthodontic treatment now in the mixed dentition	1 (1.3%)	5 (2.0%)
Unclear**	4 (6.4%)	4 (1.6%)
No need for orthodontic treatment	19 (24.4%)	141 (57.8%)

*Participants who were in their permanent dentition stage were included under this category

**'Unclear' refers to borderline assessments where a decision could not be made regarding the assessed need for orthodontic treatment, this was included under 'no need for orthodontic treatment' in the primary outcome (Tables 4.7 and 4.8)

4.1.5.2 Association between orthodontic treatment need, PEPT and socio-demographic variables

The mean age for participants assessed in need of orthodontic treatment was 10.2 years with the majority being females (n=92/153, 60.1%). Most participants were from South Asian origin (n=134/153, 87.6%) and more than a quarter were eligible for free school meals (n=39/153, 25.5%). When comparing the participants in need and no need for orthodontic treatment, no statistical difference was observed between groups in terms of age, gender, ethnicity, and eligibility for free school meals.

When comparing the assessed need for orthodontic treatment (need and no need) by socio-demographic variables, no significant difference was found. Socio-demographic characteristics of participants assessed in need and no need for orthodontic treatment were summarised in Table 4.11.

Table 4.11 Descriptive of participants assessed in need for orthodontic treatment (need and no need) by socio-demographic characteristics

Variables		**In need of orthodontic treatment n=153**	**No need for orthodontic treatment n=169**	***P* value***
		Mean (SD)**	Mean (SD)**	
Age		10.2 (0.8)	10.2 (0.8)	0.65
		n=153	**n=169**	***P* value***
		n (%)	n (%)	
Gender	Female	92 (60.1%)	98 (58.0%)	0.70
	Male	61 (39.9%)	71 (42.0%)	
Ethnicity	South Asian	134 (87.6%)	139 (82.2%)	0.36
	British	14 (9.2%)	20 (11.8%)	
	Other	5 (3.3%)	10 (5.9%)	
Eligibility for free school meals	Yes	39 (25.5%)	45 (26.6%)	0.82
	No	114 (74.5%)	124 (73.4%)	

*Chi-square test except for age, Mann-Whitney U test was used, a *P* value of <0.05 was considered statistically significant

**Mean and standard deviation (SD) were reported because age was normally distributed based on Skewness (-0.08)

Logistic regression to examine whether sociodemographic characteristics including age, gender, ethnicity, and eligibility for free school meals were associated with an increased need for orthodontic treatment, did not show a significant association (Table 4.12). An unadjusted logistic regression model

showed a strong association between PEPT and the assessed need for orthodontic treatment (OR=3.3, 95% CI=1.9-5.7, *P*<0.001). Adjusting for covariates including age, gender, ethnicity, and eligibility for free school meals showed a significant association between PEPT and the assessed need for orthodontic treatment (OR=3.2, 95% CI=1.9-5.6, *P*<0.001) (Table 4.13).

Table 4.12 Logistic regression relating socio-demographic characteristics (age, gender, ethnicity, and eligibility for free school meals) to the orthodontic need in PEPT and no-PEPT participants

Variables	OR*	95% CI**	*P* value***
Age	1.0	0.73-1.31	0.90
Gender	0.9	0.61-1.54	0.89
Ethnicity	0.6	0.39-1.73	0.61
Eligibility for free school meals	0.9	0.58-1.65	0.95

*OR=odds ratio

**CI=confidence interval

***A *P* value of <0.05 was considered statistically significant

Table 4.13 Unadjusted and adjusted regression analysis model for 322 participants to investigate the association between PEPT and the assessed need for orthodontic treatment

	Unadjusted	Adjusted*
	OR (95% CI)**	OR (95% CI)**
PEPT* **	<0.001	<0.001
Yes** **	3.3 (1.91-5.68)	3.2 (1.86-5.62)

*Adjusted for age, gender, ethnicity, and eligibility for free meals

**OR=odds ratio, CI=confidence interval

***A *P* value of <0.05 was considered statistically significant

****Reference group: no-PEPT

4.1.5.3 Association between orthodontic treatment need, PEPT under GA and socio-demographic variables

Logistic regression to examine whether sociodemographic characteristics including age, gender, ethnicity, and eligibility for free school meals were associated with an increased need for orthodontic treatment, did not show a significant association (Table 4.14). An unadjusted logistic regression model showed a strong association between PEPT under GA and the assessed need for orthodontic treatment (OR=7.6, 95% CI=3.04-18.81, *P*<0.001). Adjusting for covariates including age, gender, ethnicity, and eligibility for free school meals showed a significant association between PEPT under GA and the assessed need for orthodontic treatment (OR=7.7, 95% CI=3.07-19.22, *P*<0.001) (Table 4.15).

Table 4.14 Logistic regression relating socio-demographic variables (age, gender, ethnicity, and eligibility for free school meals) to the orthodontic need in PEPT under GA and no-PEPT participants

Variables	OR*	95% CI**	*P* value***
Age	0.9	0.69-1.30	0.74
Gender	0.9	0.55-1.52	0.74
Ethnicity	1.1	0.49-2.30	0.89
Eligibility for free school meals	0.92	0.52-1.61	0.76

*OR=odds ratio

**CI=confidence interval

***A *P* value of <0.05 was considered statistically significant

Table 4.15 Unadjusted and adjusted regression analysis model for 281 participants to investigate the association between PEPT under GA and the assessed need for orthodontic treatment

	Unadjusted	**Adjusted***
	OR (95% CI)**	OR (95% CI)**
PEPT***	<0.001	<0.001
Yes******	7.6 (3.04-18.81)	7.7 (3.07-19.22)

*Adjusted for age, gender, ethnicity, and eligibility for free meals

**OR=odds ratio, CI=confidence interval

***A *P* value of <0.05 was considered statistically significant

****Reference group: no-PEPT

Chapter Five: Results-secondary outcomes

5.1 The impact of PEPT on Oral Health-Related Quality of Life (OH-RQoL)

The preliminary results of the OH-RQoL section were presented at the British Society of Paediatric Dentistry Annual Conference 2021. The abstract was selected for oral presentation as a finalist in the Research Prize category (Appendix 5.1).

5.1.1 Response rate and questionnaire data

Out of 322 participants who were assessed for the need of orthodontic treatment, 318 completed the questionnaire with a response rate of 98.8%. Participants completed the questionnaire by themselves. Of these, 78 had premature extraction of primary teeth (PEPT) and 240 did not have PEPT (no-PEPT). Their mean age at the time of completing the questionnaire was 10.14 years (standard deviation=0.75).

Descriptive statistics using frequencies and proportions for all items of the short form of the Child Oral Health Impact Profile (COHIP-SF 19) according to the study group, including general oral health perception question are summarised in Table 5.1. The highest and lowest frequencies and proportions are highlighted in bold.

Under the oral health domain (questions 1-5), most responses for participants with PEPT were sometimes for tooth pain (n=33/78, 42.3%), crooked teeth or

spacing (n=25, 32.1%), sometimes, almost never, and never for bad breath (n=24, 30.8%), and never for discoloured teeth (n=53/78, 67.9%) and bleeding gums (n=88, 36.7%). In contrast, most responses for no-PEPT participants were sometimes for tooth pain (n=96, 40%) and never for crooked teeth or spacing (n=94, 39.2%), discoloured teeth (n=165, 68.8%), bad breath (n=76, 31.7%), and bleeding gums (n=30, 38.5%). Under the socio-emotional well-being domain (questions 6-15), most participants with PEPT and no-PEPT responded with never for being unhappy, worried or anxious, not wanting to speak in class, avoiding smiling, being teased, feeling they were attractive, and feeling they looked different because of their teeth, mouth, or face. Most participants responded with sometimes for being confident because of their teeth, mouth, or face (n=21, 26.9% and n=82, 34.2% for PEPT and no-PEPT respectively). Under the functional well-being domain (questions 16-19), most participants responded with never for having difficulty eating foods they would like, trouble sleeping, difficulty saying certain words, and difficulty keeping their teeth clean. Participants with PEPT had also responded with sometimes for having difficulty in eating foods they would like (n=27, 34.6%). Most participants rated their oral health as being good (n=28, 35.9% and n=96, 40% for PEPT and no-PEPT respectively) (question 20).

Table 5.1 Descriptive of participant study groups by COHIP-SF 19 items

Serial no.*	Item	Frequency (%)									
		Almost all times		**Fairly often**		**Sometimes**		**Almost never**		**Never**	
		PEPT**	no-PEPT***	PEPT	no-PEPT	PEPT	no -PEPT	PEPT	no-PEPT	PEPT	no-PEPT
1	Have you ever had pain in your teeth/toothache?										
		0 (0%)	5 (2.1%)	6 (7.7%)	7 (2.9%)	**33 (42.3%)**	**96 (40%)**	15 (19.2%)	40 (16.7%)	24 (30.8%)	92 (38.3%)
2	Have you ever had crooked tooth or spaces between your teeth?										
		11 (14.1%)	17 (7.1%)	7 (9%)	25 (10.4%)	**25 (32.1%)**	66 (27.5%)	12 (15.4%)	38 (15.8%)	23 (29.5%)	**94 (39.2%)**
3	Have you ever had discoloured teeth or spots on your teeth?										
		1 (1.3%)	7 (2.9%)	0 (0%)	20 (4.2%)	15 (19.2%)	25 (10.4%)	9 (11.5%)	33 (13.8%)	**53 (67.9%)**	**165 (68.8%)**
4	Have you ever had bad breath?										
		2 (2.6%)	13 (5.4%)	4 (5.1%)	18 (7.5%)	**24 (30.8%)**	73 (30.4%)	**24 (30.8%)**	60 (25%)	**24 (30.8%)**	**76 (31.7%)**
5	Have you ever had bleeding gums?										
		14 (4.8%)	8 (10.3%)	27 (11.3%)	1 (1.3%)	63 (26.3%)	23 (29.5%)	48 (20%)	16 (20.5%)	**88 (36.7%)**	**30 (38.5%)**
6	Have you ever been unhappy or sad because of your teeth, mouth, or face?										
		4 (5.1%)	11 (4.6%)	2 (2.6%)	20 (8.3%)	18 (23.1%)	45 (18.8%)	12 (15.4%)	22 (9.2%)	**42 (53.8%)**	**142 (59.2%)**
7	Have you ever missed school for any reason because of your teeth, mouth, or face?										
		3 (3.8%)	3 (1.3%)	1 (1.3%)	0 (0%)	13 (16.7%)	23 (9.6%)	12 (15.4%)	23 (9.6%)	**49 (62.8%)**	**191 (79.6%)**

..continued

	Almost all times		Fairly often		Sometimes		Almost never		Never	
8	Have you ever been confident because of your teeth, mouth, or face?									
	15 (19.2%)	37 (15.4%)	10 (12.8%)	35 (14.6%)	**21 (26.9%)**	**82 (34.2%)**	12 (15.4%)	26 (10.8%)	20 (25.6%)	60 (25%)
9	Have you ever felt worried or anxious because of your teeth, mouth, or face?									
	1 (1.3%)	1 (0.4%)	1 (1.3%)	11 (4.6%)	8 (10.3%)	46 (19.2%)	19 (24.4%)	34 (14.2%)	**49 (62.8%)**	**148 (61.7%)**
10	Have you ever not wanted to speak/read out loud in class?									
	2 (2.6%)	11 (4.6%)	1 (1.3%)	11 (4.6%)	16 (20.5%)	38 (15.8%)	12 (15.4%)	32 (13.3%)	**47 (60.3%)**	**148 (61.7%)**
11	Have you ever avoided smiling or laughing with other children because of your teeth, mouth, or face?									
	3 (3.8%)	10 (4.2%)	4 (5.1%)	19 (7.9%)	11 (14.1%)	35 (14.6%)	9 (11.5%)	27 (11.3%)	**51 (65.4%)**	**149 (62.1%)**
12	Have you ever been teased, bullied, or called names by other children because of your teeth, mouth, or face?									
	0 (0%)	8 (3.3%)	2 (2.6)	2 (0.8%)	4 (5.1%)	25 (10.4%)	8 (10.3%)	18 (7.5%)	**64(82.1%)**	**187 (77.9%)**
13	Have you ever felt that you were attractive (good looking) because of your teeth, mouth, or face?									
	7 (9%)	16 (6.7%)	3 (3.8%)	7 (2.9%)	18 (23.1%)	58 (24.2%)	11 (14.1%)	36 (15%)	**39(50%)**	**123 (51.2%)**
14	Have you ever felt that you look different because of your teeth, mouth, or face?									
	3 (3.8%)	4 (1.7%)	5 (6.4%)	10 (4.2%)	16 (20.5%)	48 (20%)	13 (16.7%)	24 (10%)	**41(52.6%)**	**154 (64.2%)**
15	Have you ever been worried about what other people think about your teeth, mouth, or face?									
	2 (2.6%)	12 (5%)	4 (5.1%)	9 (3.8%)	14 (17.9%)	43 (17.9%)	13 (16.7%)	31 (12.9%)	**45(57.7%)**	**145 (60.4%)**

..continued

	Almost all times		**Fairly often**		**Sometimes**		**Almost never**		**Never**	
16	Have you ever had difficulty eating foods you would like because of your teeth, mouth, or face?									
	1 (1.3%)	8 (3.3%)	8 (10.3%)	19 (7.9%)	**27 (34.6%)**	50 (20.8%)	15 (19.2%)	31 (12.9%)	**27 (34.6%)**	**132 (55%)**
17	Have you ever had trouble sleeping because of your teeth, mouth, or face?									
	1 (1.3%)	1 (0.4%)	5 (6.4%)	8 (3.3%)	11 (14.1%)	35 (14.6%)	12 (15.4%)	26 (10.8%)	**49 (62.8%)**	**170 (70.8%)**
18	Have you ever had difficulty saying certain words?									
	3 (3.8%)	7 (2.9%)	3 (3.8%)	10 (4.2%)	22 (28.2%)	40 (16.7%)	10 (12.8%)	32 (13.3%)	**40 (51.3%)**	**151 (62.9%)**
19	Have you ever had difficulty keeping your teeth clean?									
	4 (5.1%)	10 (4.2%)	7 (9%)	13 (5.4%)	20 (25.6%)	61 (25.4%)	16 (20.5%)	57 (23.8%)	**31 (39.7%)**	**99 (41.3%)**
20 Global self-rated oral health: Overall, please rate your oral health.										
	Poor		Fair		Average		Good		Excellent	
	1 (1.3%)	12 (5%)	5 (6.4%)	24 (10%)	25 (32.1%)	59 (24.6%)	**28 (35.9%)**	**96 (40%)**	19 (24.4%)	49 (20.4%)

*Oral health domain (1-5), socio-emotional well-being domain (6-15), functional well-being domain (16-19)

**PEPT=participants with premature extraction of primary teeth (exposure group)

***No-PEPT=participants without premature extraction of primary teeth (control group)

Note: Bolding highest and lowest frequencies and proportions

5.2 The Impact of PEPT on the orthodontic need and OH-RQoL

COHIP-SF 19 scores ranged from 15-75 (poor to optimal). The median and interquartile range were reported because questionnaire data were negatively skewed (Skewness=-1.006). The median total COHIP-SF 19 score was 57 (interquartile range (IQR)=52-60) for participants with PEPT and 58 (IQR=51-64) for participants without PEPT, which was not statistically significant. The difference in median scores between participants with and without PEPT in all three domains (oral health well-being, socio-emotional well-being, and functional well-being domains) was not statistically significant except for the functional well-being domain (*P*=0.007, minimal important difference (MID)=1); however, the difference would not be considered clinically significant.

The median total COHIP-SF 19 score was 57.5 (IQR=50-61.25) for participants in need of orthodontic treatment and 59 (IQR=52-64) for participants with no need for orthodontic treatment, which was statistically significant but not clinically insignificant (*P*=0.016, MID=1.5). The difference in median scores between participants in need and no need for orthodontic treatment in all three domains was not statistically significant except for the socio-emotional well-being domain (*P*=0.013, MID=1), however, this would not be considered clinically significant.

The difference in medians for the total and domain COHIP-SF 19 scores according to socio-demographic variables (gender, eligibility for free school meals, and ethnicity) were insignificant.

Table 5.2 summarises the medians and interquartile ranges for the total and domain COHIP-SF 19 scores according to study group, assessed need for orthodontic treatment, and socio-demographic characteristics.

Table 5.2 Comparison of medians and interquartile ranges (IQR) for the total and domain COHIP-SF 19 scores by study group, assessed need for orthodontic treatment, and socio-demographic characteristics

	Overall COHIP-SF 19 score (0-75)	**Oral health well-being domain (0-20)***	**Socio-emotional well-being domain (0-40)***	**Functional well-being domain (0-16)***
Study group	Median (IQR)			
PEPT (n=78)	57 (52-60)	14 (12.75-16)	30 (27-33)	12 (11-14)
No-PEPT (240)	58 (51-64)	15 (12-17)	31 (26-34)	13 (11-15)
Significance**	0.12	0.39	0.45	**0.01**
Clinical significance***	No	No	No	No
Need for orthodontic treatment	Median (IQR)			
In need (n=158)	57 (50-61)	14 (12-16)	29.5 (25-33)	13 (11-14)
No need (n=160)	59 (52-64)	15 (12-17)	31 (28-34)	13 (12-15)
Significance**	**0.01**	**0.03**	**0.01**	0.32
Clinical significance***	No	No	No	No
Gender	Median (IQR)			
Female (n=188)	58 (52-63.75)	15 (12-17)	30 (27-33)	13 (11-15)
Male (n=130)	58 (50-63)	14 (12-17)	31 (26-34)	13 (11-14.25)
Significance**	0.75	0.25	0.68	0.25
Clinical significance***	No	No	No	No

..continued

Ethnicity	**Median (IQR)**			
South Asian (269)	58 (51-63)	15 (12-17)	31 (27-33)	13 (11-15)
White British (34)	58 (51.5-62.25)	15 (12-17)	29.5 (25.75-32.35)	14 (12-15)
Other (15)	60 (49-71)	16 (12-19)	32 (25-36)	13 (10-16)
Significance**	0.67	0.38	0.85	0.70
Clinical significance***	No	No	No	No
Eligibility for free school meals	Median (IQR)			
Yes (83)	59 (50-63)	15 (12-16)	31 (26-34)	12 (10-15)
No (235)	58 (52-64)	15 (11-15)	31 (27-33)	13 (12-15)
Significance**	0.36	0.70	0.46	0.20
Clinical significance***	No	No	No	No

*Please refer to Table 5.1 for questions under this domain

** Mann-Whitney U test, a *P* value of <0.05 was considered statistically significant

***For clinical significance, the Minimally Important Difference (MID) should be >±4 points (Masood et al., 2014)

5.2.1 Association between COHIP-SF 19 total scores, PEPT and socio-demographic variables

Linear regression analysis relating socio-demographic characteristics including age, gender, ethnicity, and eligibility for free school meals to the COHIP-SF 19 total scores did not show significant association (Table 5.3). Unadjusted and adjusted models to investigate the association between PEPT (exposure) and COHIP-SF 19 total scores (outcome) by covariates (age, gender, ethnicity, and eligibility for free school meals) showed insignificant results (coefficient beta=-1.10 95% CI=-3.73-1.52, *P*=0.41 and coefficient beta=-0.98 95% CI=-3.66-1.70, *P*=0.47 respectively) (Table 5.4).

Table 5.3 Linear regression analysis relating sociodemographic characteristics to COHIP-SF 19 total scores

Variables	Coefficients Beta	95% CI*	*P* value**
Age	0.47	-0.98-1.93	0.52
Gender	-0.48	-2.80-1.84	0.68
Ethnicity	0.87	-1.40-3.13	0.45
Eligibility for free school meals	-0.65	-3.26-1.96	0.63

*Confidence interval

**A *P* value of <0.05 was considered statistically significant

Table 5.4 Unadjusted and adjusted regression analysis model for 318 participants to investigate the association between PEPT and COHIP-SF 19 total scores

	Unadjusted	**Adjusted***
	Coefficients Beta (95% CI**)	Coefficients Beta (95% CI)
PEPT***	0.41	0.47
Yes****	-1.10 (-3.73-1.52)	-0.98 (-3.66-1.70)

*Adjusted for age, gender, ethnicity, and eligibility for free meals

**Confidence interval

***A *P* value of <0.05 was considered statistically significant

******Reference group: no-PEPT

5.3 The impact of PEPT and Orthodontic Need on Health Economics

5.3.1 Results

In this section, dental care pathway (models) are hypothesised and health utilisation for participants with premature extraction of primary teeth (PEPT) and without premature extraction of primary teeth (no-PEPT) are presented. This was followed by an estimation of costs between two different outcomes, need and no need for orthodontic treatment.

5.3.2 Response rate and frequency of health resource utilisation

Out of 75 BiB parents of participants with PEPT under general anaesthetic (GA) or local anaesthetic (LA), 42 parents (24 under GA and 18 under LA) replied to the questionnaire focused on health utilisation before and around the time of dental extractions under GA or LA. The most frequent utilised health service was visiting the family dentist (n=32), followed by community dental service (n=23) and the use of over-the-counter pain killers (n=16). Data regarding the unit cost for National Health Service (NHS) health resource use were collected. The frequency of health utilisation by the PEPT and no-PEPT groups are summarised in Table 5.5.

Table 5.5 The frequency of health utilisation by participants with PEPT under GA and LA

Type of health care service	Unit Cost	GA (n=24) Frequency*	Total cost	LA (n=18) Frequency*	Total cost
Family Dentist	£23.80	35	£833	32	£761.60
Community Dental Service	£119	19	£2,261	15	£1,785
Painkiller/Pharmacy	£3.91	10	£39.10	7	£34.37
Emergency Dentist	£23.80	9	£214.20	12	£285.60
General Practitioner	£39.23	4	£156.92	4	£156.92
Practice/School nurse	£49.50	3	£148.50	-	
Health visitor	£54	3	£162	-	
Accident and Emergency	£32	2	£64	-	
Other		1		-	
Total			£3,878.72		£3,022.57

*Parents were asked how frequent they have utilised each health care service for their child, for example, how many times they had visited the family dentist to manage dental pain before PEPT

The direct and indirect dental and non-dental health-care costs for each timepoint were reported in Tables 5.6a-e (please refer to section 3.3.13.1 for more information on different timepoints). The estimated unit cost for healthcare utilisation for participants with PEPT under GA and LA was £161.61 and £167.92 respectively. The estimated unit cost for undergoing orthodontic treatment including at least one permanent tooth extraction (as a result of space loss and crowding following PEPT) was £2,362.60. The total estimated unit cost for PEPT under GA, LA, and no-PEPT was £4,244.16, £2,890.47, and £214.20 respectively. The estimated unit costs are presented in Figure 5.1.

The assessed need for orthodontic treatment in participants with PEPT under GA, LA, and no-PEPT was 91.9%, 56.1%, and 41.8% respectively (please refer to section 4.1.3.1 Primary outcome: the assessed need for orthodontic treatment using the dental health component of the Index of Orthodontic Treatment Need (IOTN-DHC), for more details). The total estimated cost per participant in need of orthodontic treatment, with PEPT under GA, LA, and no-PEPT was £2,251.79, £1,806.88, and £1,560.66 respectively. The estimated average costs per participant in need of orthodontic treatment are presented in Figure 5.2.

Tables 5.6a-e The unit costs for NHS health resource use

Table 5.6a Timepoint 1: Direct dental healthcare unit costs in the PEPT group

Item	Unit	Cost	Notes	Reference
Emergency dental treatment*	Emergency care in a primary care NHS dental practice such as pain relief or a temporary filling	£23.80	-	Dental Costs-Understanding NHS Dental Charges*
Dental examination and prevention/family dentist*	An examination, diagnosis (including X-rays), advice on how to prevent future problems, a scale and polish if clinically needed, and preventative care such as the application of fluoride varnish or fissure or fissure sealant if appropriate	£23.80		Dental Costs-Understanding NHS Dental Charges*
Community-based health care dentist-NHS Dentist	Unit costs available 2019/2020	£105 per hour £133 per hour of patient contact	-	Unit Costs of Health and Social Care 2021**
Tooth extraction in hospital for a child aged 5 and under	-	£836	-	Public Health England 2017***
Tooth extraction	-	£65.20	-	Dental Costs-Understanding NHS Dental Charges****

*https://www.nhs.uk/nhs-services/dentists/dental-costs/understanding-nhs-dental-charges/

**https://kar.kent.ac.uk/92342/25/Unit%20Costs%20Report%202021%20-%20Final%20version%20for%20publication%20%28AMENDED2%29.pdf

***https://assets.publishing.service.gov.uk/government/uploads/system/uploads/image_data/file/63736/6.3318_PHE_KG_Health_Matters_April_2017_Online_960x640_px_4.png

****https://www.nhs.uk/nhs-services/dentists/dental-costs/understanding-nhs-dental-charges/

Table 5.6b Timepoint 1: Direct non-dental healthcare unit costs in the PEPT group

Item	Unit	Cost	Notes	Reference
Over the counter pain killer	Calpol infant sugar free oral suspension	£3.50	-	Boots.com
	Calpol SixPlus sugar free suspension	£4.25	-	Boots.com
	Neurofen for children 3 months to 9 years suspension	£3.99	-	Boots.com
General Practitioner	Per surgery consultation lasting 9.22 minutes	£39.23	Including direct care staff cost	Unit Costs of Health and Social Care 2021*
	Prescription cost per consultation	£33.10	-	Unit Costs of Health and Social Care 2021*
Practice nurse	Unit costs available 2020/2021	£42 per hour	Including General Practitioner qualification	Unit Costs of Health and Social Care 2021*
		£133 per hour of patient contact	-	Unit Costs of Health and Social Care 2021*
School nurse	School-based children's health core (other services)-one to one	£57 per care contact	-	Unit Costs of Health and Social Care 2021*
Health visitor	The mean average cost for a face-to-face contact in health visiting services	£54 £44 (£50) per hour; £66 (£76) per hour of patient-related work.	-	Unit Costs of Health and Social Care 2015**

A&E services	Accident and emergency-walk in services leading to admitted (not admitted)	£32 (£41)	Unit Costs of Health and Social Care 2012***

*https://kar.kent.ac.uk/92342/25/Unit%20Costs%20Report%202021%20-%20Final%20version%20for%20publication%20%28AMENDED2%29.pdf

**https://www.pssru.ac.uk/pub/uc/uc2015/full.pdf

***https://www.pssru.ac.uk/pub/uc/uc2012/full-with-covers.pdf

Table 5.6c Timepoint 1: Indirect healthcare unit costs in the PEPT group

Item	Unit	Cost	Notes	Reference
Time off school	3 days off school 2-10 days attending hospital for dental GA and recovery	Lack of uncertainty of the unit cost, for example frequency of using painkillers	-	(Goodwin et al., 2015)
Sleepless nights	Median/mode 3/10 (1-10+ min-max) nights	Lack of uncertainty of the unit cost, for example frequency of using painkillers	-	(Goodwin et al., 2015)
Parental time off work	Average hourly pay*	£13.57	Average weekly hours of work 36.2 (7.24 hours per day)** Cost per day £98.25	GOV.UK Work, pay and benefits* Office for National Statistics CENSUS 2021**
Travel	-	Lack of uncertainty of the unit cost, for example the use of different means of transportation	-	-

*https://www.ethnicity-facts-figures.service.gov.uk/work-pay-and-benefits/pay-and-income/average-hourly-pay/latest

**https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/timeseries/ybuy/lms

Table 5.6d Timepoint 3: Direct unit healthcare costs for orthodontic treatment

Item	Unit	Cost	Notes	Reference
Orthodontic Assessment and accept treatment (patient aged 10-17)	60.28 per unit*, 1+20 unit of activity**	£1,265.88	-	*Orthodontic Services in Oxford, Thame, Eastleigh and Dover to NHS England and NHS Improvement (NHSE/I) South East **How many units of activity (UDA/UOA) does a course of treatment (COT) receive?

*https://bidstats.uk/tenders/2022/W21/775422372

**https://faq.nhsbsa.nhs.uk/knowledgebase/article/KA-01976/en-us

Table 5.6e Timepoint 3: Indirect health-care costs for orthodontic treatment

Item	Unit	Cost	Notes	Reference
Parental time off work	½ day*	£49.12	Average hourly pay £13.57** Average weekly hours of work 36.2 (3.62 hours per half day)*** Cost per day £98.25 Average number of visits for orthodontic treatment 21 days**** (£1,031.52 for 21 days)	*(Goodwin et al., 2015)

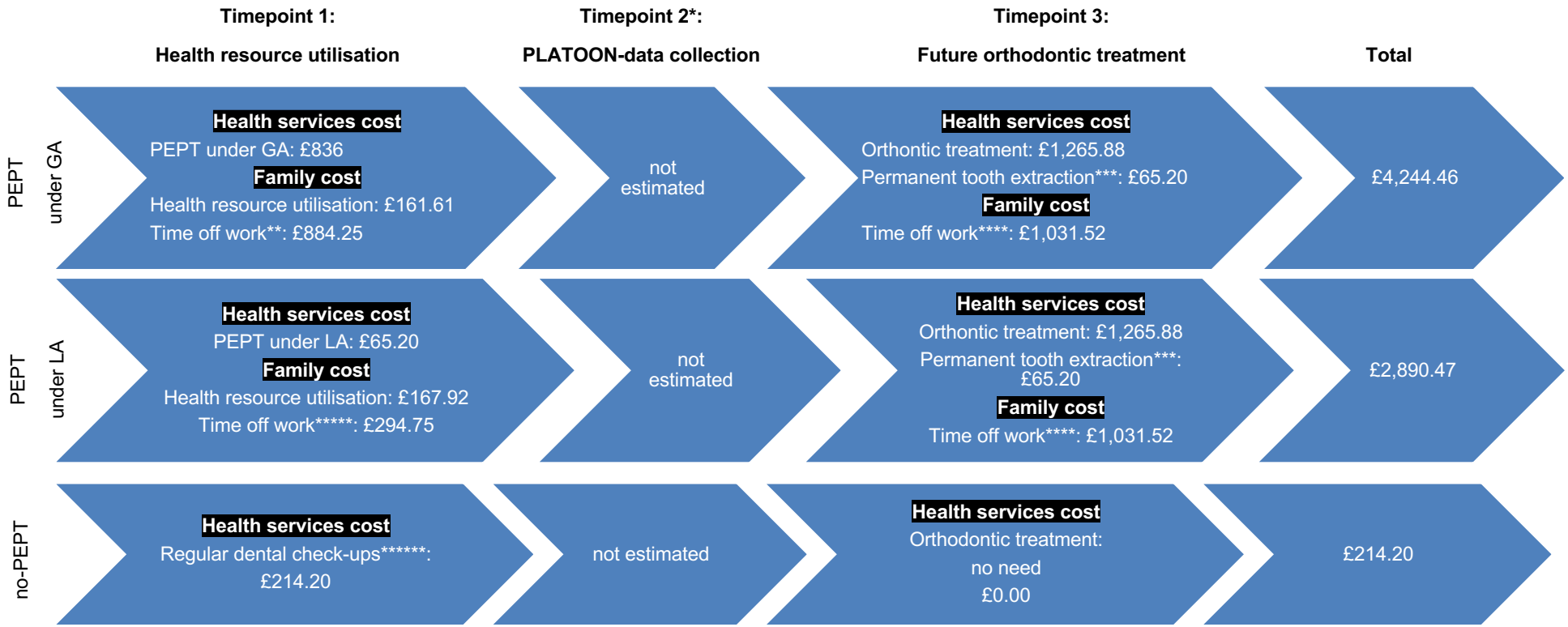
*(Goodwin et al., 2015)

**https://www.ethnicity-facts-figures.service.gov.uk/work-pay-and-benefits/pay-and-income/average-hourly-pay/latest

***https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/timeseries/ybuy/lms

****https://faq.nhsbsa.nhs.uk/knowledgebase/article/KA-01976/en-us

Figure 5.1 The estimated unit cost for PEPT under GA, LA, and no-PEPT per participant



*Costs were not explored at this timepoint

**9 working days on average (3 days for dental problems prior to GA and 6 days for hospital admission and recovery) (Goodwin et al., 2015)

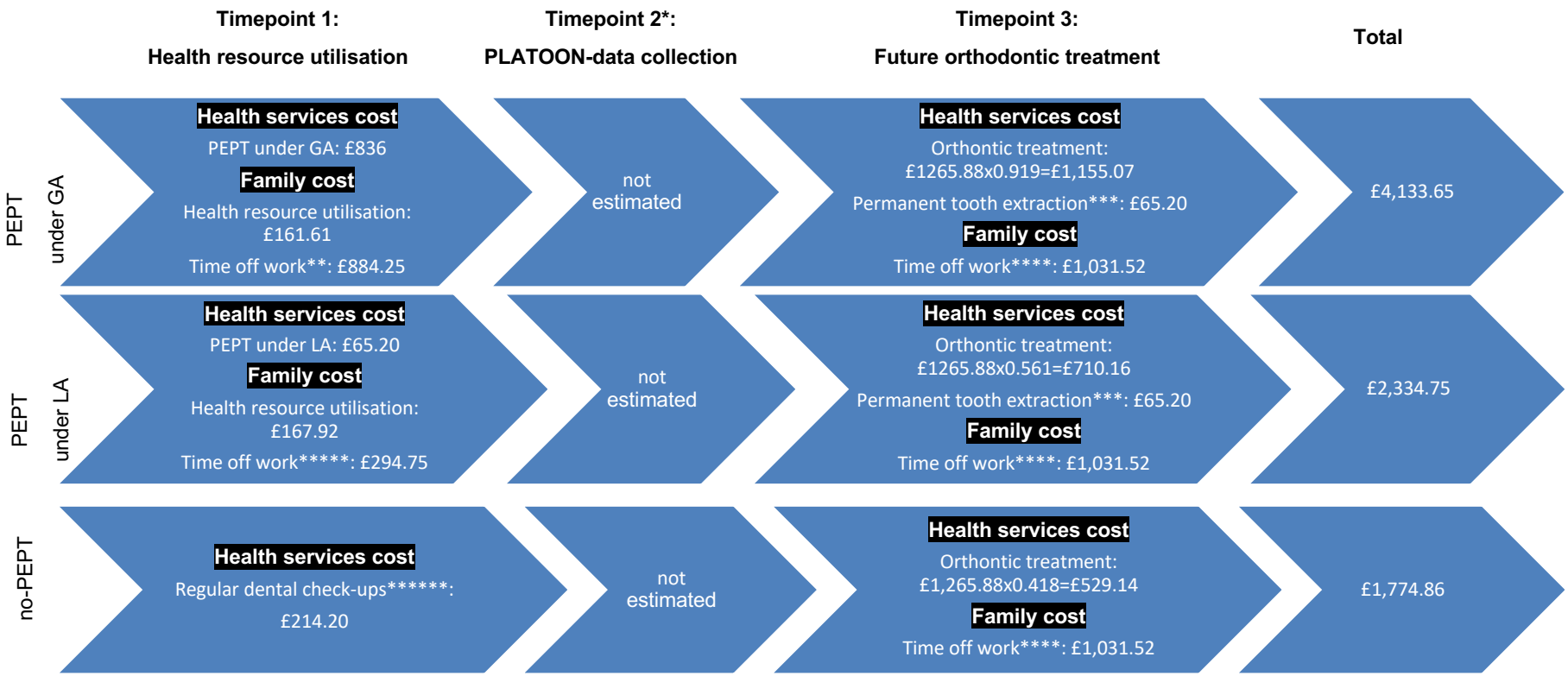
***Assuming that the child would require at least one tooth extracted for orthodontic treatment

****Assuming that the child would require 21 visits for orthodontic treatment (please refer to Table 5.1e for more details)

*****3 working days (for dental problems) (Goodwin et al., 2015)

******The frequency of visits was based of the mean average of child's age at PEPT i.e., five years, and assuming that child visited the dentist before their first birthday and biannually from the age of 1 year old as recommended by national guidance (https://dentalcheckbyone.co.uk/)

Figure 5.2 The estimated average cost for PEPT under GA, LA, and no-PEPT per participant with orthodontic need



*Costs were not explored at this timepoint

**9 working days on average (3 days for dental problems prior to GA and 6 days for hospital admission and recovery) (Goodwin et al., 2015)

***Assuming that the child would require at least one tooth extracted for orthodontic treatment

****Assuming that the child would require 21 visits for orthodontic treatment (please refer to Table 5.1e for more details)

*****3 working days (for dental problems) (Goodwin et al., 2015)

******The frequency of visits was based of the mean average of child's age at PEPT i.e., five years, and assuming that child visited the dentist before their first birthday and biannually from the age of 1 year old as recommended by national guidance https://dentalcheckbyone.co.uk/

Chapter Six: Discussion

6.1 Introduction and principal findings

This was the first dental study to explore the impact of premature extraction of primary teeth (PEPT) on the orthodontic need and oral health-related quality of life (OH-RQoL) of Born in Bradford (BiB) children in the mixed dentition. The principal findings showed that PEPT under general anaesthetic (GA) and local anaesthetic (LA) was associated with an increased need for orthodontic treatment (OR=3.3, 95% CI=1.9-5.7, $P<0.001$). PEPT was not associated with a significantly poorer OH-RQoL approximately five years after their dental extractions. An exploratory analysis of health economics impact of these outcomes suggested additional costs to 5-15 years after the initial extraction of one or more primary teeth. The results reinforce the importance of retaining primary teeth until their natural exfoliation and align with the latest European guidelines that encourage restoration over extraction of primary teeth when indicated and possible (Duggal et al., 2022). The researcher believes that the data set collected will provide the foundations for further dental projects.

6.2 Study design

This study was an observational cross-sectional study that recruited and captured data from participants who were exposed to PEPT and those who were not exposed to PEPT (no-PEPT). Space loss following PEPT is well established in the literature with time of extraction being a major factor (Rönnerman, 1977; Magnússon, 1979; Kaklamanos et al., 2017). Prior to the

commencement of this study, a data linkage study (Day, 2018) allowed the identification of participants with PEPT under GA. The period between PEPT under GA and participation in the study was approximately five years (mean age of extraction under GA=five years, mean age of participants with PEPT under GA=10 years). It was estimated that this timeframe is sufficient for the impacts of PEPT on the occlusal changes to be observed in the mixed dentition. However, it was not possible to collate data about the age of participants with PEPT under LA who were identified from the no-PEPT group during data collection. This would have required time and cost to access their primary care dental records. In addition, these participants may have had multiple extractions at different timepoints, which can complicate the analysis.

Observational studies can aid in creating in-depth knowledge about disease outcomes that appear over time. However, they are subject to selection bias, loss to follow-up and inability to collect variables which potentially influence the outcome of interest (Sedgwick, 2014). In our study, we acknowledge the presence of recall bias as a limitation. We recognise that the reliance on self-reported data, particularly when parents were asked in the consent form whether their child had PEPT under LA, introduced some inaccuracies. A small proportion of parents reported a negative history of PEPT under LA for their child (7.9%, n=19/244). However, clinical examination of these participants showed primary tooth loss in a carious dentition that did not correspond with natural exfoliation times. Intra-oral photographs of these participants were reviewed by the researcher and the Chief Investigator, both

paediatric specialists, to determine whether tooth loss was likely due to natural exfoliation or PEPT under LA.

Also, participants were asked to complete the short form of the Child Oral Health Impact Profile (COHIP-SF 19) questionnaire to measure the OH-RQoL. The recall period as indicated in the questionnaire was three months. Most studies in the literature were designed to measure OH-RQoL using a pre-test-post-test design (Knapp et al., 2017; Feu et al., 2022). In our study, PEPT had already occurred five years on average before the commencement of the study and a pre-test would not be applicable. The study therefore assesses OH-RQoL based on the child's oral health rather than variables and morbidity associated with the time at which the teeth were extracted. While every effort was made to minimise bias, we acknowledge that it remains an inherent challenge in observational studies of this nature.

6.3 Study population

This was the first dental study to be carried out within the BiB cohort. BiB maintains an electronic database that enabled data linkage and identification of over 1,150 BiB children with PEPT under GA. The research infrastructure and earlier research work enabled the linkage of data collated for these participants and provided an ideal opportunity to explore the research question.

The link between deprivation and dental caries is well established in the literature (Masood et al., 2019). Therefore, it was anticipated that the rates of dental caries, and consequently PEPT would be high in Bradford. We found that the proportion of participants aged 8-11 years who had obvious dental caries in their primary teeth was 36.3%. This figure was similar to the one observed in Bradford, where 36% of five-year-old children had dental caries in their primary dentition (PHE, 2020) but in a different age group (8-11 years old). The same survey reported that the proportion of five-year-old children with PEPT was of 23.1%, whereas the proportion of participants with PEPT in our study was 32%. Various factors can influence the prevalence of PEPT such as sampling methods, age groups, and study population.

During the data collection phase, children were between eight and 11 years old, from a variety of ethnic backgrounds. The majority (n=280/322, 87%) were in the mixed-dentition and provided a unique opportunity for future observational longitudinal studies as these children develop into their permanent dentition. This will help assess the accuracy of predictions made in our study, by using the dental health component of the Index of Orthodontic Treatment Need (IOTN-DHC).

The population of Bradford is not representative of the country owing to the higher levels of ethnic diversity and deprivation in the city. However, the BiB cohort was representative of the population in Bradford (Wright et al., 2012). In our study, the levels of deprivation were slightly lower as compared to the

wider BiB cohort (26.1%, n=84/322 compared to 31.5%, n=675/2166) using the measure of the proportion of participants eligible for free school meals (Yang et al., 2022). As such, results of this study may be generalised based on the socio-economic status and to this specific study population. The majority of participants within the BiB cohort were South Asian (50.1%) (Wright et al., 2012). Despite the variety in school locations that were visited for the study, the study population was not representative of the population of the BiB cohort as the majority were from South Asian origin (84.8%). This may be attributed to selection bias and/or the total number of the study participants. In addition, the pandemic prevented further data collection which had initially concentrated on schools in the near vicinity of Bradford Royal Infirmary which have high proportions of children with a South Asian origin. Consequently, our results cannot be generalised to the BiB cohort which affects the external validity of the study.

6.4 Methods

6.4.1 Development and operationalisation of the research protocol

The aetiology of malocclusion and the subsequent need for orthodontic treatment is complex and multifactorial. Also, the measures of malocclusion as well as OH-RQoL vary widely in the literature. As such, the development of robust research methodology to evaluate the impact of PEPT on the orthodontic need and OH-RQoL in the mixed dentition required a multidisciplinary research team (Brown et al., 2019).

A close working relationship with the wider BiB research team and the research infrastructure established for wider BiB projects played a pivotal role in the successful development of the protocol and delivery of the study. The research team discussed the study design, parent and child information sheets, and recruitment strategy with representatives from BiB parents' group. The feedback provided was invaluable in making adaptations to the study methods and has led to the production of the YouTube information video.

The process of operationalising the research protocol into the BiB cohort with several studies running simultaneously was challenging and complex. The researcher attended monthly meetings with the BiB study team. During these meetings, the progress of each study running within the BiB cohort was discussed. Listening and learning from experienced researchers provided valuable insights and helped us better comprehend and address various challenges related to school access and participant recruitment.

Before the commencement of the study, the researcher had the opportunity to shadow data collection for the BRIGHT Trial, a school-based study that aimed at investigating ways to improve oral health in young people (Marshman et al., 2019). The researcher found it valuable to gain insights into the day-to-day running of a study based in schools across West Yorkshire, including Bradford. This included learning how to effectively lead a data collection team, use team guidance notes, set up the dental kit (with all

required instruments and materials) into a mobile dental clinic for data collection, and manage time efficiently.

6.4.2 Recruitment of the data collection team and dental kit preparation

Finding a qualified data collection team proficient in effective communication and management of children's behaviour was crucial for the success of the study. Some participants struggled during taking intra-oral photographs or dental impressions, primarily due to an exaggerated gag reflex. The dental therapist and the research dental nurse played a pivotal role by employing distraction techniques and utilising 'childrenese' language (using terms that are child friendly for example: dental dough for alginate impression). These techniques were instrumental in providing the participants with a positive experience.

Special considerations were made when purchasing the dental kit to ensure the selection of latex-free products, thus eliminating the risk of allergic reactions among participants with latex allergy. In addition, special considerations were made when choosing dental materials, including a thorough review of ingredients that might raise concerns for Muslim participants, such as alcohol or porcine derivatives. This consideration was particularly important, given that Islam represents the second most common faith in Bradford, accounting for 30.5% of its population (Colborn, 2022). Furthermore, using paediatric sizes for dental equipment (such as cheek retractors, dental photography mirrors and dental impression trays), along

with fast-setting alginate impression material were essential. This facilitated the collection of 309 (93.1%) complete sets of intra-oral photographs (frontal in occlusion, upper and lower occlusal, and buccal in occlusion) and 305 (91.9%) dental impressions (both upper and lower).

Finding a suitable dental facility where the dental kit could be stored safely, instruments sterilised, and dental impressions stored for collection by the designated dental laboratory (ArKive Lab) was crucial. Westbourne Green Dental Service located in Bradford was chosen as a suitable facility that fulfilled the requirements for the safe storage of the dental kit. While there were a couple of instances where the laboratory courier missed collecting the dental impressions, it is noteworthy that this did not compromise the quality of the dental casts produced. This was largely due to the use of a dental impression material that was dimensionally stable for five days. The flexibility in collection times proved advantageous, particularly in cases where data collection coincided with Fridays and required the secure storage of dental impressions in the designated fridge over the weekend.

6.4.3 Recruitment of primary schools

Data collection was conducted in primary schools in Bradford. While some birth cohorts such as Avon Longitudinal Study of Parents and Children had invited participants to attend a central clinic, and had achieved considerable success with questionnaire-based data collection, including oral health questionnaires at a response rate of approximately 45% (Dudding et al.,

2018), the nature of data required for our study was different. Based on BiB experience, it was evident that data collection via a centralised research clinic was not the most effective approach. (Wright et al., 2012). Various challenges, including language barriers and socio-economic factors, had been encountered previously. Taking into account past experience within the BiB cohort, such as Glasses in Classes study (Bruce et al., 2018), it became apparent that school-based data collection was the most practical and appropriate method for capturing clinical data to assess the orthodontic need.

Using the primary schools profile output (Appendix 3.1) helped in identifying which schools had the highest number of BiB children, particularly those with PEPT under GA. In addition, other factors were considered when selecting schools for recruitment. This included assessing their engagement with other BiB studies and taking into account their Office for Standards in Education school rating, with particular focus on schools rated ‘good’ and ‘outstanding’. It was anticipated that such schools would exhibit a higher level of engagement with clinical research.

Approaching schools for recruitment primarily involved direct communication with the headteachers through email or phone. Given the busy nature of school administrations, there were instances where we encountered occasional delays, prompting us to initiate multiple reminder communications to get a response back. Additional strategies included proactive engagement

with headteachers during school group meetings, such as those held as part of the SHINE group (SHINE, 2023) and participation in BiB conferences.

The initially planned timeline for participant recruitment was disrupted due to the challenges posed by the COVID-19 pandemic. Nonetheless, there were additional challenges that made recruitment more difficult. Gaining access to schools, for instance, proved to be time consuming, and obtaining school's consent sometimes presented its own set of challenges. Schools, understandably, expressed hesitation due to concerns about potential increases in their workload and disruptions to their daily routines. Emphasising the benefits of clinical research, including the role of birth cohort studies, was sometimes successful in overcoming these hesitations. Despite BiB's well-established connections with primary schools runninng multiple studies simultaneosly, engaging schools in yet another study involving clinical data collection could be overwhelming. Once access the school was granted, the next critical step was establishing clear and effective communication with the designated point of contact.

In addition, the logistics of the school visit required careful consideration. This included finding a suitable place to set up a mobile dental clinic for data collection. It is worth noting that some schools encountered challenges in identifying a suitable space. In some instances, the designated rooms were too small (please see Figures 3.4b and c) or were located outside the school's main building.

Discussing ways to give back to the school as means of expressing our gratitude for their valuable participation was a fundamental aspect of our recruitment strategy. It is worth noting that the data collection team comprised various dental professionals, including a paediatric dentist (the researcher), a dental therapist, and a research dental nurse. Most schools expressed strong interest in involving these professionals from the Science, Technology, Engineering, and Mathematics (STEM) fields in their activities as means of inspiring students about different careers. As a result, both the researcher and the dental therapist actively participated in numerous career weeks and school assemblies. During these sessions, students were actively engaged and asked questions that demonstrated their interest in science-based professions, such as dentistry.

6.4.4 Recruitment of participants and consenting

Participant recruitment was the most challenging aspect in this study. In contrast to other BiB studies that found it practical and effective to recruit the entire class, irrespective of their participation in the BiB study (Shire, 2020), our approach was different. This was primarily due to the availability of the wider socio-demographic details, as well as details of dental extractions under GA (including date, number and type of teeth extracted) for the BiB children, while such information was not available for other children.

Initially, information packs were sent via second class post. The pilot study revealed that sending information packs via participants' school bags was more effective than using second class post. The return rate for completed consent forms was nearly 25% when sent via school compared to only 2.5% when sent via second class post.

Different methods were explored to enhance participant recruitment, including discussions with the point of contact to brainstorm effective strategies. One of the most successful approaches was engaging a parent liaison officer, which resulted in the recruitment of 50% (n=55/110) of BiB children in a single school. However, it was not always possible to involve the parent liaison officer due to the busy nature of schools, and in some schools, only a very small number of participants were recruited.

Furthermore, some schools offered chasing up parents via text messages which proved slightly effective. In addition, the researcher was offered the opportunity to attend and promote the study during parents' meetings, coffee mornings and school assemblies. Unfortunately, these strategies yielded the least success, with minimal or no attendance at these events.

To support participant recruitment, experienced bilingual Clinical Research Network staff, proficient in both Urdu and English, affiliated with Bradford Teaching Hospital Foundation Trust, were involved. Having a bilingual recruitment team was essential because a proportion of BiB parents were not

proficient in English and completed the BiB study questionnaire in either Urdu or Mirpuri (Wright et al., 2012). To encourage participation, the YouTube information video was also dubbed into Urdu, to help both parents and their child understand what to expect during data collection at school.

The study involved clinical dental examination, both extra and intra-oral photography, as well as dental impression taking. In order to participate in the study, parental informed consent was required. The majority of the study participants were of South Asian origin. A proportion of parents (n=35/332, 10.5%) did not consent for their child to have extra-oral photographs taken. This was possibly due to conservative religious beliefs or cultural considerations, especially that the majority of participants were females (59%), and some were wearing head coverings. However, this did not impact the orthodontic assessments, as the orthodontic panel was still able to perform these assessments using intra-oral photographs and digital models only. In retrospect, extra-oral photographs provided little or no value in the assessments using IOTN-DHC. However, these data can still serve as a baseline for future studies.

6.4.5 Appropriateness of the indices

In our study, the need for orthodontic treatment was assessed using the IOTN-DHC. This tool, introduced by Brook and Shaw in 1989 (Brook & Shaw, 1989), was adopted by the National Health Service (NHS) to assess the eligibility of orthodontic treatment based on the severity of malocclusion in children under

18 years old. It is worth noting that this tool was designed to measure the orthodontic need in the permanent dentition. The majority of participants in our study were in the mixed dentition (PEPT 98.7%, n=77/78 and no-PEPT 83.2%, n=203/244). During the mixed dentition, teeth are in a dynamic stage and with variations in eruption patterns, making predictions of orthodontic need potentially less accurate (Daniels & Richmond, 2000). However, according to the literature, the IOTN-DHC was the most stable as the child transitioned from the mixed into the permanent dentition (Tarvit & Freer, 1998; Boronat-Catalá et al., 2016). Consequently, the orthodontic panel had to agree on a number of assumptions that facilitate the use of this tool in the mixed dentition. These assumptions are described in detail in section 3.3.9.2 Assessing the primary outcome: need for orthodontic treatment. However, it is important to note that there was a small proportion of participants in each group (PEPT 6.4%, n=4/78 and no-PEPT 1.6%, n=4/244) that had borderline assessments, making it challenging to determine their need for orthodontic treatment. This suggests that using the IOTN-DHC in the mixed dentition has some limitations for certain cases and may not be as accurate as in the permanent dentition. While grades 4 and 5 require treatment, there was a case with grade 3c with a clear need for orthodontic treatment owing to dehiscence, representing another example of the limitation of this tool.

The IOTN-DHC is a tool used by orthodontists and dental professionals to provide an objective assessment of the orthodontic need. Unlike the aesthetic component of the IOTN, which focuses primarily on aesthetic aspects of malocclusion, the IOTN-DHC takes into account potential risks associated

with malocclusion. It allows health service providers, such as the NHS, to prioritise the treatment need based on the severity of the index, thereby aiding policymakers in allocating limited resources by providing treatment for the most severe cases. However, this can have different implications on the stakeholders, most importantly children (patients) and their parents. It is worth noting that this objective assessment does not take into account the aesthetic concerns of the child or their parents' perceptions, especially if the parents are responsible for covering treatment costs. Aesthetic concerns may differ between children and their parents, and nowadays, people, including children, are becoming more conscious about their appearance, including teeth appearance (Holmes et al., 2015; Patel et al., 2016). It is therefore essential to balance objective professional assessment with the perception of children and their parents.

OH-RQoL was measured using COHIP-SF 19 in children with and without PEPT. This tool was valid and reliable for measuring OH-RQoL in children aged 7-18 years including those with orthodontic needs (Broder et al., 2012). Participants in our study fell mainly within this age range (8-11 years old). In addition, 47.5% (n=153/322) were assessed in need for orthodontic treatment, making this tool particularly suitable for our study objectives. Moreover, the validation of the tool ensures its suitability for longitudinal data collection from the same cohort, when they are in their permanent dentition stage.

The majority of participants found the questions in the COHIP-SF 19 questionnaire easy to read and understand, and they were able to fill out the questionnaire independently. However, a small number of participants (fewer than 20) needed clarification for specific words, such as ‘crooked’ (meaning twisted). Some children with special educational needs faced challenged in completing the questionnaire, which accounted for the slightly lower number of responses received (n=318/322, 98.8%).

6.4.6 Data collection sheets and data entry

Paper forms are simple and easy to complete during data collection, but they come with various challenges. These challenges include difficulties in interpreting handwriting, the time required for data entry, inaccuracies during data transfer, and staffing needs. While using paper forms may be quicker and easier for researchers in the field, web-based forms were found to be more cost-effective and had higher completeness rates (Ebert et al., 2018). Web-based forms also enhance data confidentiality by eliminating the need to physically transport the paper forms from schools to the research site. Consequently, following the approval of data collection sheets, we worked closely with the BiB data team to develop a secure bespoke web-based application for live data entry. An example of data collected for a dummy participant using this application is presented in Chapter Three-Figures 3.5a and 3.7.

Tablets/iPads, along with a wireless fidelity (Wi-Fi) device, were used for live data entry. However, finding a suitable dongle presented challenges, necessitating multiple communications with the service provider to ensure the proper functioning of the Wi-Fi device. Furthermore, some schools had specific protocols governing the use of electronic devices, including the use of the school's Wi-Fi and restrictions on mobile phone usage within the school's premises. Adhering to these protocols was of utmost importance.

Incorporating the COHIP-SF 19 questionnaire in the web-based application was advantageous in making all fields mandatory, thus reducing the likelihood of participants missing any questions. The data collection team experienced smooth access to the web-based application during all their visits. Nevertheless, on a few occasions (involving fewer than 20 participants), the data collection team had to use hard copies of data collection sheets for those participants who returned their consent forms on the day of the school visit. Subsequently, the data from these sheets were manually entered into the system at Bradford Institute for Health Research (BIHR). This approach allowed for the collection of data from as many participants as possible on the same day, negating the need to schedule additional visits.

6.4.7 Data collection

A pilot study was conducted to test the feasibility of the research methods. During the pilot study, it became evident that schools were very busy, and fitting a dental-based clinical study into the school's schedule was very

challenging. Some of these challenges included adhering to the school's schedule, dealing with participant absences, and unexpected quizzes taking place on the same day of our visit for data collection.

The data collection methods were piloted on 52 participants during the pilot study. It was quite surprising to observe the cooperation and enthusiasm among most participants. Some participants struggled when taking upper dental impressions due to an exaggerated gag reflex. To address this issue and minimise discomfort and gag reflex during dental impression taking, a fast-setting alginate was used, and lower dental impressions were taken first. Despite these measures, a small number of participants struggled with intra-oral photographs (n=13) and dental impressions (n=17). In addition to the gag reflex, these challenges were often associated with the presence of a soft tissue lesion, such as an ulcer or an abscess. In such cases, participants were always asked whether they felt comfortable proceeding with a second attempt or if they preferred to discontinue the process, ensuring that their comfort was prioritised throughout the data collection.

Of interest, intra-oral scanners are becoming more popular and offer a potential alternative to obtaining digital models. This method has the advantage of potentially minimising the gag reflex, which can be a significant issue during traditional impression taking. However, it is important to note that intra-oral scanning can be time consuming, taking approximately two minutes per arch, and would require three scans: for the upper arch, lower arch and

in occlusion. In addition, the scanners themselves can be bulky, which requires more cooperation and patience from the child being scanned. Furthermore, using intra-oral scanners in the field would require additional equipment to capture and store the images securely. While this method holds promise, more studies are required to determine the validity and reproducibility of its use in children (Goracci et al., 2016). Ongoing development in this technology may address some of the current challenges associated with its use.

It is worth noting that participants with special educational needs, were generally able to cooperate for all aspects of data collection, except for completing the COHIP-SF 19 questionnaire. In one of the schools, a teaching assistant suggested that a consented BiB child could serve as a model for their BiB classmate with special educational needs. With the participant's approval, this approach proved to be successful in facilitating the cooperation of the child with special educational needs. However, there were instances where data collection was not feasible, particularly when the child with special educational needs had limited communication skills or displayed low levels of cooperation due to their condition (n=1).

Initially, the data collection process took approximately 30 minutes per participant, excluding the time required to fetch the child from their classroom. However, we discovered that by fetching two participants simultaneously and ensuring privacy in the designated room, with one undergoing the dental

examination while the other completed the COHIP-SF 19 questionnaire, we were able to save approximately 10 minutes per participant. This efficient approach allowed us to increase the number of participants seen during the day and significantly reduced the need for additional school visits, thereby minimising disruptions to the school day.

After the pilot study, the orthodontic panel reviewed ten randomly selected data sets and determined that the collected data were of high quality. Subsequently, major and minor amendments were made to the ethics and data collection protocols to enhance recruitment and the data collection process (Appendix 4.4). In addition, the stand map, which resembled a protractor (Figure 3.3), proved to be a valuable tool during data collection. It helped guide participants to the appropriate standing position for extra-oral orthodontic photography, contributing to improved consistency and the overall quality of the extra-oral photographs.

6.4.8 Data analysis

The orthodontic panel was blinded to the study group and assessed the need for orthodontic treatment for each data set via organised virtual meetings during the COVID-19 pandemic. With the appropriate permissions and protocols followed to ensure participants' confidentiality, virtual meetings were found to be successful and feasible for the panel.

The availability of a variety of data types for analysis, including intra-oral photographs and digital models within each data set, provided the orthodontic panel with the flexibility to assess the need for orthodontic treatment, even when some participants had one of these data types not collected.

Some participants had incomplete data sets for various reasons such as lack of consent for specific aspects of data collection, like extra-oral photographs (n=35/332, 10.9%), or experiencing difficulties with one or more aspects of data collection, primarily related to the taking of upper dental impressions (n=6/322, 1.9%). Dental and orthodontic charting were essential to supplement the photographic data and digital models. The high quality of the intra-oral photographs and digital models enabled the orthodontic panel to assess the orthodontic need for these participants. In cases where dental impressions were not taken, it was not possible to measure the CDE space, but assessing the orthodontic need was usually possible from intra-oral photographs.

In addition, there was one instance where an error occurred during the transfer of photographs for a small number of participants (n=5/322) from the SD card to the hard drive at BIHR. Fortunately, these participants had their dental impressions taken, allowing the orthodontic panel to assess their orthodontic need using the digital models alone.

The eligibility for free school meals was selected as an indicator for socioeconomic status. It is a simple measure, relevant to children of school age and is likely to be more up to date than some other measures (including latent class profiles and index of multiple deprivation) which is based on baseline data collected approximately 8-10 years earlier. This measure is widely used in Child Dental Health Surveys and BiB research (Holmes et al., 2015; Yang et al., 2022). Children eligible for free school meals likely suffer from food insecurity which was found to be associated with untreated dental caries in children aged 5-17 years old (Bahanan et al., 2021). The index of multiple deprivation is another measure that classifies relative deprivation and is widely used in the United Kingdom (UK) (DCLG, 2015). This was used in the oral health survey reports of the National Dental Epidemiology Programme for England, but not the Children's Dental Health Surveys. Other measures could have been used such as family income. However, in a community like Bradford, employment status or income support may not be a consistent measure of deprivation for families who may be running home businesses for a living. More complex methods such as latent class analysis have been undertaken for the BiB cohort. This approach identified five subgroups within the BiB cohort based on their socioeconomic position, ranging from 'least economically deprived and most educated to most economically deprived' and others (Fairley et al., 2014). In their study, a strong association was found between these subgroups and ethnicity. Therefore, interpretation of this multidimensional measure is needed, especially when looking at groups from different ethnic backgrounds.

6.5 Results

6.5.1 Sample size

As mentioned in section 6.4.4 Recruitment of participants and consenting, recruitment was the most challenging aspect in our study due to several reasons including access to schools and engagement with the parent liaison officer. Moreover, visiting schools following the onset of the COVID-19 pandemic was not possible owing to the ongoing challenges of the pandemic. We initially calculated statistical power to recruit 500 participants in each group, PEPT and no-PEPT, to detect at least 10% difference in the need for orthodontic treatment between both groups (please refer to section 3.4 Estimation of sample size power, for more details). However, the size of the difference was much larger than estimated with a 28.6% difference between the groups (unadjusted odds ratio (OR)=3.3, 95% CI=1.91-5.68, P<0.001). While the smaller sample size, which was ultimately achieved, may have limited the generalisability of our findings, the study still provides evidence about the association between PEPT and the assessed need for orthodontic treatment.

6.5.2 Primary outcome: the need for orthodontic treatment

Our findings showed that PEPT was strongly associated with an increased need for orthodontic treatment based on the IOTN-DHC (OR=3.3, 95% CI=1.91-5.68, P<0.001). Adjusting for covariates including age, gender, ethnicity, and eligibility for free school meals, showed minimal change and did not seem to influence the outcome (OR=3.2, 95% CI=1.86-5.62, P<0.001). Considering the BiB's study location in Bradford, a multiethnic city with high

levels of deprivation, it was anticipated that the levels of dental caries would be high. Although dental caries is strongly associated with deprivation, comparing the eligibility for free school meals between groups did not show a significant difference (*P*=0.82).

However, results from a detailed dental examination showed that the proportion of participants with PEPT, who had dental caries in their permanent dentition (21.8%, n=17/78) was higher compared to no-PEPT (11.5%, n=28/244, *P*=0.02). It is well acknowledged that dental caries in the primary dentition is a strong indicator for caries in the permanent dentition (Powell, 1998). Since participants with PEPT had their carious primary teeth extracted, leaving the mouth with a smaller number of teeth, any difference in the prevalence of dental caries in primary teeth between groups was not detected (PEPT n=31/78, 39.7%, and no-PEPT 86/244, 35.2%, *P*=0.5).

Furthermore, the proportion of participants with hypomineralised primary teeth was higher in the PEPT group compared to the no-PEPT group (PEPT n=10, 12.8%, no-PEPT n=13, 5.3%, *P*=0.03). Due to their abnormal and weak structure, hypomineralised teeth are more susceptible to dental caries and post-eruptive breakdown (Weerheijm et al., 2003; SDCEP, 2018). Typically, primary second molars are the most commonly affected by hypomineralisation, although other primary teeth such as primary first molars and canines can be affected. In the Generation R Cohort Study in the Netherlands, 9% (n=499/6,161) of children had primary molar

hypomineralisation (Elfrink et al., 2012). Of these, 11.2% (n=56/499) had atypical extractions of primary molars. In fact, our findings showed that the most commonly extracted teeth under GA were primary molars (at least one primary molar in all participants with PEPT under GA, n=37). In certain cases, hypomineralisation may have contributed to the severity of post-operative breakdown and/or dental caries resulting in PEPT.

As these children transitioned into the mixed dentition and were around 10 years old during data collection, it was evident that a considerable proportion of participants with PEPT underwent notable occlusal changes, including space loss and crowding. This was represented by 45% (n=35/78) of the PEPT group who were assessed as having insufficient space within the arch for permanent canines and premolars. In contrast, only 8.6% (n=21/244) in the no-PEPT group were assessed as having insufficient space for the same. The literature supports our findings where PEPT can lead to space loss (Clinch, 1972; Kaklamanos et al., 2017; Magnússon, 1979; Tunison et al., 2008). Consequently, crowding may impede the eruption of permanent teeth, contributing to IOTN-DHC grade 5i, characterised by the impeded eruption of permanent teeth owing to crowding or displacement, observed in 47.4% (n=37/78) of participants with PEPT.

Following space loss resulting from PEPT, different features of malocclusion can develop (Bhujel et al., 2016). A significant proportion of participants with PEPT had an increased overjet (37.9%, n=29/78), while the majority of

participants with no-PEPT had an average overjet (52.5%, n=128/244). The literature also hints an association between PEPT and an increased overjet (Bhujel et al., 2016). This association may have contributed to the IOTN-DHC grades of 5a and 4a in the PEPT group, accounting for 5.1% (n=4/78) and 10.3% (n=8/78) respectively.

Another significant difference between groups was palpability of permanent upper canines, which was not detected in a small proportion of participants with PEPT (2.6%, n=2/78) compared to no-PEPT (0.4%, n=1/78). Typically, canines should be palpable around the age of 10-11 years. The literature reports a prevalence of 1.5% for ectopic permanent upper canines (where they cannot be palpable) (Husain et al., 2022). While the exact aetiology remains unknown and is thought to be genetically determined (Mitchell, L., 2019), it's unlikely that these cases were influenced by PEPT. Given our age group ranged from 8-11 years old, and permanent canine palpation is expected between 10-11 years old, it might be early to determine whether the identified cases have impacted permanent canines or not.

Furthermore, PEPT under GA was associated with an increased need for orthodontic treatment (OR=7.6, 95% CI=3.04-18.81, P<0.001). Adjusting for covariates including age, gender, ethnicity, and eligibility for free school meals, showed minimal change and did not seem to influence the outcome (OR=7.7, 95% CI=3.07-19.22, P<0.001). It is also worth noting that 83.8% (n=31/37) of participants with PEPT under GA, were assessed in need for

orthodontic treatment, compared to 56.1% (n=23/41) of participants with PEPT under LA and 40.6% (n=99/244) of those with no-PEPT. Several factors could have contributed to the increased need for orthodontic treatment in the PEPT under GA group including the age at extractions, number, and type of extracted teeth.

Participants with PEPT under GA had tooth extractions at around five years old (mean=5.3, standard deviation=1.25). By the time of data collection, these children were around 10 years old with an interval of approximately five years since their exposure to PEPT under GA. Given the other factors that can contribute to malocclusion, such as genetics and crowding (Rock, 2002), it was anticipated that the time elapsed since GA would be sufficient for occlusal changes to be observed. The literature suggests that space loss occurs faster the first year following PEPT in six-year-old children (Northway et al., 1984), an age close to the average age of the PEPT under GA group.

In addition, most participants with PEPT under GA had five or more primary teeth extracted (n=36/37, 97.3%), with a mean number of 10 (IQR=7.5-12) teeth per participant. A previous study conducted by the research group (Bhujel, 2014), suggested that the number of prematurely extracted primary teeth (median=6.5, interquartile range=2-9) was associated with an increased need for orthodontic treatment (OR=1.2, 95% CI=1.01 to 1.37). However, the assessment methods were slightly different, as the previous study used the modified IOTN-DHC in 12-year-old participants in their permanent dentition,

distinct from our age group (8-11 years), where the majority were in their mixed dentition.

In addition, 94.6% (n=35/37) of participants with PEPT under GA had their primary second molar extracted in one or more quadrants. Previous studies suggest that space loss occurred more when second primary molars were prematurely extracted (Bjerklin & Kurol, 1983; Clinch, 1972) and clinical guidelines recommend placing a space maintainer when second primary molar teeth are prematurely extracted to prevent space loss (Rock, 2002).

6.5.3 Secondary outcomes: OH-RQoL and health economics

6.5.3.1 OH-RQoL

In our study, it was anticipated that participants with PEPT would have poorer OH-RQoL owing to functional difficulties following multiple extractions such as difficulties in eating. However, it is now five years later, so children may have got used to it and permanent molars will have erupted providing occlusion posterior to the extraction sites. This was represented by the majority of participants who responded to the 'Global self-rated oral health: Overall, please rate your oral health', by 'Good' (PEPT n=28/78, 35.9% and no-PEPT n=96/244, 40%). However, a mean important difference score of 4 or more, that is required for clinical significance between both groups was not detected in any of the domains or the COHIP-SF 19 total scores.

Moreover, these children did not have their OH-RQoL measured before PEPT. When measuring OH-RQoL in children, a pre-test-post-test study design is preferable (Knapp et al., 2017). This approach allows the change in OH-RQoL to be quantified following a dental intervention such as PEPT.

The literature lacks evidence that quantifies the long-term impact of PEPT on OH-RQoL. In addition, most studies investigated the impact of OH-RQoL in children who underwent dental management including PEPT under GA, without segregating different interventions (PEPT versus full mouth rehabilitation). Further research with longer follow-up periods is required in this area because there are not enough studies looking at the long-term impact of PEPT on OH-RQoL.

6.5.3.2 Health economics

The aim of our economic model was to compare family and health services costs associated with two different outcomes, the need and no need for orthodontic treatment. Results from our model showed that the PEPT under GA group incurred the highest cost, followed by those with PEPT under LA, with the no-PEPT group having the least costs. The overall estimated cost for orthodontic treatment, including family and health services costs, doubled for a child with PEPT under GA (£4,133.65) compared to PEPT under LA (£2,334.74). Moreover, because malocclusion is genetically determined to a large extent, a proportion of children would still need orthodontic treatment, with an estimated cost of £1,774.86 for a child with no-PEPT.

The estimated cost of health utilisation per child was £122.81. Similarly, costs were estimated for those children who had had PEPT under LA. The main difference between these two pathways was the cost of the general anaesthetic (£835) and the estimated time off work. Interviews to identify health care utilisation by parents of participants with PEPT were made during the COVID-19 pandemic. This was subject to recall bias due to the long time elapsed between acute management of the dental caries (approximately five years earlier for participants with PEPT under GA). However, it provided an overview of the utilisation of health services for these participants. Other associated costs that couldn't be precisely calculated were time off school and travel expenses.

The cost at the time of dental examination was not estimated. The proportion of dental caries in primary teeth was 39.7% and 35.2% in the PEPT and no-PEPT groups respectively. With this high proportion of dental caries in both groups, it was anticipated that estimating costs at this stage would increase the costs for all groups.

Literature related to estimating the costs of orthodontic treatment following PEPT is scarce. However, researchers recognise the importance of understanding the implications of PEPT on the orthodontic need. Studies in this area can provide insights into the long-term potential costs of orthodontic treatment.

Annually, around 800 children in Bradford undergo PEPT under GA (Bradford District Care NHS Foundation Trust, 2015). Based on our study results, if we assumed that 83.8% of these children (n=670.4) were in need for orthodontic treatment, this would cost the NHS more than £818,069 for orthodontic treatment.

This level of expenditure, despite all its limitations, is high. Dental caries is preventable, and these costs should be placed within the context of the costs of primary prevention rather that secondary prevention. This can help reduce inequalities in oral healthcare. For example Public Health England anticipated that the return on investment would be £12.71 after five years for every £1 invested (PHE, 2017a). This would allow the reduction in the number of missed school days and gaining more than 1,600 school days per 10,000 children. The same report showed that for targeted supervised tooth brushing programmes, the anticipated return on investment is £3.06 for every £1 invested. This would allow gaining more than 3,000 school days per 5,000 children.

6.6 Clinical implications

Malocclusion is predominantly caused by genetic predisposition, not behavioural or biological influences (Lundström, 1955). However, the impact of PEPT on malocclusion cannot be overlooked. Our findings showed that PEPT was associated with an increased need for orthodontic treatment in the mixed dentition and a potential increase in the treatment cost. In addition,

IOTN-DHC assessments showed that participants with PEPT under GA needed more orthodontic care than participants with PEPT under LA. Children going to GA have more teeth extracted probably to avoid a second GA.

Orthodontic treatment is time consuming, expensive, and can subject the young person to a higher risk of developing enamel demineralisation, especially if the appliance is not appropriately maintained. Other risks include root resorption, gingivitis (usually temporary), and incomplete treatment, as well as the costs to the child and parent. The Children's Dental Health Survey 2013 found that 37% of 12-year-olds and 20% of 15-year-olds had an unmet need for orthodontic treatment (Holmes et al., 2015). In England, they identified that 20% of children aged 12 years and 16% of children aged 16 years were undergoing active orthodontic treatment (Holmes et al., 2015). The discussion of these findings highlighted that malocclusion was predominantly related to genetic predisposition but in some cases can also be influenced by disease or behaviour (Holmes et al., 2015).

It may not be possible to prevent malocclusion due to genetic factors, however, by preventing dental caries in the primary dentition, the need for PEPT and its negative consequences on malocclusion can be minimised.

6.6.1 Prevention of dental caries

It is widely acknowledged that the primary tooth acts as 'an ideal space maintainer' until it is replaced by its permanent successor (Rock, 2002).

Individual behaviour change for parents of young children is not always sufficient to prevent dental caries and therefore public health interventions that tackle the wider determinants of oral health and upstream interventions have the potential of reducing health inequalities (Watt & Sheiham, 2012).

Findings from a longitudinal birth cohort in Germany showed that a holistic approach to oral health promotion and prevention from birth was successful at reducing dental caries (3.1% vs 37.3%) in children at eight years of age (n=127/227 in the prevention group and n=100/227 in the control group) (Wagner et al., 2020). The same study showed an increased need for orthodontic treatment due space loss following PEPT (41% vs 7.9%). Participants from the most deprived areas in Scotland, who took part in the ChildSmile Nursery Supervised Toothbrushing programme were significantly less likely to develop dental caries in their primary teeth after being engaged for 12 months in the study (adjusted OR=0.60; 95% CI 0.55 to 0.66) with an annual cost of only £15.26-£16.89 per child (Kidd et al., 2020).

Water fluoridation schemes in England have proven to be successful in caries prevention. In fluoridated areas, hospital admissions for PEPT in young children were less by 55% and five-year-olds were less likely to have carious primary teeth by 28% compared to non-fluoridated areas (PHE, 2017a). The average cost of these schemes did not exceed 50 pence per person per year. However, professionals should be aware of the raised voices of anti-fluoride

which can seem convincing the public, despite the strong evidence in favour of water fluoridation (Westgarth, 2021).

There are well established primary prevention programmes for example ChildSmile and Design to Smile in Scotland and Wales. The health economic estimations from ChildSmile have shown clear finance benefits not including those for the child, their schooling, their family and wider society. Moreover, where primary prevention is not success preserving carious primary teeth, were appropriate, until exfoliation would have significant benefits.

As such, preventive public health interventions can be effective in reducing the prevalence and cost for the management of dental caries and providing an equal opportunity to all children despite their socioeconomic status. The involvement of other health professionals including midwives, health visitors, school nurses, general practitioners and paediatricians, and pharmacists can also help support dental health at an early stage by promoting oral health and delivering preventive advice (PHE, 2017a).

6.6.2 Restoration of carious primary teeth

The Scottish Dental Clinical Effectiveness Programme guidance on the Prevention and Management of Dental Caries 2018 provides a wide range of strategies for the management of early and more advanced dental caries (SDCEP, 2018). Stressing the importance of early and regular dental visits, it highlights the importance of thorough clinical examination and the use of

bitewing radiographs. This maximises the chances of identifying dental caries at an early stage where PEPT can be avoided and hence preventing longer term consequences to the malocclusion.

The latest European Academy of Pediatric Dentistry policy document for managing deep carious lesions concluded that ‘managing deep carious lesions in primary teeth can be challenging and must consider the patient’s compliance, operator skills, materials, and costs’ (Duggal et al., 2022). Timely management of dental caries is crucial for the success of these methods. With proper dental training and knowledge, the need for PEPT can be avoided.

6.6.3 Space maintenance

In a cohort where the rates of dental caries and the number of prematurely extracted primary teeth are high, these factors should be considered before making any clinical decisions to place space maintenaners.

6.6.4 Access to health care

Children living in socially deprived areas have worse oral health which is considered one of the marked indicators of inequality in health across the UK. Dental caries is a preventable disease. Despite the reduction in the proportion of dental caries in primary teeth over the years, widening health inequalities still exist for children from the most deprived backgrounds who have had little improvements in their oral health (Masood et al., 2019).

In 2019, Bradford District was ranked nationally fifth and sixth most income deprived and employment deprived respectively, with 22% of children living ‘below the poverty line’ (Colborn, 2019). Our findings showed that a big proportion of participants with and without PEPT had untreated dental caries in their primary dentition (n=31/78, 39.7% and n=86/244, 35.2% respectively) with some children having dental caries in their permanent dentition (n=17/78, 21.8% and n=28/244, 11.5% respectively). In the UK, the average number of primary care dentists is 5.3 dentists per 10,000 of the population. In Bradford City there are 12.6 primary care dentists per 10,000 of the population, which compares very favourably to other areas in the UK where it is as low as 3.4 per 10,000 in West Norfolk and North Lincolnshire (NAO, 2020).

In a deprived community like Bradford, children are at high risk of developing dental caries and the utilisation of health services may be low due to literacy and poverty barriers. The intergenerational transmission of risk factors that contribute the development of dental caries, such as poor oral habits (Shearer and Thomson 2010) can create a viscous cycle of oral health problems if not addressed at an early stage. Untreated dental caries leading to PEPT, for instance, and the subsequent need for orthodontic treatment, can perpetuate this cycle, passing from one generation to the other.

Therefore, implementing preventive interventions that have been proven to be successful, such as supervised toothbrushing programmes in nurseries and

schools or water fluoridation may help improve oral health in these children and mitigate for the limited availability of dentists in the local area. Future work should focus on ‘closing the gap’ of oral health inequalities where governments build equity into the communities and health systems that instigate healthy living standards for everyone.

6.7 Study limitations and further work

COVID-19 pandemic prevented the resumption of further data collection in primary schools due to school closure and ongoing challenges following its opening. In fact, many schools are still recovering from the impact of the pandemic and their ability to take on research projects is significantly diminished. A larger sample may have been beneficial and would have allowed the study results to be more generalisable. However, even with the smaller numbers than anticipated, the impact of PEPT on orthodontic need was clear with a clinical difference found between the two groups of 28.6%.

This was an observational, cross-sectional study that measured the association between PEPT and the need for orthodontic treatment. Unlike prospective studies, with longitudinal data collection, a major limitation was the inability to make a causal inference. However, our study has provided baseline data during the mixed dentition stage for a future study (during the permanent dentition stage) to follow-up the same sample using a prospective, longitudinal cohort research design.

This would enable the accuracy of IOTN-DHC predictions to be established. A follow-up study will enable verification as well as explore the casual pathways of how PEPT leads to malocclusion or exacerbates pre-existing malocclusion. Moreover, differences in the health economics models can have significant weighting owing to costs of orthodontic treatments and the prevalence of orthodontic need between the PEPT under GA, PEPT under LA and no-PEPT groups.

The logistics of undertaking a follow-up study are significant. One challenging aspect of carrying out a future study would be the retention rate of the same participants. Collecting data with repeating the same measures from participants who took part in the original study would allow a causal relationship to be established. However, considerations should be given for sufficient follow-up time with higher possibility of dropouts (30% as estimated by initial BiB study data) (Wright et al., 2012). Another option would be collecting data from a wider sample assuming that the results of the original study could be generalised to the same cohort.

Replication, potential to use data linkage studies to explore this area however, the availability of orthodontic care in Bradford, the inequalities in its availability and the NHS/private provision of orthodontics would make it very difficult. However, some of these biases could be minimised through larger sample sizes which are available when analysing secondary data sets.

More research is required on the long-term impact of PEPT on the orthodontic need and OH-RQoL. An ideal study design would be a prospective randomised controlled study where the impact of PEPT on space loss, malocclusion, and OH-RQoL could be assessed. However, such studies would require around 10-12 years to observe the impact of PEPT. Another challenging aspect would be recruitment of study participants, examiner calibration, and finding a suitable tool to measure OH-RQoL in participants at a younger age before PEPT and several years after PEPT when they are older.

6.8 Conclusion

This was the first study in the UK to investigate the impact of PEPT on the orthodontic need in the mixed dentition using a validated index, the IOTN-DHC. The main conclusion that can be drawn from our study is that PEPT was associated with an increased need for orthodontic treatment in the mixed dentition stage. The odds ratio of orthodontic treatment need in participants with PEPT versus non-PEPT was OR=3.3 (95% CI=1.9-5.7, P<0.001). The prevalence of orthodontic need varied between groups. Of importance, is that over 90% of children who had received PEPT under GA needed orthodontic treatment owing to their malocclusion compared to around 40% of children who had not experienced PEPT. This reinforces the importance of primary prevention as well as restoring dental caries in primary teeth when indicated.

List of References

AAPD. (2008). Definition of Early Childhood Caries (ECC). In: American Academy of Pediatric Dentistry. Retrieved 30 October 2022 from https://www.aapd.org/assets/1/7/d_ecc.pdf

AAPD. (2016). Guideline on Caries-risk Assessment and Management for Infants, Children, and Adolescents. *Pediatr Dent*, *38*(6), 142-149.

AAPD. (2022). Management of the developing dentition and occlusion in pediatric dentistry. *The Reference Manual of Pediatric Dentistry. Chicago, Ill.: American Academy of Pediatric Dentistry*, *40*(6), 424-441.

Abed, R., Bernabe, E., & Sabbah, W. (2019). Family Impacts of Severe Dental Caries among Children in the United Kingdom. *Int J Environ Res Public Health*, *17*(1).

Acs, G., Shulman, R., Ng, M. W., & Chussid, S. (1999). The effect of dental rehabilitation on the body weight of children with early childhood caries [Comparative Study]. *Pediatr Dent*, *21*(2), 109-113.

Ahmad, A. J., Parekh, S., & Ashley, P. F. (2018). Methods of space maintenance for premature loss of a primary molar: a review. *Eur Arch Paediatr Dent*, *19*(5), 311-320.

Alrashed, M., & Alqerban, A. (2021). The relationship between malocclusion and oral health-related quality of life among adolescents: a systematic literature review and meta-analysis. *Eur J Orthod*, *43*(2), 173-183.

Amin, M. S., Bedard, D., & Gamble, J. (2010). Early childhood caries: recurrence after comprehensive dental treatment under general anaesthesia. *Eur Arch Paediatr Dent*, *11*(6), 269-273.

Bahanan, L., Singhal, A., Zhao, Y., Scott, T., & Kaye, E. (2021). The association between food insecurity, diet quality, and untreated caries among US children. *J Am Dent Assoc*, *152*(8), 613-621.

BDA. (2023). Decay going unchallenged as no. 1 reason for child hospital admissions. In: British Dental Association. Retrieved 15 April 2023 from https://bda.org/news-centre/press-releases/Pages/Decay-going-unchallenged-as-no-1-reason-for-child-hospital-admissions.aspx

Bhujel, N., Duggal, M., Munyombwe, T., Godson, J., & Day, P. (2014). The effect of premature extraction of primary teeth on the subsequent need for orthodontic treatment. *Eur Arch Paediatr Dent*, *15*(6), 393-400.

Bhujel, N., Duggal, M., Singh, P., & Day, P. (2016). The impact of premature extraction of primary teeth on the subsequent need for orthodontic treatment: a systematic review. *Eur Arch Paediatr Dent*, *17*, 423-434.

Bjerklin, K., & Kurol, J. (1983). Ectopic eruption of the maxillary first permanent molar: Etiologic factors. *American Journal of Orthodontics*, *84*(2), 147-155.

Boronat-Catala, M., Bellot-Arcis, C., Montiel-Company, J. M., Catala-Pizarro, M., & Almerich-Silla, J. M. (2016). Orthodontic treatment need of 9, 12 and 15 year-old children according to the Index of Orthodontic Treatment Need and the Dental Aesthetic Index. *J Orthod*, *43*(2), 130-136.

Boronat-Catalá, M., Bellot-Arcís, C., Montiel-Company, J. M., Catalá-Pizarro, M., & Almerich-Silla, J. M. (2016). Orthodontic treatment need of 9, 12 and 15 year-old children according to the Index of Orthodontic Treatment Need and the Dental Aesthetic Index. *J Orthod*, *43*(2), 130-136.

Bradford District Care NHS Foundation Trust. (2015). *Service evaluation of dental extractions under general anaesthetic*. Bradford.

Broder, H. L., Wilson-Genderson, M., & Sischo, L. (2012). Reliability and validity testing for the Child Oral Health Impact Profile-Reduced (COHIP-SF 19). *J Public Health Dent*, *72*(4), 302-312.

Brook, P. H., & Shaw, W. C. (1989). The development of an index of orthodontic treatment priority. *Eur J Orthod*, *11*(3), 309-320.

Brown, L. R., Barber, S., Benson, P. E., Littlewood, S., Gilthorpe, M. S., Wu, J., Al-Nunuaimi, E., Mason, D., Waiblinger, D., McEachan, R. C., Day, P. F. (2019). PLATOON: Premature Loss of bAby Teeth and its impact On Orthodontic Need - protocol. *J Orthod*, 1465312519843305.

Bruce, A., Kelly, B., Chambers, B., Barrett, B. T., Bloj, M., Bradbury, J., & Sheldon, T. A. (2018). The effect of adherence to spectacle wear on early developing literacy: a longitudinal study based in a large multiethnic city, Bradford, UK. *BMJ Open*, *8*(6), e021277.

Carvalho, T. S., Abanto, J., Pinheiro, E. C. M., Lussi, A., & Bönecker, M. (2018). Early childhood caries and psychological perceptions on child's oral health increase the feeling of guilt in parents: an epidemiological survey. *Int J Paediatr Dent*, *28*(1), 23-32.

Clinch, L. M. (1972). The results of premature extraction of deciduous teeth. *J Ir Dent Assoc*, *18*(4), 185-188.

Colborn, C. (2019). Poverty and deprivation: Deprivation and poverty in Bradford District. In. City of Bradford Metropolitan District Council Retrieved 21 January 2023 from https://ubd.bradford.gov.uk/media/1580/poverty-and-deprivation-jan-2020-update.pdf

Colborn, C. (2022). Ethnicity and religion. In: City of Bradford Metropolitan District Council. Retrieved 21 January 2023 from https://ubd.bradford.gov.uk/about-us/ethnicity-and-religion/

Conway, D. I., Quarrell, I., McCall, D. R., Gilmour, H., Bedi, R., & Macpherson, L. M. (2007). Dental caries in 5-year-old children attending multi-ethnic schools in Greater Glasgow--the impact of ethnic background and levels of deprivation. *Community Dent Health*, *24*(3), 161-165.

Daniels, C., & Richmond, S. (2000). The development of the index of complexity, outcome and need (ICON). *J Orthod*, *27*(2), 149-162.

Day, P. F. Petherick, E., Godson, J., Owen, J., Douglas, G. (2018). Dental Public Health in Action: A feasibility study to explore the governance processes required for linkage between dental epidemiological, and birth cohort, data in the UK. *Community Dent Health*, *35*(4), 201-203.

DCLG. (2015). The English Index of Multiple Deprivation (IMD) 2015 – Guidance. In: Department for Communities and Local Government. Retrieved 31 March 2023 from https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/464430/English_Index_of_Multiple_Deprivation_2015_ -_Guidance.pdf

de Souza, M. C., Harrison, M., & Marshman, Z. (2017). Oral health-related quality of life following dental treatment under general anaesthesia for early childhood caries – a UK-based study. *International Journal of Paediatric Dentistry*, *27*(1), 30-36.

Dudding, T., Haworth, S., Sandy, J., & Timpson, N. J. (2018). Age 23 years + oral health questionnaire in Avon Longitudinal Study of Parents and Children. *Wellcome Open Res*, *3*, 34.

Duggal, M., Gizani S, Albadri S, Krämer N, Stratigaki E, Tong HJ, Seremidi K, Kloukos D, BaniHani A, Santamaría RM, Hu S, Maden M, Amend S, Boutsiouki C, Bekes K, Lygidakis N, Frankenberger R, Monteiro J, Anttonnen V, Leith R, Sobczak M, Rajasekharan S, Parekh S. (2022). Best clinical practice guidance for treating deep carious lesions in primary teeth: an EAPD policy document. *Eur Arch Paediatr Dent*, *23*(5), 659-666.

Ebert, J. F., Huibers, L., Christensen, B., & Christensen, M. B. (2018). Paper- or Web-Based Questionnaire Invitations as a Method for Data Collection: Cross-Sectional Comparative Study of Differences in Response Rate, Completeness of Data, and Financial Cost. *J Med Internet Res*, *20*(1), e24.

Elfrink, M. E., ten Cate, J. M., Jaddoe, V. W., Hofman, A., Moll, H. A., & Veerkamp, J. S. (2012). Deciduous molar hypomineralization and molar incisor hypomineralization. *J Dent Res*, *91*(6), 551-555.

Fairley, L., Cabieses, B., Small, N., Petherick, E. S., Lawlor, D. A., Pickett, K. E., & Wright, J. (2014). Using latent class analysis to develop a model of the relationship between socioeconomic position and ethnicity: cross-sectional analyses from a multi-ethnic birth cohort study. *BMC Public Health*, *14*, 835.

Farahani, A. B. (2011). 'An Overview of Selected Orthodontic Treatment Need Indices', in Naretto, S. (2011). *Principles in contemporary orthodontics*. (pp. 215-236). Intech Open.

Fayle, S. A., Welbury, R. R., & Roberts, J. F. (2001). British Society of Paediatric Dentistry: a policy document on management of caries in the primary dentition. *Int J Paediatr Dent*, *11*(2), 153-157.

Feu, D., Lessa, F. C. R., Barcellos, L. A., Goulart, M. A., Grillo, C. B., & Freitas, L. A. (2022). The impact on the quality of life caused by the early loss of primary molars. *Int J Dent Hyg*, *20*(4), 620-626.

Fields, H. W., Proffit, W. R. (2019).'Moderate Nonskeletal Problems in Preadolescent Children: Preventive and Interceptive Treatment in Family Practice', in Proffit, W. R., Fields, H. W., & Sarver, D. M. (2014). *Contemporary Orthodontics*. Elsevier Health Sciences (6e, pp. 356-401). Elsevier Inc.

Finucane, D. (2012). Rationale for restoration of carious primary teeth: a review. *Eur Arch Paediatr Dent*, *13*(6), 281-292.

Fisher-Owens, S. A., Gansky, S. A., Platt, L. J., Weintraub, J. A., Soobader, M. J., Bramlett, M. D., & Newacheck, P. W. (2007). Influences on children's oral health: a conceptual model [Research Support, N.I.H., Extramural]. *Pediatrics*, *120*(3), e510-520.

Genderson, M. W., Sischo, L., Markowitz, K., Fine, D., & Broder, H. L. (2013). An overview of children's oral health-related quality of life assessment: from scale development to measuring outcomes. *Caries Res*, *47 Suppl 1*(0 1), 13-21.

Gerritsen, A. E., Allen, P. F., Witter, D. J., Bronkhorst, E. M., & Creugers, N. H. (2010). Tooth loss and oral health-related quality of life: a systematic review and meta-analysis. *Health Qual Life Outcomes*, *8*, 126.

Gibas-Stanek, M., & Loster, B. W. (2018). The effect of premature extraction of primary molars on spatial conditions and formation of malocclusion – a systematic review. *Journal of Stomatology*, *71*(5), 420-431.

Godson, J., Venkatesh, V., Csikar, J., & Seymour, D. (2012). Better Oral Health in Bradford and Airedale, Oral Health Needs Assessment 2012. In: City of Bradford Metropolitan District Council. Retrieved 21 January 2023 from https://jsna.bradford.gov.uk/documents/Physical%20health%20including%20long%20term%20conditions/Oral%20Health%20Needs%20Assessment/NHS%20Bradford%20and%20Airedale%20Oral%20Health%20Needs%20Assessment%202012.pdf

Goodman, A. (1986). BCS70 - The 1970 British Cohort Study: The Sixteen-year Follow-up In: UK Data Service. Retrieved 30 April 2023 from https://cls.ucl.ac.uk/cls-studies/1970-british-cohort-study/

Goodwin, M., Sanders, C., Davies, G., Walsh, T., & Pretty, I. A. (2015). Issues arising following a referral and subsequent wait for extraction under general anaesthetic: impact on children. *BMC Oral Health*, *15*, 3.

Goracci, C., Franchi, L., Vichi, A., & Ferrari, M. (2016). Accuracy, reliability, and efficiency of intraoral scanners for full-arch impressions: a systematic review of the clinical evidence. *Eur J Orthod*, *38*(4), 422-428.

Guarnizo-Herreño, C. C., & Wehby, G. L. (2012). Children's dental health, school performance, and psychosocial well-being. *J Pediatr*, *161*(6), 1153-1159.

Holan, G., & Needleman, H. L. (2014). Premature loss of primary anterior teeth due to trauma--potential short- and long-term sequelae. *Dent Traumatol*, *30*(2), 100-106.

Holmes, R., Porter, J., Vernazza, C., Tsakos, G., Ryan, R., & Dennes, M. (2015). *Children's Dental Health Survey 2013 Country specific report: England*. Health and Social Care Information Centre. Retrieved 08 December 2020 from https://files.digital.nhs.uk/publicationimport/pub17xxx/pub17137/cdhs2013-england-report.pdf

Hong, C. L., Broadbent, J. M., Thomson, W. M., & Poulton, R. (2020). The Dunedin Multidisciplinary Health and Development Study: Oral health findings and their implications. *J R Soc N Z*, *50*(1), 35-46.

Husain, J., Donald, B., Patrick, M., & Hania, M. (2022). Management of the Palatally Ectopic Maxillary Canine. In: *National Clinical Guidelines, Faculty of Dental Surgery, Royal College of Surgeons of England*. Retrieved 11 September 2023 from https://www.rcseng.ac.uk/-/media/files/rcs/fds/guidelines/2management-of-the-palatally-ectopic-maxillary-canine--revised-with-edits-25-jan-2023.pdf

Innes, N. P., Evans, D. J., & Stirrups, D. R. (2007). The Hall Technique; a randomized controlled clinical trial of a novel method of managing carious primary molars in general dental practice: acceptability of the technique and outcomes at 23 months. *BMC Oral Health*, *7*, 18.

Jankauskiene, B., & Narbutaite, J. (2010). Changes in oral health-related quality of life among children following dental treatment under general anaesthesia. A systematic review [Review]. *Stomatologija*, *12*(2), 60-64.

Javidi, H., Vettore, M., & Benson, P. E. (2017). Does orthodontic treatment before the age of 18 years improve oral health-related quality of life? A systematic review and meta-analysis. *Am J Orthod Dentofacial Orthop*, *151*(4), 644-655.

Kaklamanos, E. G., Lazaridou, D., Tsiantou, D., Kotsanos, N., & Athanasiou, A. E. (2017). Dental arch spatial changes after premature loss of first primary molars: a systematic review of controlled studies. *Odontology*, *105*(3), 364-374.

Kidd, J. B., McMahon, A. D., Sherriff, A., Gnich, W., Mahmoud, A., Macpherson, L. M., & Conway, D. I. (2020). Evaluation of a national complex oral health improvement programme: a population data linkage cohort study in Scotland. *BMJ Open*, *10*(11), e038116.

Kim Seow, W. (2012). Environmental, maternal, and child factors which contribute to early childhood caries: a unifying conceptual model. *Int J Paediatr Dent*, *22*(3), 157-168.

Knapp, R., Gilchrist, F., Rodd, H. D., & Marshman, Z. (2017). Change in children's oral health-related quality of life following dental treatment under general anaesthesia for the management of dental caries: a systematic review. *Int J Paediatr Dent*, *27*(4), 302-312.

Legovic, M., & Mady, L. (1999). Longitudinal occlusal changes from primary to permanent dentition in children with normal primary occlusion. *Angle Orthod*, *69*(3), 264-266.

Listl, S., Galloway, J., Mossey, P. A., & Marcenes, W. (2015). Global Economic Impact of Dental Diseases. *J Dent Res*, *94*(10), 1355-1361.

Logan, W. H. G., & Kronfeld, R. (1933). Development of the Human Jaws and Surrounding Structures from Birth to the Age of Fifteen Years**From the Research Department of the Chicago College of Dental Surgery, Dental Department of Loyola University.Read at the Third General Meeting of the Seventy-Fourth Annual Session of the American Dental Association, Buffalo, N. Y., Sept. 14, 1932. *The Journal of the American Dental Association (1922)*, *20*(3), 379-428.

Magnússon, T. E. (1979). The effect of premature loss of deciduous teeth on the spacing of the permanent dentition. *Eur J Orthod*, *1*(4), 243-249.

Malden, P. E., Thomson, W. M., Jokovic, A., & Locker, D. (2008). Changes in parent-assessed oral health-related quality of life among young children following dental treatment under general anaesthetic. *Community Dent Oral Epidemiol*, *36*(2), 108-117.

Marks, S. C., Jr., & Schroeder, H. E. (1996). Tooth eruption: theories and facts. *Anat Rec*, *245*(2), 374-393.

Marshman, Z., Ainsworth H, Chestnutt IG, Day P, Dey D, El Yousfi S, Fairhurst C, Gilchrist F, Hewitt C, Jones C, Kellar I, Pavitt S, Robertson M, Shah S, Stevens K, Torgerson D, Innes N. (2019). Brushing RemInder 4 Good oral HealTh (BRIGHT) trial: does an SMS behaviour change programme with a classroom-based session improve the oral health of young people living in deprived areas? A study protocol of a randomised controlled trial. *Trials*, *20*(1), 452.

Masood, M., Masood, Y., Saub, R., & Newton, J. T. (2014). Need of minimal important difference for oral health-related quality of life measures. *Journal of Public Health Dentistry*, *74*(1), 13-20.

Masood, M., Mnatzaganian, G., & Baker, S. R. (2019). Inequalities in dental caries in children within the UK: Have there been changes over time? *Community Dent Oral Epidemiol*, *47*(1), 71-77.

Masood, Y., Masood, M., Zainul, N. N., Araby, N. B., Hussain, S. F., & Newton, T. (2013). Impact of malocclusion on oral health related quality of life in young people. *Health Qual Life Outcomes*, *11*, 25.

McNair, A., & Morris, D. (2010). Managing the Developing Occlusion: A guide for dental practitioners (revised). *Br Dent J* 209, 322 (2010). https://doi.org/10.1038/sj.bdj.2010.881

Melsen, B., & Terp, S. (1982). The influence of extractions caries cause on the development of malocclusion and need for orthodontic treatment. *Swed Dent J Suppl*, *15*, 163-169.

Milsom, K. M., Tickle, M., Humphris, G. M., & Blinkhorn, A. S. (2003). The relationship between anxiety and dental treatment experience in 5-year-old children. *Br Dent J*, *194*(9), 503-506; discussion 495.

Mitchell, L. (2019).'The aetiology and classification of malocclusion', in Littlewood, S. J., Mitchell, L. (2019). *An Introduction to Orthodontics*. (Fifth Edition, pp.11-22). Oxford University Press.

Moles, D. R., & Ashley, P. (2009). Hospital admissions for dental care in children: England 1997-2006. *Br Dent J*, *206*(7), E14; discussion 378-379.

NAO. (2020). Dentistry in England. In: National Audit Office.Retrieved 31 March 2022 from https://www.nao.org.uk/reports/dentistry-in-england/

NHS Digital. (2016). *Annual NHS dental statistics*. Retrieved 03 November 2019 from https://digital.nhs.uk/data-and- information/publications/statistical/nhs-dental-statistics/nhs-dental-statistics-for-england-2015-16#:~:text=In%20the%2024%20month%20period,cent%20of%20the%20child%20population

Northway, W. M., & Wainright, R. W. (1980). D E space--a realistic measure of changes in arch morphology: space loss due to unattended caries. *J Dent Res*, *59*(10), 1577-1580.

Northway, W. M., Wainright, R. L., & Demirjian, A. (1984). Effects of premature loss of deciduous molars. *Angle Orthod*, *54*(4), 295-329.

Nyström, M., & Peck, L. (1989). The period between exfoliation of primary teeth and the emergence of permanent successors. *Eur J Orthod*, *11*(1), 47-51.

OHID. (2023a). Hospital tooth extractions in 0 to 19 year olds 2022. In: Office for Health Improvement and Disparities. Retrieved 15 February 2023 from https://www.gov.uk/government/statistics/hospital-tooth-extractions-in-0-to-19-year-olds-2022/hospital-tooth-extractions-in-0-to-19-year-olds-2022#:~:text=year%2Dolds%2D2022-,Main%20findings,0%20to%2019%20year%20olds

OHID. (2023b). National Dental Epidemiology Programme (NDEP) for England: oral health survey of 5 year old children 2022. In: Office for Health Improvement and Disparities. Retrieved 15 February 2023 from https://www.gov.uk/government/statistics/oral-health-survey-of-5-year-old-children-2022/national-dental-epidemiology-programme-ndep-for-england-oral-health-survey-of-5-year-old-children-2022

Patel, N., Hodges, S. J., Hall, M., Benson, P. E., Marshman, Z., & Cunningham, S. J. (2016). Development of the Malocclusion Impact Questionnaire (MIQ) to measure the oral health-related quality of life of young people with malocclusion: part 1 - qualitative inquiry. *J Orthod*, *43*(1), 7-13.

Pedersen, J., Stensgaard, K., & Melsen, B. (1978). Prevalence of malocclusion in relation to premature loss of primary teeth. *Community Dentistry and Oral Epidemiology*, *6*(4), 204-209.

Peres, K. G. Peres, M. A., Thomson, W. M., Broadbent, J., Hallal, P. C., Menexes, A. B. (2015). Deciduous-dentition malocclusion predicts orthodontic treatment needs later: Findings from a population-based birth cohort study. *American journal of orthodontics and dentofacial orthopedics*, *147*(4), 492-498.

Peres, M. A., Peres, K. G., Thomson, W. M., Broadbent, J. M., Gigante, D. P., & Horta, B. L. (2011). The influence of family income trajectories from birth to adulthood on adult oral health: findings from the 1982 Pelotas birth cohort. *Am J Public Health*, *101*(4), 730-736.

PHE. (2017a). Health matters: child dental health. In: Public Health England.Retrieved 05 March 2022 from https://www.gov.uk/government/publications/health-matters-child-dental-health/health-matters-child-dental-health

PHE. (2017b). *Oral health survey of 5 year old children: 2017*. Retrieved 29 October 2019 from https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/768368/NDEP_for_England_OH_Survey_5yr_2017_Report.pdf

PHE. (2018a). *Guidance: Child oral health: applying All Our Health*. Public Health England. Retrieved 29 October 2019 from https://www.gov.uk/government/publications/child-oral-health-applying-all-our-health/child-oral-health-applying-all-our-health

PHE. (2018b). *National Dental Epidemiology Programme for England: oral health survey of five-year-old children 2017*. Public Health England. Retrieved 04 March 2021 from https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/768368/NDEP_for_England_OH_Survey_5yr_2017_Report.pdf

PHE. (2020). National Dental Epidemiology Programme for England: oral health survey of 5-year-olds 2019. In: Public Health England. Retrieved 05 March 2022 from https://www.gov.uk/government/statistics/oral-health-survey-of-5- year-old-children-2019

PHE. (2021). Hospital tooth extractions of 0 to 19 year olds. In: Public Health England. Retrieved 05 March 2022 from https://www.gov.uk/government/publications/hospital-tooth-extractions-of-0-to-19-year-olds

Poulton, R., Moffitt, T. E., & Silva, P. A. (2015). The Dunedin Multidisciplinary Health and Development Study: overview of the first 40 years, with an eye to the future. *Soc Psychiatry Psychiatr Epidemiol*, *50*(5), 679-693.

Powell, L. V. (1998). Caries prediction: a review of the literature. *Community Dent Oral Epidemiol*, *26*(6), 361-371.

Rajab, L. D. (2002). Clinical performance and survival of space maintainers: evaluation over a period of 5 years. *ASDC J Dent Child*, *69*(2), 156-160, 124.

Ramakrishnan, M., Dhanalakshmi, R., & Subramanian, E. M. G. (2019). Survival rate of different fixed posterior space maintainers used in Paediatric Dentistry - A systematic review. *Saudi Dent J*, *31*(2), 165-172.

Ravaghi, V., Baker, S. R., Benson, P. E., Marshman, Z., & Morris, A. J. (2019). Socioeconomic Variation in the association between Malocclusion and Oral Health Related Quality of Life. *Community Dent Health*, *36*(1), 17-21.

Rock, W. P. (2002). UK National Clinical Guidelines in Paediatric Dentistry. Extraction of primary teeth -- balance and compensation. *Int J Paediatr Dent*, *12*(2), 151-153.

Rönnerman, A. (1977). The effect of early loss of primary molars on tooth eruption and space conditions. A longitudinal study. *Acta Odontol Scand*, *35*(5), 229-239.

SDCEP. (2018). Prevention and Management of Dental Caries in Children. In (2nd Edition): Scottish Dental Clinical Effectiveness Programme. Retrieved 03 October 2022 from https://www.sdcep.org.uk/media/2zbkrdkg/sdcep-prevention-and-management-of-dental-caries-in-children-2nd-edition.pdf

Sedgwick, P. (2014). Case-control studies: advantages and disadvantages. *BMJ : British Medical Journal*, *348*, f7707.

Shearer, D. M., & Thomson, W. M. (2010). Intergenerational continuity in oral health: a review. *Community Dent Oral Epidemiol*, *38*(6), 479-486.

Shearer, D. M., Thomson, W. M., Caspi, A., Moffitt, T. E., Broadbent, J. M., & Poulton, R. (2012). Family history and oral health: findings from the Dunedin Study. *Community Dent Oral Epidemiol*, *40*(2), 105-115.

SHINE. (2023). SHINE. In. Retrieved 29 November 2022 from https://shinetrust.org.uk/

Shire, K. a. A., E and Barber, S and Bruce, A and Corkett, J and Hill, LJB and Kelly, B and McEachan, RRC and Mon-Williams, M and Tracey, L and Waterman, AH and Wright, J. (2020). Starting School: a large-scale start of school assessment within the Born in Bradford longitudinal cohort. *Wellcome Open Research*, *5*(47).

Spodzieja, K., & Olczak-Kowalczyk, D. (2022). Premature Loss of Deciduous Teeth as a Symptom of Systemic Disease: A Narrative Literature Review. *Int J Environ Res Public Health*, *19*(6).

Sullivan, A., Brown, M., Hamer, M., & Ploubidis, G. B. (2022). Cohort Profile Update: The 1970 British Cohort Study (BCS70). *Int J Epidemiol*, 52(3), e179-e186.

Sun, L., Wong, H. M., & McGrath, C. P. (2017). Relationship Between the Severity of Malocclusion and Oral Health Related Quality of Life: A Systematic Review and Meta-analysis. *Oral Health Prev Dent*, *15*(6), 503-517.

Sun, L., Wong, H. M., & McGrath, C. P. J. (2018). Association Between the Severity of Malocclusion, Assessed by Occlusal Indices, and Oral Health Related Quality of Life: A Systematic Review and Meta-Analysis. *Oral Health Prev Dent*, *16*(3), 211-223.

Tarvit, D. J., & Freer, T. J. (1998). Assessing malocclusion--the time factor. *Br J Orthod*, *25*(1), 31-34.

Tunison, W., Flores-Mir, C., ElBadrawy, H., Nassar, U., & El-Bialy, T. (2008). Dental arch space changes following premature loss of primary first molars: a systematic review. *Pediatr Dent*, *30*(4), 297-302.

Victora, C. G., & Barros, F. C. (2006). Cohort profile: the 1982 Pelotas (Brazil) birth cohort study. *Int J Epidemiol*, *35*(2), 237-242.

Wagner, Y., Knaup, I., Knaup, T. J., Jacobs, C., & Wolf, M. (2020). Influence of a programme for prevention of early childhood caries on early orthodontic treatment needs. *Clin Oral Invest*, 24(12), 4313-4324.

Watt, R. G., & Sheiham, A. (2012). Integrating the common risk factor approach into a social determinants framework. *Community Dentistry and Oral Epidemiology*, *40*(4), 289-296.

Weerheijm, K. L., Duggal, M., Mejàre, I., Papagiannoulis, L., Koch, G., Martens, L. C., & Hallonsten, A. L. (2003). Judgement criteria for molar incisor hypomineralisation (MIH) in epidemiologic studies: a summary of the European meeting on MIH held in Athens, 2003. *Eur J Paediatr Dent*, *4*(3), 110-113.

Westgarth, D. (2021). Turning the taps on: Is water fluoridation closer to becoming a reality? *BDJ In Practice*, *34*(7), 12-17.

WHO. (2018). *Oral Health*. World Health Organization. Retrieved 29 October 2019 from https://www.who.int/news-room/fact-sheets/detail/oral-health

Wright, J., Small N, Raynor P, Tuffnell D, Bhopal R, Cameron N, Fairley L, Lawlor DA, Parslow R, Petherick ES, Pickett KE, Waiblinger D, West J; Born in Bradford Scientific Collaborators Group (2012). Cohort Profile: The Born in Bradford multi-ethnic family cohort study. International *Journal of Epidemiology*, *42*(4), 978-991.

Yang, T. C., Power, M., Moss, R. H., Lockyer, B., Burton, W., Doherty, B., & Bryant, M. (2022). Are free school meals failing families? Exploring the relationship between child food insecurity, child mental health and free school meal status during COVID-19: national cross-sectional surveys. *BMJ Open*, *12*(6), e059047.

Zaror, C., Matamala-Santander, A., Ferrer, M., Rivera-Mendoza, F., Espinoza-Espinoza, G., & Martínez-Zapata, M. J. (2022). Impact of early childhood caries on oral health-related quality of life: A systematic review and meta-analysis. *Int J Dent Hyg*, *20*(1), 120-135.

List of Abbreviations

BiB	Born in Bradford
BIHR	Bradford Institute for Health Research
CI	Confidence Interval
COHIP-SF 19	Short form of the Child Oral Health Impact Profile
COVID-19	Coronavirus disease
CRN	Clinical Research Network
GA	General anaesthetic
IOTN	Index of Orthodontic Treatment Need
IOTN-AC	Aesthetic Component of the Index of Orthodontic Treatment Need
IOTN-DHC	Dental Health Component of the Index of Orthodontic Treatment Need
IQR	Inter-quartile range
LA	Local anaesthetic
MID	Minimal important difference
NHS	National Health Service
no-PEPT	No premature extraction of primary teeth
OH-RQoL	Oral health-related quality of life
OR	Odds ratio
PEPT	Premature extraction of primary teeth
SD	Standard deviation
UK	United Kingdom
WiFi	Wireless fidelity

Appendices

Appendix 1.1 Protocol paper

Scientific Section

Journal of Orthodontics

Journal of Orthodontics
1–8
DOI: 10.1177/1465312519843305

PLATOON: Premature Loss of bAby Teeth and its impact On Orthodontic Need - protocol

Lucy R Brown[1], Sophy Barber[2], Philip E Benson[3], Simon Littlewood[4], Mark S Gilthorpe[5], Jianhu Wu[6], Silviya Nikolova[7], Eman Al-Nunuaimi[1], Dan Mason[8], Daigmar Waiblinger[8], Rosie C McEachan[8] and Peter F Day[9]

Abstract

Objective: To investigate the impact of premature extraction of primary teeth (PEPT) on orthodontic treatment need in a cohort of children participating in the Born in Bradford (BiB) longitudinal birth cohort.

Design: Observational, cross-sectional cohort.

Participants: We aim to recruit 1000 children aged 7–11 years: 500 with a history of PEPT and 500 matched non-PEPT controls.

Methods: After informed consent/assent, orthodontic records will be collected, including extra and intra-oral photographs and alginate impressions for study models. Participants will also complete a measure of oral health-related quality of life (COHIP-SF 19). The records will be used to quantify space loss, identify other occlusal anomalies and assess orthodontic treatment need using the Index of Orthodontic Treatment Need. For each outcome, summary statistics will be calculated and the data for children with and without PEPT compared. The records of the children identified to be in need of orthodontic treatment will be examined by an expert orthodontic panel to judge if this treatment should be undertaken at the time of the records or delayed until the early permanent dentition.

Collecting robust records in the mixed dentition provides the clinical basis to link each stage of the causal chain and enable the impact of PEPT on orthodontic need to be characterised. This study is the first to provide the foundations for future longitudinal data collection allowing the long-term impact of PEPT to be studied.

Keywords

local causes of malocclusion, aetiology of malocclusion and growth, IOTN, orthodontic need, primary teeth, premature loss, premature extraction

Date received: 19 December 2018; accepted: 19 March 2019

[1]Paediatric Dentistry Department, University of Leeds, Leeds, UK
[2]Orthodontic Department, University of Leeds, Leeds, UK
[3]Academic Unit of Oral Health, Dentistry & Society, University of Sheffield, Sheffield, UK
[4]Orthodontic Department, Bradford Teaching Hospitals NHS Foundation Trust, Bradford, UK
[5]Leeds Institute for Data Analytics, School of Medicine, University of Leeds, Leeds, UK
[6]School of Dentistry, University of Leeds, Leeds, UK
[7]Leeds Institute of Health Sciences, University of Leeds, Leeds, UK
[8]Bradford Institute for Health Research, Bradford Teaching Hospitals NHS Foundation Trust, Bradford, UK
[9]Bradford District Care NHS Foundation Trust, UK

Corresponding author:
Lucy R Brown, Paediatric Dentistry Department, University of Leeds, Worsley Building, Clarendon Way, Leeds LS2 9LU, UK.
Email: lucy.brown14@nhs.net

Introduction

Background and rationale

Extraction of carious primary teeth is the most common reason for young children to have a general anaesthetic in England. In 2015–2016, > 45,000 children (NHS Digital, 2015–2016) underwent this procedure at an estimated cost of £50.5 million to the NHS (Public Health England, 2017). In addition to the financial cost, these have a significant impact for children and their families with associated anxiety, reduced school attendance and postoperative morbidity (Knapp et al., 2016; Rodd et al., 2014; Wong et al., 2015).

Professional bodies (American Academy Of Paediatric Dentistry, 2014; Faculty of Dental Surgery, 2015; Fayle et al., 2001) urge clinicians to restore primary teeth where feasible, to maintain the space for the permanent dentition and thereby reduce malocclusion and the potential future need for orthodontic treatment. A systematic review by Bhujel et al. (2016) examined the impact of premature extraction of primary teeth with orthodontic treatment need in the permanent dentition. Bhujel et al. (2016) found six short-term studies (Clinch and Healy, 1959; Kau et al., 2004; Leighton, 1981; Ronnerman 1965, 1977; Sayın and Türkkahraman, 2006) which examined the impact of premature extraction of primary teeth (PEPT) in the mixed dentition, with each study identifying space loss as a sequela. One longitudinal case-control study was identified (Hoffding and Kisling, 1978) which reported a 10% increase in the frequency of at least one feature of malocclusion in children with a history of PEPT, compared to children with no history of PEPT (non-PEPT). None of the previous studies used a validated index to measure orthodontic treatment need and thus quantify the impact of PEPT.

Tooth loss has been shown to have a negative impact on oral health-related quality of life (OHRQoL) in the permanent dentition (Gerritsen et al., 2010). However, the impact of PEPT on the quality of life of children has received very little attention. Monte-Santo et al. (2018) recently published their study, which used the child OHRQoL to investigate the impact of untreated caries and PEPT on a Brazilian cohort of 667 children aged 8–9 years. Children with PEPT presented with significantly greater OHRQoL scores especially in the domains of oral symptoms, functional limitation and emotional wellbeing.

The aetiology of malocclusion is complex involving both genetic and environmental factors. To date, the literature to support and characterise the contribution of PEPT to malocclusion is very limited. Robust longitudinal studies are required, which include data collection in both the mixed and permanent dentitions.

In Bradford, approximately 800 children each year undergo extraction of primary teeth under general anaesthetic with each child having an average of eight primary teeth extracted (Bradford District Care NHS Foundation Trust, 2015). There is substantial heterogeneity in the number of teeth extracted, thereby providing a natural experiment in which to explore the impact of PEPT, as well as the contribution of the number and the type of primary teeth extracted. An earlier retrospective study in Bradford showed association between the number of teeth extracted and orthodontic need; however, the study design and small numbers (116 children with 66 having a history of PEPT) limited the external validity of the findings (Bhujel et al., 2014).

The Born in Bradford birth cohort (BiB) offers a unique chance to examine the impact of PEPT on the development of malocclusion and subsequent orthodontic treatment need. BiB is a population-based, longitudinal, prospective study (Wright et al., 2012) developed to provide evidence about the causes of health and disease, by following the lives of 13,858 children born between 2007 and 2011.

This paper describes the protocol for a study that will explore the effect that PEPT has on malocclusion and subsequent orthodontic need. This study will improve on previous study designs by collecting robust records of space loss and occlusal anomalies in the mixed dentition and providing the clinical basis to link each stage of the causal chain and enable the impact of PEPT on orthodontic need to be characterised. It will also provide the base for further longitudinal data collection to examine the effects of PEPT in the permanent dentition.

Objectives

To compare a group of children aged 7–11 years who have undergone PEPT with a similar cohort of children who have not undergone PEPT (non-PEPT) in regard to:

- the effect on space loss and other occlusal anomalies;
- the proportion of children judged to need orthodontic treatment;
- the timing of future orthodontic treatment. Children deemed to need orthodontic treatment will be categorised into those who require treatment in either the mixed dentition or in the early permanent dentition. This will be judged by a panel of specialist orthodontists;
- to explore the impact of PEPT on children's OHRQoL.

Design

This stage of the study is an observational, cross-sectional design involving a sample from the BiB longitudinal birth cohort. The study will provide baseline data for a prospective, longitudinal cohort study. During development of the project, representatives from the BiB parents group met the research team to discuss the project design, child and parent information sheets, and recruitment strategy. This feedback was extremely valuable and informed adaptions to the project methodology.

Methods: participants, interventions and outcomes

Study population: The BiB birth cohort: a total of 13,858 children were recruited to the BiB cohort over a five-year period, 11,711 of whom are known currently to be attending primary schools in Bradford. The cohort is predominantly from a multi-ethnic origin with 45% Pakistani, 39% White British and 15% from other ethnic groups. Following ethics and appropriate research permissions, we will recruit at least 500 BiB children aged 7–11 years who have undergone

dental extractions. An ongoing dental data linkage feasibility study, funded by the Wellcome Institutional Strategic Support fund, has identified BiB children who have received extraction of primary teeth under general anaesthesia. To date, this study has recruited 1139 BiB children and identified information such as age at the time of the operation, number and type of teeth extracted.

An equal number of BiB children (at least 500) with no history of dental extractions will be recruited for a non-PEPT control group. To ensure control group children have not undergone PEPT with local anaesthetic, parents and children will be asked about any previous extractions. The control group will be matched for academic year group and where possible by the school they attend.

Eligibility criteria: Children will be eligible to be included in the study if:

- they are an active participant in the BiB cohort, with ongoing family consent;
- aged 6–11 years.

Participants will have either:

- a history or clinical evidence of premature extraction of one or more primary (baby or deciduous) tooth under either local or general anaesthetic (PEPT group)

Or

- no history or clinical evidence of premature extraction of primary (baby or deciduous) molars (non-PEPT group).

Children will be ineligible if the fit any of the following:

- not an active participant in the BiB cohort;
- history or clinical evidence of extraction of any secondary (adult or permanent) teeth;
- unable to manage or do not give consent to having dental records, including a dental exam, dental impressions and intra- and extra-oral photographs. Reasons may include medical history, learning impairments, gag reflex or anxiety regarding the procedure;
- history of orthodontic (brace) treatment;
- currently undergoing orthodontic (brace) treatment;
- cleft of the lip or palate.

Study setting: Data collection will be undertaken in primary schools in Bradford. A designated private area away from the normal classroom will be used for the dental assessment. Requests to visit schools will be made in advance and the number of visits will be kept as low as possible to minimise disruption.

Outcomes:

Primary outcome:

- to quantify the proportion of children who are assessed as having a need for orthodontic treatment.

Secondary outcomes:

- space loss and occlusal anomalies in the mixed dentition;
- to assess the proportions who would be treated in the mixed dentition or in the early permanent dentition;
- to explore the impact of PEPT on children's OHRQoL.

Sample size: power calculation: The primary outcome is a binary outcome of Need/No Need for orthodontic treatment using the current NHS threshold Index of Orthodontic Treatment Needs (IOTN) score of 4 or 5 in the Dental Health Component (DHC) or 3 (DHC with a score of 6–10 in the Aesthetic Component [AC] (Brook and Shaw, 1989). Based on this, we have used the raw data from the 2008 Dental Epidemiology Survey for Bradford to evaluate statistical power. A sample size of 1000 individuals (of which 50% are PEPT cases) could achieve at least 81% of power at a 5% significance level to detect a difference of 10% in the orthodontic treatment need (Table 1).

Recruitment: Identification of potential participants in both groups will be undertaken by the BiB research team. Lists of children taking part in the BiB cohort, the school they attend and their contact details will be collated. These details will only be available to the BiB research team and the Clinical Research Network (CRN) team who will initially send out recruitment letters. Invitation letters will be sent to family addresses alongside information sheets. To enhance the understanding of the data collection process for children and their families, and to reduce anxiety about unfamiliar procedures, an information video has been produced (https://www.youtube.com/watch?v=eY9LAwunaBY). This explains the purpose of the research and shows how the examination, impressions and photographs will be collected. The video aims to provide an alternative format of information for those with low literacy or English as a second language and enhance the consent process. The use of an information video is relatively novel in dental research recruitment and the research team plan to evaluate the efficacy of this tool. Evaluation will be undertaken through questions embedded into the YouTube video and a questionnaire (Figures 1 and 2) during the recruitment process. The questionnaire aims to evaluate the number of potential participants watching the video, whether it encouraged their participation and whether it alleviated any anxieties about taking part.

A Gantt chart (Figure 3) shows the expected timing for recruitment, data collection analysis and dissemination.

Table 1. Power calculation for a combination of parameters.

Power (%)	PEPT cases	Total sample size	Allocation ratio	Clinically relevant difference in orthodontic need (%)	Multiple correlation between the exposure and the other independent variables	Alpha
85	500	1000	1	10	0.1	0.05
81	500	1000	1	10	0.2	0.05
91	500	1000	1	11	0.1	0.05
88	500	1000	1	11	0.2	0.05
95	500	1000	1	12	0.1	0.05
93	500	1000	1	12	0.2	0.05
91	600	1200	1	10	0.1	0.05
87	600	1200	1	10	0.2	0.05
95	600	1200	1	11	0.1	0.05
93	600	1200	1	11	0.2	0.05
91	500	1250	1.5	10	0.1	0.05
87	500	1250	1.5	10	0.2	0.05
95	500	1250	1.5	11	0.1	0.05
93	500	1250	1.5	11	0.2	0.05
93	500	1500	2	10	0.1	0.05
90	500	1500	2	10	0.2	0.05

Figure 1. Questions asked electronically immediately after the video via a pop-up question box.

"Did this video help you decide if you want to take in the Bradford Smiles Study?"
- ☐ Yes, it helped me decide
- ☐ No, I had already decided
- ☐ No, I'm still not sure if I want to part

"Did this video help you understand what was going to happen?"
- ☐ Yes
- ☐ No, I already knew what was going to happen
- ☐ No, I'm still not sure what is going to happen

"Has this video made you less worried about taking part in the Bradford Smile Study?"
- ☐ Yes
- ☐ No, I wasn't worried
- ☐ No, I'm still a bit worried

"Do you think you will take part in the Bradford Smile Study?"
- ☐ Yes
- ☐ No
- ☐ I'm still not sure

Figure 2. Questions on the consent form.

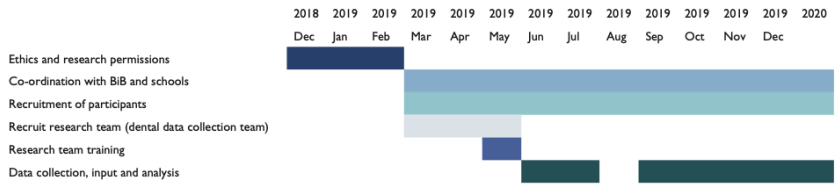
"Did you watch the YouTube video about the Bradford Smile Study?"
- ☐ Yes
- ☐ No

"Did the YouTube video help you to decide if you want to take in the Bradford Smile Study?"
- ☐ Yes, it helped me decide
- ☐ No, I had already decided
- ☐ No, I'm still not sure if I want to part

"Did the video help you understand what was going to happen?"
- ☐ Yes
- ☐ No, I already knew what was going to happen
- ☐ No, I'm still not sure what is going to happen

"Has this video made you less worried about taking part in the Bradford Smile Study?"
- ☐ Yes
- ☐ No, I already knew what was going to happen
- ☐ No, I'm still not sure what is going to happen

Figure 3. Gantt chart showing expected timing for the study.



Methods: data collection, management and analysis

Data collection: Overarching protocols from the National Child Dental Health Survey, which is conducted in a school setting, will be followed (Health and Social Care Information Centre [HSCIC], 2015). The research team (1× dentist or dental therapist, 1× dental nurse) will complete a dental examination. This will allow intra-oral photographs to be validated and correct inter-digitation of study models. The number of teeth present as well as obvious dental findings, e.g. cavitated dental caries and molar incisor hypo-mineralisation, will also be recorded.

The team will take standardised intra- and extra-oral orthodontic photographs. Alginate impressions will be taken and scanned to facilitate the production of digital study models, with the articulation validated by intra-oral photographs. Children will be asked to complete the Child Oral Health Impact Profile–Short Form 19 (COHIP-SF 19) questionnaire (Broder et al., 2012).

Training of examiners: The research team will undertake bespoke training in orthodontic photography and impression taking. During the early stages of data collection an orthodontist will accompany the research team to ensure consistency in record taking.

Data management: Data will be hosted in the BiB data warehouse at Bradford Teaching Hospitals NHS Foundation Trust and managed in accordance with well-established BiB data access and security protocols. Consultation with the Health Research Authority ensured that patient information sheets complied with the new General Data Protection Regulation (GDPR) guidance (Local Government Association, 2018) introduced in May 2018.

Analysis

Statistical methods

The exposure, PEPT or non-PEPT, will be captured as a single event. Confounders in the two groups will be

identified within a directed acyclic graph and appropriate minimally sufficient adjustment sets of confounders will be accommodated in all subsequent analyses (Greenland et al., 1999), allowing appropriate causal inferences to be made.

Analysis of secondary outcomes

To characterise space loss and occlusal anomalies in the mixed dentition

For each child, the following information will be recorded from the clinical photographs and digital study models: molar and incisor relationship; overjet; overbite; crossbites; skeletal pattern; and the degree of crowding or spacing. From the study models, further measurements will be calculated for each arch and will include: arch perimeter and hemi-perimeter; arch length; arch width; and E and D space as defined by Northway (Northway and Wainright, 1980).

This analysis will be required in order to allow the primary outcome to be evaluated.

For each measurement, an appropriate summary statistic will be calculated for children in the PEPT and non-PEPT groups. The groups will be compared either descriptively or through appropriate statistical test to detect any differences.

Analysis of the primary outcome

To quantify the proportion of children who are assessed as having a need for orthodontic treatment

Using the study models and photographs (but with no access to radiographs), each child's records will be assessed by the research team following appropriate training, using the IOTN Dental Health Component.

Orthodontic indices, including the Index of Orthodontic Treatment Need (IOTN), the Index of Complexity, Outcome and Need (ICON) and the Dental Aesthetic Index (DAI), have been used in the mixed dentition to measure prevalence of malocclusion and estimate orthodontic treatment need (Mohamed et al., 2014; Rauten et al., 2016; Tausche et al., 2004) and to assess changes in occlusal features and treatment need over time (Boronat-Catala et al., 2016; Lagana et al., 2013). The IOTN was more stable than other indices for estimating treatment need across different age groups (Baubiniene et al., 2009; Boronat-Catala et al., 2016; Costa et al., 2011; Tarvit and Freer, 1998) and while not developed specifically to predict future treatment need, IOTN may be used as a guide to estimate this. To date, no studies have observed a single group of participants longitudinally to quantify the predictive ability of any index in the mixed dentition. After discussion within the research team, IOTN was judged to be the most appropriate objective measure of orthodontic need that is currently available.

Analysis of secondary outcomes

To assess the proportions who would be treated in the mixed dentition or in the early permanent dentition

An expert panel of three specialist orthodontists will independently examine the clinical photographs and digital study models for those children who have an orthodontic treatment need according to IOTN DHC or are deemed by the expert panel to require interceptive orthodontic treatment. A decision will be made as to whether they would recommend orthodontic treatment to be undertaken at the time that the records were taken (e.g. in the mixed dentition) or to wait and treat in the early permanent dentition. A standardised data collection form will provide a systematic and objective format for evaluating records and determining the timing of any orthodontic need. Disagreements will be resolved through discussion.

To explore the impact of PEPT on children's oral health-related quality of life

Several measures are available to assess children's OHRQoL including Child Perceptions Questionnaire (CPQ), the Child Oral Impacts on Daily Performances (C-OIDP) and the COHIP (Broder et al., 2012; Gilchrist et al., 2014). Each self-reported measure has been validated and has been shown to discriminate between groups. Certain measures have been adapted for specific age groups (Gilchrist et al., 2014; Humphris et al., 2005).

The COHIP-SF 19 (Broder et al., 2012) will be used to assess any impact PEPT has on children's OHRQoL. Although CPQ 8-10 (Humphris et al., 2005) was used to measure children's OHRQoL in previous PEPT studies (Monte-Santo et al., 2018), COHIP-SF 19 was felt to be most appropriate for this study for several reasons. This tool has been validated for use in children aged 7–15 years (Broder et al., 2012; Gilchrist et al., 2014). This is crucial to allow the continuous use of this OHRQoL measurement tool in the planned longitudinal data collection of this cohort. The COHIP-SF 19 is also short to complete thus allowing ease of use and reducing the impact on participants during data collection.

The results of the COHIP-SF 19 will be computed by summing the values of each question. The total score will be in the range of 0–76. The distribution of the total score will be assessed. If normally distributed, the total COHIP-SF 19 score will be compared between PEPT and non-PEPT groups using a two-sided two-sample t-test; otherwise the non-parametric Mann–Whitney U test will be used. Generalised linear model will be used to assess the difference in OHRQoL between PEPT and non-PEPT groups adjusting for other explanatory variables (e.g. presence of decayed teeth). If statistical significance is found for PEPT, then the significance of different sub-domains will be explored.

Ethics and dissemination

Research ethics approval. Full ethical approval via the Health Research Authority and an NHS Research Ethics Committee was sought and granted (18/YH/04).

Consent. Informed consent will be collected from BiB children's parents or legal guardians. The CRN staff or member of the BiB team who collect the consent are all trained in Good Clinical Practice and highly skilled in collecting informed consent. Verbal assent will be gained from the children before data collection. Children will be informed that they can stop at any point if they wish.

Ethical considerations. Dental staff collecting records will receive tailored training. Safeguarding principles will be followed and children with extensive untreated caries or signs of dental infection will be highlighted with a letter sent to their parents.

Dissemination policy. Dissemination of the study findings will aim to engage all important stakeholders including: (1) participants, their families and the wider BiB community; (2) dental professionals; and (3) commissioners and policymakers involved in children's dental services. BiB representatives will inform the approach for public-facing dissemination and innovative methods to share research findings will be explored in collaboration with University of Leeds School of Dentistry public engagement champions. Professional dissemination will include publication in peer-reviewed journals, presentation at relevant international conferences and sharing of the key findings through appropriate social media channels.

Discussion

Multiple factors affect the development of malocclusions and subsequent orthodontic need. There is also no accepted single measure of malocclusion. As such, designing a study to evaluate the effect that PEPT has on the developing occlusion is challenging. A multidisciplinary approach has been required to overcome these challenges to develop a robust research methodology to answer the research questions.

Embedding a dental study within an existing longitudinal birth cohort provides both exciting opportunities and logistical challenges. A strong relationship with the BiB research team has been crucial in developing the protocol, which is considerate of wider research projects, participant burden and goodwill of local primary schools. Ultimately the study is only possible as a result of the research funding and infrastructure established for other studies involving the cohort.

The research team aim to utilise the opportunities of working within a longitudinal birth cohort. An additional aim to the study is to provide the foundation for future longitudinal data collection, when children are in the permanent dentition. Future data collection will allow the accuracy of the IOTN prediction analysis to be examined and enable the effects of PEPT to be studied. The impact of PEPT on current and future orthodontic need will also be characterised. A decision tree, based on the predicted care pathways, will be constructed and this will allow the costs associated with different clinical outcomes (need or no need for orthodontic treatment) to be estimated.

Acknowledgements

Born in Bradford is only possible because of the enthusiasm and commitment of the children and parents in BiB. We are grateful to all the participants, health professionals and researchers who have made BiB happen. The BiB New Wave project is supported by a number of grants including:

- a joint grant from the UK Medical Research Council (MRC) and UK Economic and Social Science Research Council (ESRC): MR/N024391/1;
- The British Heart Foundation (BHF) (CS/16/4/32482);
- a Wellcome Trust infrastructure grant (WT101597MA);
- The National Institute for Health Research under its Collaboration for Applied Health Research and Care (CLAHRC) (IS-CLA-0113-10020);
- The NIHR Clinical Research Network which provided research delivery support for this study.

Many thanks to Adam Jones, Joshua Thornton, Colin O'Sullivan and Tim Zoltie for their help in producing the patient information video.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

This research is supported by a grant from the British Orthodontic Society Foundation. The initial dental data linkage was supported by grants from the Oral Dental Research Trust and the Wellcome Institutional Strategic Support Fund. Two of the authors of this paper (PD, RM) were supported by the NIHR CLAHRC Yorkshire and Humber (www.clahrc-yh.nihr.ac.uk). The views and opinions expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

ORCID iDs

Lucy R Brown https://orcid.org/0000-0002-6793-9990
Sophy Barber https://orcid.org/0000-0003-2881-6194
Philip E Benson https://orcid.org/0000-0003-0865-962X
Dan Mason https://orcid.org/0000-0002-0026-9216

References

American Academy Of Pediatric Dentistry (2014) *Guideline on Management of the Developing Dentition and Occlusion in Pediatric*

Dentistry. Chicago, IL: AAPD. Available at: http://www.aapd.org/media/Policies_Guidelines/G_DevelopDentition.pdf (accessed 23 October 2018).

Baubiniene D, Sidlauskas A and Miseviciene I (2009) The need for orthodontic treatment among 10–11- and 14–15-year-old Lithuanian schoolchildren. *Medicina (Kaunas)* 45: 814–821.

Bhujel N, Duggal M, Munyombwe T, Godson J and Day P (2014) The effect of premature extraction of primary teeth on the subsequent need for orthodontic treatment. *European Archives of Paediatric Dentistry* 15: 393–400.

Bhujel N, Duggal MS, Saini P and Day PF (2016) The effect of premature extraction of primary teeth on the subsequent need for orthodontic treatment. *European Archives of Paediatric Dentistry* 17: 423–434.

Boronat-Catala M, Bellot-Arcis C, Montiel-Company JM, Catala-Pizarro M and Almerich-Silla JM (2016) Orthodontic treatment need of 9, 12 and 15 year-old children according to the Index of Orthodontic Treatment Need and the Dental Aesthetic Index. *Journal of Orthodontics* 43: 130–136.

Bradford District Care NHS Foundation Trust (2015) *Service evaluation of dental extractions under general anaesthetic*. Bradford.

Broder HL, Wilson-Genderson M and Sischo L (2012) Reliability and validity testing for the Child Oral Health Impact Profile-Reduced (COHIP-SF 19). Journal of Public Health Dentistry 72: 302–312.

Brook P and Shaw W (1989) The development of an index of orthodontic treatment priority. *European Journal of Orthodontics* 11: 309–320.

Clinch L and Healy M (1959) A longitudinal study of the results of premature extraction of deciduous teeth between 3–4 and 13–14 years of age. *Dental Practice* 9: 109–127.

Costa RN, Abreu MH, Magalhaes CS and Moreira AN (2011) Validity of two occlusal indices for determining orthodontic treatment needs of patients treated in a public university in Belo Horizonte, Minas Gerais State, Brazil. *Cadernos de saude publica* 27: 581–590.

Faculty of Dental Surgery (2015) *The state of children's oral health in England*. London: Royal College of Surgeons of England.

Fayle SA, Welbury RR and Roberts JF British Society of Paediatric Dentistry (2001) British Society of Paediatric Dentistry: a policy document on management of caries in the primary dentition. *International Journal of Paediatric Dentistry* 11: 153–157.

Gerritsen AE, Allen PF, Witter DJ, Bronkhorst EM and Creugers NHJ (2010) Tooth loss and oral health-related quality of life: a systematic review and meta-analysis. *Health and Quality of Life Outcomes* 8: 126.

Gilchrist F, Rodd H, Deery C and Marshman Z (2014) Assessment of the quality of measures of child oral health-related quality of life. *BMC Oral Health* 14: 40.

Greenland S, Pearl J and Robins JM (1999) Causal diagrams for epidemiologic research. *Epidemiology* 10: 37–48.

Hoffding J and Kisling E (1978) Premature loss of primary teeth: part I, its overall effect on occlusion and space in the permanent dentition. *ASDC Journal of Dentistry for Children* 45: 279–283.

HSCIC (2015) Children's Dental Health Survey 2013. Summary. Available at: http://digital.nhs.uk/catalogue/PUB17137 (accessed 23 October 2018).

Humphris G, Freeman R, Gibson B, Simpson K and Whelton H (2005) Oral health-related quality of life for 8–10-year-old children: an assessment of a new measure. *Community Dentistry and Oral Epidemiology* 33: 326–332.

Kau CH, Durning P, Richmond S, Miotti FA and Harzer W (2004) Extractions as a form of interception in the developing dentition: a randomized controlled trial. *Journal of Orthodontics* 31: 107–114.

Knapp R, Gilchrist F, Rodd HD and Marshman Z (2017) Change in children's oral health-related quality of life following dental treatment under general anaesthesia for the management of dental caries: a systematic review. *International Journal of Paediatric Dentistry* 27: 302–312.

Lagana G, Masucci C, Fabi F, Bollero P and Cozza P (2013) Prevalence of malocclusions, oral habits and orthodontic treatment need in a 7- to 15-year-old schoolchildren population in Tirana. *Progress in Orthodontics* 14: 12.

Leighton B (1981) Longitudinal study of features which might influence space loss after early extraction of lower deciduous molars. *Proceedings of the Finnish Dental Society* 77: 95–103.

Local Government Association (2018) General Data Protection Regulation (GDPR). Available at: https://local.gov.uk/our-support/general-data-protection-regulation-gdpr (accessed 23 October 2018).

Mohamed AM, Ariffin WFM, Rosli TI and Mahyuddin A (2014) The feasibility of Index of Orthodontic Treatment Need (IOTN) in labial segment malocclusion among 8–10 years old. *Archives of Orofacial Sciences* 9: 76–84.

Monte-Santo AS, Viana SVC, Moreira KMS, Imparato JCP, Mendes FM and Bonini G (2018) Prevalence of early loss of primary molar and its impact in schoolchildren's quality of life. *International Journal of Paediatric Dentistry* 28: 595–601.

NHS Digital (2015–2016) Hospital Admitted Patient Care.

Northway WM and Wainright RW (1980) D E space–a realistic measure of changes in arch morphology: space loss due to unattended caries. *Journal of Dental Research* 59: 1577–1580.

Public Health England (2017) *Health Matters: Child Dental Health*. London: PHE. Available at: www.gov.uk/government/publications/health-matters-child-dental-health/health-matters-child-dental-health (accessed 23 October 2018).

Rauten AM, Georgescu C, Popescu MR, Maglaviceanu CF, Popescu D, Gheorghe D, et al. (2016) Orthodontic treatment needs in mixed dentition - for children of 6 and 9 years old. *Romanian Journal of Oral Rehabilitation* 8: 28–39.

Rodd H, Hall M, Deery C, Gilchrist F, Gibson BJ and Marshman Z (2014) 'I felt weird and wobbly.' Child-reported impacts associated with a dental general anaesthetic. *British Dental Journal* 216: E17.

Ronnerman A (1965) Early extraction of deciduous molars and canines–its incidence and influence on spacing. *Report of the congress. European Orthodontic Society* 41: 153–168.

Ronnerman A (1977) The effect of early loss of primary molars on tooth eruption and space conditions. A longitudinal study. *Acta Odontologica Scandinavica* 35: 229–239.

Sayın M and Türkkahraman H (2006) Effects of lower primary canine extraction on the mandibular dentition. *Angle Orthodontist* 76: 31–35.

Tarvit DJ and Freer TJ (1998) Assessing malocclusion–the time factor. *British Journal of Orthodontics* 25: 31–34.

Tausche E, Luck O and Harzer W (2004) Prevalence of malocclusions in the early mixed dentition and orthodontic treatment need. *European Journal of Orthodontics* 26: 237–244.

Wong M, Copp PE and Haas DA (2015) Postoperative pain in children after dentistry under general anesthesia. *Anesthesia Progress* 62: 140–152.

Wright J, Small N, Raynor P, Tuffnell D, Bhopal R, Cameron N, et al. (2012) Cohort profile: The Born in Bradford multi-ethnic family cohort study. *International Journal of Epidemiology* 42: 978–991.

Appendix 1.2 British Orthodontic Society Foundation funding approval

Dr Peter Day, Associate Professor and Consultant in Paediatric Dentistry

Room 6.037, School of Dentistry, Worsley Building,

Clarendon Way,

University of Leeds

LS2 9LU

11th December 2017

Dear Dr Day

Re: BOSF funding application: The impact of premature extraction of primary teeth on orthodontic treatment need in a longitudinal birth cohort.

I am delighted to confirm that the BOSF are happy to support your research project with the award of £75,000.00 As with all BOSF awards, it is given on the basis that this research budget will not be exceeded nor that there will be any substantial changes to the protocol. The research directorate looks forward to learning about your research in the future. The first report is a 6 month interim report due in June 2018 with annual reports thereafter. Please send your report using the report form attached. I have also attached " An explanation of BOSF funding" for your guidance.

I should be grateful if you would send me a short abstract (around 200 words) explaining your project in terms easy to understand for the average dentist and a photo of yourself/ your team. We will use this for the website and any BOS news articles.

Once again many congratulations on receiving this award

Best wishes

NMandall

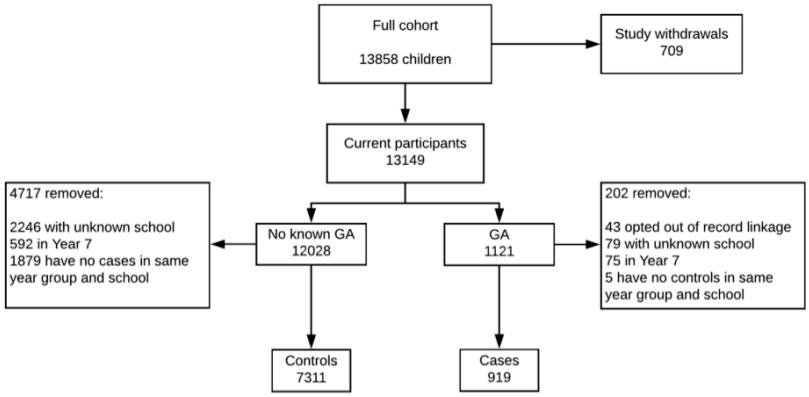
Nicky Mandall

BOSF

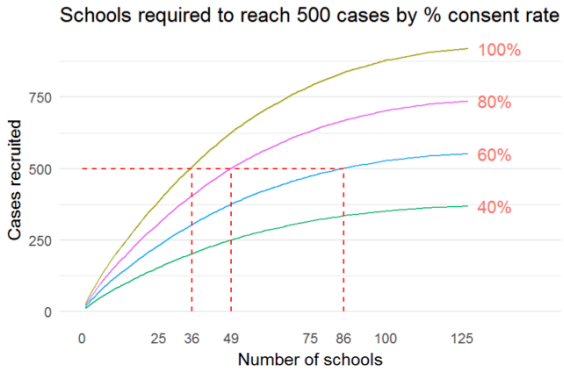
Appendix 3.1 Primary schools profile output

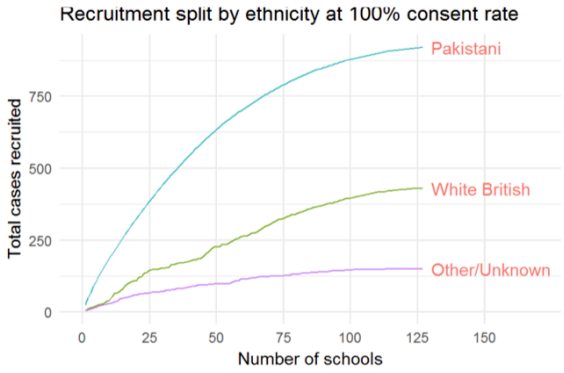
Dental schools matching

Case and control sampling frame selection



Recruitment trajectory





Schools in descending order by total number of cases

Year group designation is for 2018/2019 academic year.

[1] [redacted]

	Cases	Controls
Whole School	25	31
White British	4%	26%
Pakistani	76%	52%
Y3	3	8
Y4	2	15
Y5	13	5
Y6	7	3

[2] [redacted]

	Cases	Controls
Whole School	23	131
White British	9%	3%
Pakistani	78%	85%
Y3	3	15
Y4	11	34
Y5	4	43
Y6	5	39

[3] [redacted]

	Cases	Controls
Whole School	20	132
White British	5%	0%
Pakistani	75%	71%
Y3	3	17
Y4	7	44
Y5	6	36
Y6	4	35

[4] [redacted]

	Cases	Controls
Whole School	20	106
White British	0%	1%
Pakistani	90%	87%
Y3	6	19
Y4	4	25
Y5	4	33
Y6	6	29

[5] [redacted]

	Cases	Controls
Whole School	19	105
White British	0%	1%
Pakistani	79%	90%
Y3	3	12
Y4	3	31
Y5	9	28
Y6	4	34

[6] [redacted]

	Cases	Controls
Whole School	17	98

Appendix 3.2 Parent consent form

BRADFORD SMILE STUDY

We are family BORNINBRADFORD

Name: ..... **Date of Birth:** .....

Please send this copy back to us

BiB – Bradford Smile Study

Consent Form for Parents or Carers of BiB Children participating in this study.
V7 20.08.19

Taking part in the study

1	I have read the BiB parents (V7 20.08.19) information sheet and have had the chance to consider the information and ask any questions.	Yes ☐
2	I understand why my child is being asked to take part in this study and agree that they can take part.	Yes ☐
3	I understand that it is my decision whether they take part and that I can change my mind at any time, without giving a reason and without my child's health care or legal rights being affected.	Yes ☐
4	I understand that any information collected will be kept securely and used for research purposes only. It will not be possible for anyone outside of the research group to link any information gathered regarding my child or me.	Yes ☐
5	I understand that relevant sections of my child's dental notes and data collected during the study may be looked at by individuals from Born in Bradford and University of Leeds, from the NHS Trust or regulatory authorities, where it is relevant to me taking part in this research.	Yes ☐
6	If I wish to withdraw my child from the study in the future I agree the moulds and photos may be retained and used unless I specifically request that they are destroyed, in which case I understand that the research team will make every effort to do so.	Yes ☐

Measurements

7	I agree to photographs of my child's face to allow orthodontic measurements of the face to be taken. (See 'Information for Parents and Carers V7 20.08.19' for information')	Yes ☐	No ☐
8	I agree to photographs of my child's teeth to allow orthodontic and dental measurements to be taken. (See 'Information for Parents and Carers V7 20.08.19' for information')	Yes ☐	No ☐
9	I agree that dental impressions can be taken.	Yes ☐	No ☐

BRADFORD SMILE STUDY

We are family BORNINBRADFORD

		Yes	No
10	I understand photographs and digital models will be stored securely. I understand that the impressions will be sent to a UK laboratory for scanning and construction of a digital model.	☐	☐

Data linkage and future dental research

		Yes	No
11	I agree for dental data collected in this study about my child to be linked with other dental data linkage collected by the NHS. This may include, but not limited to, data held by my child's high street dentist/s, other specialist dental services (such as orthodontists) and central NHS organisations (such as the NHS Business Service Authority, NHS Digital and the Health and Social Care Information Centre). This information will help us to examine your child's dental journey from birth and into the future.	☐	☐
12	I agree that the dental information, photographs and virtual models can be stored securely for use in future studies.	☐	☐
13	I agree to be contacted in the future about a follow-up study to explore my child's need for orthodontic treatment when they are older. (e.g. secondary school or in later life)	☐	☐
14	Has your child had teeth (either primary or permanent) extracted either at the dentist or in hospital?	☐	☐

Other

		Yes	No
15	Does your child have a history of allergy to any type of food or material? If yes, please mention below:	☐	☐

If you want to talk to a member of the team or leave the study, you can contact us on: Tel: 0127383454 , Email address: borninbradford@bthft.nhs.uk

BiB child's name (Please print)

Child's name:

Parent or Carer's Name (Please print)

....

Parent or Carer's signature Date

Researcher's signature (if applicable) Date

BRADFORD SMILE STUDY

We are family BORNINBRADFORD

If you would like to attend while your child has his/her dental records taken at school, please send us an email: borninbradford@bthft.nhs.uk

Patient information video (optional questions)

www.tinyurl.com/BradfordSmileStudy
www.tinyurl.com/BradfordSmileStudy-URDU

	Yes	No
15. Did you watch the YouTube video about the Bradford Smiles Study? (If Yes, please answer 16-18)	☐	☐

16. Did the YouTube video help you to decide if you want to take part in the Bradford Smiles Study?

	Yes	No
	☐	☐

17. Did the YouTube video help you understand what was going to happen?

☐ Yes

☐ No, I already knew what was going to happen

☐ No, I'm still not sure what is going to happen

18. Did the YouTube video make you less worried about taking part in the Bradford Smiles Study?

☐ Yes

☐ No, I wasn't worried

☐ No, I'm still a bit worried

Bradford District NHS

NHS Bradford Teaching Hospitals NHS Foundation Trust

UNIVERSITY OF LEEDS

[School's name]
Parent/Carer of [Child's Name]
[Mother's name]
[Address]

Appendix 3.3 Dental research kit

Category	Item
Dental examination	Saddle stool
	Surgitel LED headlight
	Disposable mouth mirrors
	HS Dri-gard Bibs Yellow 500 pk
	Bib Connector Chain
	HS Face Shield Visor Frame Blue Transparent
	HS Face Shield Visor Frame Pink Transparent
	HS Faceshield Visor Refill 25 pk
	Kleersite Safety Glasses Junior Clear
	DEHP Gloves Nitrile Exam Powdered/F Blue Small 200 pk
	HS Aprons Disposable Polyethylene 75x125 cm 0.014 mm Thick 100pk
	Deb Cutan Foam Hand Sanitiser Pump 400 ml
	Johnson's Baby Cotton Touch Wipes - Pack of 18, Total 1008 Wipes
	Disposable Rulers
Dental photography	Cheek retractors stainless steel-child
	Intra-oral occlusal mirror-child
	Intra-oral occlusal mirror-adult
	Super Value White Poster Board - 50 Sheets of White Card 270 gsm (558 mm x 711 mm Slightly smaller than A1 size) in Re-closable Storage Carton - Ideal for all types of Classroom Projects - including Reward Charts, Birthday Boards, Mounting Work, Models etc
	Bostik B183836 Blu Tack - White
Dental impressions	Hydrogum 5 Intro Kit Zhermack
	Hydrogum 5 Refill 453 g
	DEHP Flexible Mixing Bowl Medium 10.5 cm
	Alginate Mixing Spatula
	Ortho Impression Trays Size 3 Lower Small Blue 10 pk
	Ortho Impression Trays Size 3 Upper Small Blue 10 pk
	Ortho Impression Trays Size 4 Lower Medium Green 10 pk
	Ortho Impression Trays Size 4 Upper Medium Green 10 pk

	Ortho Impression Trays Size 5 Lower Large Yellow 10 pk
	Ortho Impression Trays Size 5 Upper Large Yellow 10 pk
	Fix Tray Adhesive Spray 200 ml
	Unoguard
	Perform-ID Bath
	DEHP Gauze Square 15x15 cm 500 pk
	Serial barcode stickers
	Topper 8 Swabs (Sterile) 100 mm x 100 mm - 4 Ply
	TENATEX pink modelling wax
	Plain specimen bags 23x15 cm with document wallet 18 x 15 cm and grip seal
	Thermos Stainless King Flask, Midnight Blue, 1.2 L
	Perform Timer
	Dental laboratory slip
	Plastic cups
Infection control	Clinell Universal Cleaning Wipes 200pk
	HS C-Fold Towel 2Ply White 25 x 31cm 16 x 152 pcs (2432 pcs/box)
Other	Shatterproof Face Mirror Hand-held
	Urine and Vomit Spill Kit by GV Health-clean up-to 6 spillages
	Disposable GP X Vomit Bowl 200 pk
	Folding Hand Truck, Wilbest 70 Kg/155 lbs Heavy Duty 4-Wheel Solid Construction Utility Cart Compact and Lightweight for Luggage, Personal, Travel, Auto, Moving and Office Use - Portable Fold Up Dolly
	Vaseline
	1.5-inch Smiley Face Stickers Roll Happy Face Stickers Circle Dots Paper Labels Reward Stickers Teachers Stickers 500 Pieces per Roll (1.5 inch Yellow)

Appendix 3.4 School consent form

BRADFORD SMILE STUDY

I, _____ [Head teacher name] consent to _____ [school name]

participating in the Born in Bradford (BiB): The Bradford Smile Study

I have discussed this with a member of the research team and understand that as part of this involvement:

- Written consent will have been taken for children aged 6-11 years old to take part.
- Children can withdraw from data collection if they wish.
- Children will be asked to brush their teeth before the examination.
- A dental examination will be undertaken.
- Dental records will be taken including dental moulds and facial and mouth photographs.
- The school will not be identified in any way in any resulting publication or publicity surrounding the research without my consent.
- All data from individuals will be stored in line with Data Protection legislation and all personal or identifying details will be kept confidential.
- Parents have the right not to provide consent. If so no records will be taken of their child.
- I have the right to withdraw consent at any time

Signed: _____ Date:_____

Please sign two copies and retain one for your records and return the other by email to XXX, or by post to Born in Bradford, Bradford Institute for Health Research, Bradford Royal Infirmary, Duckworth Lane, Bradford BD9 6RJ
We appreciate your participation in this important study. If you have any further queries please don't hesitate to contact a member of the research team:

Peter Day
Contact details

Thank you

Bradford District NHS Bradford Teaching Hospitals NHS NHS Foundation Trust UNIVERSITY OF LEEDS BORNINBRADFORD For a Healthy Future

BRADFORD SMILE STUDY

Please complete this form to tell us
WHO the person is that we should contact
at your school to organise our visit

School Name:

Contact person name:

Job title:

Telephone number:

Email address:

Thank you

Appendix 3.5 Follow-up email to point of contact

Dear (point of contact),
Hope this email finds you well.
Thank you for your interest in taking part in the Bradford Smile Study. It was great visiting you/talking to you over the phone earlier today. Please find below further information about the study:

The link to the YouTube video about our study is:
English: http://tinyurl.com/BradfordSmileStudy or
Urdu: http://tinyurl.com/BradfordSmileStudy-Urdu

What is the Bradford Smile Study? The Bradford Smile Study is a study that aims at finding out why some children will need braces and others do not. The study will collect dental information from children while at primary school (age 8-12 years old) and then again at secondary school (13-15 years old). We are simply comparing a group of children who have had their baby teeth removed early as a result of tooth decay and a group of children who haven't had their baby teeth removed.

Who is doing this study? The University of Leeds is working with Born in Bradford (BiB) to undertake this study. The study is funded by the British Orthodontic Society.

Will all children attending your primary school be asked to take part in the study? No, only children already taking part in the BiB study can participate in the Bradford Smile Study. For your school we have looked up how many children are eligible. We are simply looking to recruit children from Years 4, 5, and 6.

When are we conducting the study? We conducted a pilot study in July 2019. For this academic year (2019/20), we have already started 3rd week of September and we will continue collecting information until July 2020.

What will the study include, please see our video? The study includes the following:

- A questionnaire to be filled out by the child (the questionnaire has been validated to be filled out by children aged 8 years and above, younger children may need help, our research team will provide this support).
- A quick dental examination with a dental mirror
- Photographs of mouth and face
- Dental "putty mould"

Only children where their parents have consented to take part in the study will be included. We will follow BiB data protocols to ensure all information collected is kept confidential and safely transported back to the BiB offices at Bradford Royal Infirmary.
How will we recruit children to take part? We have already identified eligible BiB children attending your school (around 70). The study has ethical approval and the parent information sheet outlines how we will recruit and consent each child:

1. Because we found it more effective to send the letters via school, our team will drop off the letters and a list of BiB children at your school. Our team will also collect the letters from the school.
2. Parents have the right to withdraw their child at any point.
3. Children have the right to withdraw from part or all of the dental assessment.
4. A Family Liaison Officer is very welcome to help, some schools have also talked about the study in assemblies.
5. If you are using an SMS system, the below text can be used: "Bradford Smile Study is at our school over the next few weeks. Children already taking part in the Born in Bradford study will have an information pack in their school bag. Please read and return to XXX by

XXXX if you want your child to take part. A video (in English and Urdu) explains what the study
involves http://tinyurl.com/BradfordSmileStudy or http://tinyurl.com/BradfordSmileStudy-Urdu "

What will be the impact on your school? We aim to have minimal impact on your school. Three or four members of the research team will support dental data collection and our aim is to be self-sufficient. All staff members are DBS checked and we will provide these certificates before we arrive. Depending on the number of children recruited from your school, we imagine it will take 3 or 4 days for data collection.

- **How many children will be examined each day and how long will it take to examine each child?** Each day, 8-12 children can be examined. The time required for filling out the questionnaire and collecting dental data is around 30 minutes. To maximise the number of children seen on the day and to minimise disruption to your school's schedule, we can see one child every 20 minutes.

- **Where will the study take place?** The dental data collection will take place at your school. Please could we use one of your rooms. Ideally we would like a room with a good light source, a chair, a table, and preferably a sink. A research team member will take children from and back to their class if that's ok. A member of the school staff is welcome to help us if you would like.

- **Are there any other requirements that you need?** We may also need a bin for general waste, a hot water source, and privacy screens.

- **Will there be any waste and how will it be handled?** The research team will take care of medical waste handling and disposal. Medical waste will be collected in special bags and transported off site. General waste will be collected in bins provided by the school.

What are the possible benefits for each child who takes part in the study? Each child will be given a toothbrush, a piece of fruit, and a smiley sticker as a way of thanking them. The study will help us to understand why some children need braces and others do not. If we find that the child has tooth decay, we will send a letter to their parents encouraging them to take their child to their dentist.

What are the possible benefits for each school who takes part in the study? We will work with each school to identify how we can support wider oral health based activities. If possible we will support these activities or signpost your school to organisations and groups that can.

How can schools take part? Schools can take part if they give consent to participate in the Bradford Smile Study by signing the schools consent form (please see attached). Headteachers have the right to withdraw their consent at any time.

Please do not hesitate to contact me if you have any further enquiries.
Looking forward to working with you.

Best regards,
Eman Alnuaimi
Bradford Smile Study coordinator

Appendix 3.6 Reminder email to point of contact

Dear (point of contact),
Hope this email finds you well.
We are looking forward to working with you on the Bradford Smile Study.

Dates of visit: (dates, month year)

Please find below further information:
* A team of 3-4 members will attend on the day (Dental Therapist, Dental Nurse, Study Coordinator, DCT dentist)
* All team members have had their DBS and Occupational Health Clearance checked
* All team members will be wearing their ID badges and will follow the school's security measures
* Parents/carers and the child will be asked if they are allergic to any material/food
* We will follow Born in Bradford research protocols to ensure all child identifiable information will be dealt with in a confidential manner
* We will report any untoward incident during our visit to your management team in the first place as well as reporting them through the Born in Bradford protocols to Bradford Institute of Health Research

During the visit:
* Only children who are taking part in the Born In Bradford project and have already been consented will take part
* Child identification will be verified using their full name and date of birth
* The team will perform a brief dental examination, a disposable dental mirror will be used for each child and discarded after use
* Photographs of the face and mouth will be taken using a sterilised kit for each child, we will need warm water to prevent the mirrors from fogging, for the background we will use a white card and sellotape
* Dental moulds will be taken using disposable trays and a special dough, we will need water for mixing (a few children may have strong gag reflex and could possibly vomit). If this happens we will obviously clear up any mess using a specific NHS spills and body fluid kit.
* Each child will have to fill out a questionnaire, we will use our own tablets (e.g. iPad) and our own 4G WiFi device to enable data entry to an online portal at Bradford Institute for Health Research.
* We will see one child every 20 minutes, examination usually takes 30 minutes including filling out the questionnaire
* Our team will clear up after the visit and ensure the room is how we found it. We will take care of the disposal and transfer of clinical waste from the school. This process will follow Bradford District Care NHS Foundation Trust Clinical Waste and Recycling Policy.
* For each child we identify as having obvious dental needs (e.g. dental decay), we will give them a letter to give to their parents. The letter will advise the parents to take their child to the dentist. For those children with no dentist, the letter will provide information on how to find a dentist.
* Following dental examination, each child will receive a piece of fruit (an apple or a banana), a toothbrush, and a smiley sticker
* All children can withdraw from the study at any stage

To assist us further, please:
* Clarify if you would like a copy of the DBS checks to be sent in advance
* Clarify the school day and how best to fit in
* Clarify if parking slots are available and how many. This will enable us to drop off and pick up our kit.
* Clarify if there is fire alarm testing on the day

On the day of our visit, could you provide us with the following if possible:

* Hot water source
* Tables and chairs
* Privacy screens
* A bin for general waste

If you have any further questions or requirements, please do not hesitate to contact me.
Thank you again for your support to our study.

Best regards,
Eman Alnuaimi
Bradford Smile Study coordinator

Appendix 3.7 Parent and child information sheet

3.7.a Parent information sheet

BRADFORD SMILE STUDY

We are family BORNINBRADFORD

BiB – Bradford Smile Study

Information for Parents and Carers V6 29.07.19

Dear Parents of <Child's name>,
Through your help with the Born in Bradford (BiB) study, you and your family have been helping to improve the lives and health of people in Bradford for the last ten years.

We would like you and your child to help with another BiB study called the Bradford Smile Study. The study aims to look at your child's teeth and how their faces grow. Some children are likely to need braces when they are older and others are not. This study will help to explore why this is the case.

This study will collect dental records from BiB children who agree to participate. Please see our short video to see what the study involves:

- English version: www.tinyurl.com/BradfordSmileStudy
- Urdu version: www.tinyurl.com/BradfordSmileStudy-URDU

In summary, the records include a quick dental examination with a dental mirror, dental photographs and dental "putty mould". These records will be taken while your child is at school. The records will provide a baseline for us to monitor dental and facial growth and enable a further study when your child is older and at secondary school.

BRADFORD SMILE STUDY

We are family BORNINBRADFORD

How to contact us?

If you have any questions about this study, please contact
Bradford Smile Study Team
Born in Bradford Community Research Team
Telephone number: 0127383454 (office)
Mobile number: 07725642781 (Alison)
Email address: borninbradford@bthft.nhs.uk

Study Title: Bradford Smile Study

We invite your child to take part in our study

- Before you decide if you are happy for your child to take part, it is important for you and them to understand why we are carrying out the research and what it will involve
- Your child's information will be treated as confidential and we will keep it safe. It will not be disclosed in an identifiable form to anybody outside the research team
- If you have any questions or would like more information, please contact us

Important things that you need to know

- We want to find out why some children will need braces when they are older and others will not.
- You and your child are free to decide whether they take part in this study or not. They can stop participating at any point. If you have any questions or would like more information, please contact us
- Take your time to decide whether you wish your child to take part and discuss it with them

Content

BRADFORD SMILE STUDY

We are family BORNINBRADFORD

1. Why are we doing this study?
We want to explore why some children need braces when they are teenagers and others do not. The study will collect records now and potentially again in the future when your child is at secondary school.

2. Why has my child been invited to take part?
You and your child are already taking part in the wider BiB study. BiB children have excellent records from their childhood. Therefore they are a great group to work with. They will allow us to explore what the possible causes are.

3. Who is doing this study?
The University of Leeds is working with Born in Bradford to undertake this study. The study is funded by the British Orthodontic Society.

4. Does my child have to take part?
No. It is up to you and your child if they want to take part or not. If you decide to take part, you can keep this information sheet and we will ask you to sign a Consent Form.

5. What will be involved if my child takes part in this study?
Please see our short video to see what the study involves:
English: www.tinyurl.com/BradfordSmileStudy Urdu: www.tinyurl.com/BradfordSmileStudy-URDU
Our study will collect some dental records from your child. The records include a quick dental examination (with a dental mirror), dental photographs and dental impressions. These records will be taken while your child is at school. The records will be collected by a dentist (or dental therapist) and a dental nurse and will take about 10 minutes in total. We will ask your child some questions about their teeth. If you would like to attend while your child has their records taken, please provide your email and telephone details on the consent form.

The photographs will include pictures of your child's face as these are important for assessing how your child's face grows. There is an example of these pictures on our website:
English: www.tinyurl.com/BradfordSmileStudy Urdu: www.tinyurl.com/BradfordSmileStudy-URDU

In addition, our team may contact you either by telephone or face to face to find out what dental treatment your child has received in the past and also what treatment they need in the future. For example, dental treatment at their high street dentist or at a specialist dentist such as an orthodontist. As these dental records are often held by other NHS organisations such as the NHS Business Service Authority or NHS Digital we will work with them to link these records.

When your child is older we would like to contact you and your child again to see if they are happy to take part in our follow-up study to see how things have changed.

6. What are the possible benefits and disadvantages of taking part?
We will give your child a toothbrush and some fruit as a way of a thank you. Otherwise it is unlikely that your child will directly benefit from taking part. The study may help future Bradford children in that we will have a better understanding of why some children need braces.

If we find that your child has tooth decay and would benefit from seeing a dentist we will let you know by writing a letter to you.

7. Can my child and I withdraw from the study at any time?
You and your child are still free to withdraw from the study at any time, and you do not have to give a reason.

8. Will the information collected in the study be confidential?
Each child already has a BiB study number. Only authorised members of the BiB team can identify you from your study number. All information and records are stored securely and in strict confidence using this study number.
The dental moulds will be not be identifiable. They will be labelled with the BiB study number and then sent to a dental laboratory who will cast, scan and securely store them as digitalized dental models. These dental models will be securely transferred to the University of Leeds to allow them to be analysed. Following this the measurements will then be transferred to the BiB warehouse. The original impressions will be destroyed by the laboratory.

9. What will happen to the results of the study?
Once the study has ended and the results have been analysed, reports will be published in dental or medical journals and presented at conferences. The information collected may be used to support other research in the future and may be shared anonymously with other researchers.

Your child will not be identified in any study reports, publications, presentations or in information shared with other researchers.

We will work with the BiB parents group to produce a short summary for parents and children about the study results. They will help us to decide the best way to share the information with you and other BiB participants.

10. Who has reviewed this study?
The study has been reviewed by the NHS Research Ethics Committee.
If you have concerns or complaints about the study you can contact 01274383454.

11. What next?
Please sign the consent form to allow your child to take part. If we haven't heard back from you we may call you in a few days to find out if you'd like to participate. If you would like more information or have any questions or concerns about the study please contact 01274383454. It is likely that it will be a few months before we collect the dental information from your child in school.
Would you like us to give you some warning before our visit to the school? If so please provide your email address and we will contact you a few days before.

12. Data Protection
The University of Leeds is the sponsor for this study based in the United Kingdom. We will be using information from your child to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Leeds will only have access to identifiable information about your child on the day that we see your child in

school. This is to ensure we collect the dental information from the correct child. The University of Leeds will not keep any identifiable information about your child after this.

The information collected will be held by BiB on behalf of the sponsor. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting David Wardle the University Data Protection Officer (email DPO@leeds.ac.uk) and from the BiB research team (borninbradford@bthft.nhs.uk).

BiB will collect information from your child for this research study in accordance with the University of Leeds instructions. BiB will keep your name, NHS number and contact details confidential and will not pass this information to the University of Leeds except when children need to be indentified in school to enable the dental information to be collected. BiB will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. BiB will keep identifiable information about you until the end of their study. Certain individuals from the University of Leeds and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

BiB, on behalf of the University, may collect information about your child for this research study from your child's high street dentist/s, other specialist dental services (such as orthodontists) and central NHS organisations (such as the NHS Business Service Authority, NHS Digital and the Health and Social Care Information Centre). These organisations will not provide any identifying information about you to the University. BiB will use this information to examine your child's dental journey from birth.

Your child's information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance. Where there is a risk that you can be identified, your data will only be used in research that has been independently reviewed by an ethics committee.

13. Indemnity Arrangements

The University of Leeds is responsible for the design and management of the research. The NHS is responsible for the conduct of the research. The University of Leeds has in force a Public and Products Liability policy which provides cover for claims for "negligent harm" and the activities of this study are included within that coverage subject to the terms, conditions and exceptions of the policy.

Thank you for taking the time to read this information leaflet.

3.7b Child information sheet

BRADFORD SMILE STUDY

We are family BORNINBRADFORD

BiB – Bradford Smile Study

Child Participant Information

V2a. 29.07.19

Dear [Child's Name],
We are doing a project about how the position of children's teeth changes as they grow. We'd like to find out why some child need braces when they are older and others do not. We're asking lots of Born In Bradford (BiB) children if they will help by letting us look at their teeth now, and again when they are older.

Why have I been asked?
As a BiB child you have already helped us to find out about people's health in Bradford. You might be able to help again.

Do I have to help?
No, it is up to you if you want to help.

What will I have to do?
If you agree to take part a dentist will come to your school to look in your mouth with a mirror. They will take some photographs of you and your teeth and also a dental impression. If you would like to see more, please look at our video:

- English version: www.tinyurl.com/BradfordSmileStudy
- Urdu version: www.tinyurl.com/BradfordSmileStudy-URDU

What is a dental impression?
We would like to make a model of your teeth. To do this we need to take an impression of your top and bottom teeth. This means putting a squishy putty a bit like Play-Doh, over your teeth for a minute until it sets. Our video will show you more:

- English version: www.tinyurl.com/BradfordSmileStudy
- Urdu version: www.tinyurl.com/BradfordSmileStudy-URDU

or ask our team to explain to you what it involves.

Can I leave later if I want to?
Yes, you can leave at any time. No one will make you do anything that you don't want to.

BRADFORD SMILE STUDY

We are family BORNINBRADFORD

Will I get anything for taking part?
We'll give you a new toothbrush and you can choose some fruit to eat afterwards.

What should I do next?
You should talk to the person who looks after you and decide together if you are going to take part.
If you have more questions you would like to ask, then you can call 0127383454
If you do want to take part, please let your parent or carer know so they can return the form to us.

Bradford District NHS Bradford Teaching Hospitals NHS NHS Foundation Trust UNIVERSITY OF LEEDS

Appendix 3.8 Standard operating procedures (SOPs)

Appendix 3.8a SOP: Dental examination

Dental Examination		
NHS Bradford District Care NHS Foundation Trust / UNIVERSITY OF LEEDS	Author:	Eman Alnuaimi
	Job Title:	PhD Student
	Version Number:	3
	Issue date:	01.07.2019
	Date for Review:	-
	Approved by:	Peter Day (Principal Investigator)
	Applicable to:	Research team
	SOP number	1
	Is this an updated SOP (Y/N)	Y
	If Y what changes have been made:	Updated references and appendices 1, 4-5

Objectives
To ensure dental examination is done systematically, thoroughly, and consistently for each child according to the protocol.

Scope
This SOP is applicable for children who have been consented to take photographs.

Responsibility
As per delegation log.

Location:
Primary schools in Bradford city

Requirements:

- A well-lit room preferably with a wash basin
- A regular chair or table and foam roll
- Research team member trained for examination
- Personal protective equipment (PPE)
- Dental instruments/consumables
- Clinical waste bags
- Giveaways

Stages of the process
Follow the Daily Checklist (Appendix 1)
Before dental examination:

- Ensure the parent who wishes to be with their child is present
- Ensure the tablet/iPad is connected to the WiFi
- Log-in to the web platform for data entry
- Introduce yourself to the child
- Child identification using two verifiers, full name and date of birth
- Check the consent and what has been consented for the child
- Ask the child if they have watched the video, if not ask them if they would like to watch it
- Explain to the child the process of taking records and the right to withdraw at any stage

- Inform the child that if they wish to stop at any time this will be possible
- Staff should perform hand hygiene (Appendix 2) and wear appropriate PPE (Appendix 3)
- Ensure the child wears protective eyewear and has a bib placed

Dental examination:

- Ensure that the teeth are clean (wipe off any debris using gauze)
- For better vision, use a head torch
- Carry out dental examination following the data collection sheet (Appendix 4)
- Use one or two disposable dental mirrors per child, dispose it after use
- If the child needs dental care (any type of dental treatment, unusual oral/orthodontic finding i.e. nonpalpable upper permanent canines buccally, crossbites, ectopic eruption of permanent first molars in a 10-11 year old child, etc.), fill in the letter to parents and send it with the child (Appendix 5)
- Report any untoward incident to the to the Peter Day (Principal Investigator) and school's management, document in data collection sheet under notes, document in writing on the same day
- If the child becomes distressed during dental examination, please stop and try to reassure and support, however, if it's not possible to proceed, please stop
- After finishing offer the child a toothbrush and a piece of fruit

References

- PLATOON Data Collection Protocol V4.02.08.19
- https://www.who.int/gpsc/tools/GPSC-HandRub-Wash.pdf?ua=1
- https://www.who.int/gpsc/tools/5momentsHandHygiene_A3.pdf?ua=1
- https://www.cdc.gov/hai/pdfs/ppe/PPE-Sequence.pdf
- https://www.rcseng.ac.uk/-/media/files/rcs/fds/publications/canine-guideline-2016.pdf

Appendix 1

BRADFORD SMILE STUDY

PLATOON Daily Checklist

School: ..... Day/Date: ..... Total examined: ..... Total withdrawals: .....

SN.	Barcode	1. Consent checked	2. Child identified	3. Watched YouTube video	4. Explained the process	5. Allergies if any	6. Dental examination done	7. Dental photographs taken	8. Dental imp. and bite reg. taken	9. Followed infection control measures	10. Dental status letter sent to parents	11. Study group	12. Completed Questionnaire	13. Status	14. Any untoward events	15. Giveaways given	16. Tablet screen cleaned

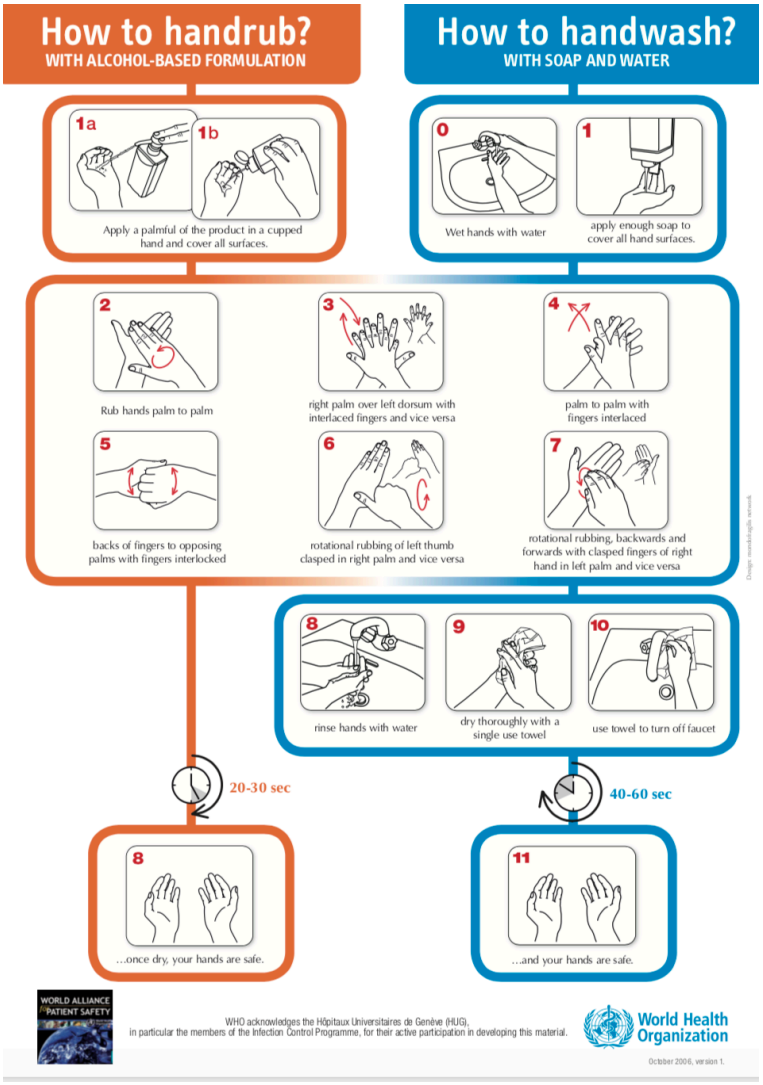
1-6, 9, 12, 14-16: Yes, No 7-8: Yes, No, Incomplete, No consent 10: Yes, No, Not required 11. Exposure, Control 13: Complete, Incomplete, Withdrawn

☐ Contacted Arkive Dental laboratory
☐ Kit and impressions dropped at Westbourne Green Community Hospital
☐ SD Card cleared at Bradford Institute for Health Research

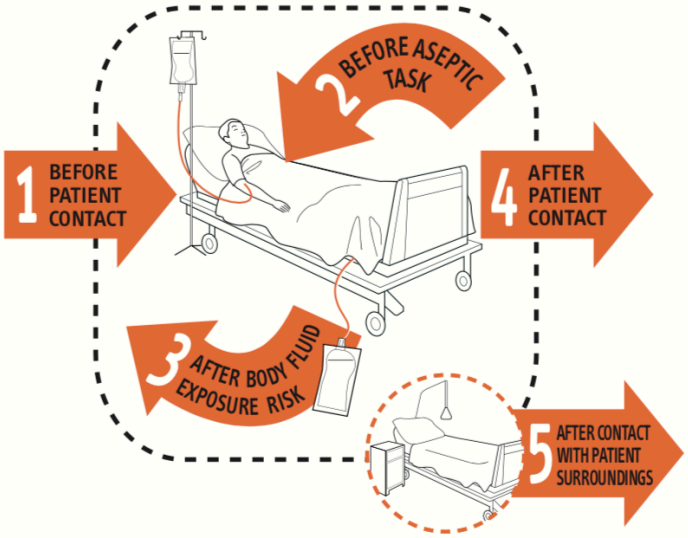
Notes: .....

Signature:

Appendix 2


How to handrub?
WITH ALCOHOL-BASED FORMULATION
How to handwash?
WITH SOAP AND WATER
1a
1b
Apply a palmful of the product in a cupped hand and cover all surfaces.
0
Wet hands with water
1
apply enough soap to cover all hand surfaces.
2
Rub hands palm to palm
3
right palm over left dorsum with interlaced fingers and vice versa
4
palm to palm with fingers interlaced
5
backs of fingers to opposing palms with fingers interlocked
6
rotational rubbing of left thumb clasped in right palm and vice versa
7
rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa
8
rinse hands with water
9
dry thoroughly with a single use towel
10
use towel to turn off faucet
20-30 sec
40-60 sec
8
...once dry, your hands are safe.
11
...and your hands are safe.
WORLD ALLIANCE FOR PATIENT SAFETY
WHO acknowledges the Hôpitaux Universitaires de Genève (HUG), in particular the members of the Infection Control Programme, for their active participation in developing this material.
World Health Organization
October 2006, version 1.

Your 5 moments for HAND HYGIENE



1	BEFORE PATIENT CONTACT	WHEN? Clean your hands before touching a patient when approaching him or her WHY? To protect the patient against harmful germs carried on your hands
2	BEFORE AN ASEPTIC TASK	WHEN? Clean your hands immediately before any aseptic task WHY? To protect the patient against harmful germs, including the patient's own germs, entering his or her body
3	AFTER BODY FLUID EXPOSURE RISK	WHEN? Clean your hands immediately after an exposure risk to body fluids (and after glove removal) WHY? To protect yourself and the health-care environment from harmful patient germs
4	AFTER PATIENT CONTACT	WHEN? Clean your hands after touching a patient and his or her immediate surroundings when leaving WHY? To protect yourself and the health-care environment from harmful patient germs
5	AFTER CONTACT WITH PATIENT SURROUNDINGS	WHEN? Clean your hands after touching any object or furniture in the patient's immediate surroundings, when leaving - even without touching the patient WHY? To protect yourself and the health-care environment from harmful patient germs

WHO acknowledges the Hôpitaux Universitaires de Genève (HUG), in particular the members of the Infection Control Programme, for their active participation in developing this material.

World Health Organization

October 2006, version 1.

Appendix 3

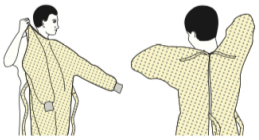
Please follow steps 2-4

SEQUENCE FOR PUTTING ON PERSONAL PROTECTIVE EQUIPMENT (PPE)

The type of PPE used will vary based on the level of precautions required, such as standard and contact, droplet or airborne infection isolation precautions. The procedure for putting on and removing PPE should be tailored to the specific type of PPE.

1. GOWN

- Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back
- Fasten in back of neck and waist



2. MASK OR RESPIRATOR

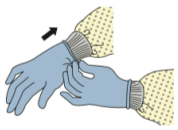
- Secure ties or elastic bands at middle of head and neck
- Fit flexible band to nose bridge
- Fit snug to face and below chin
- Fit-check respirator

3. GOGGLES OR FACE SHIELD

- Place over face and eyes and adjust to fit

4. GLOVES

- Extend to cover wrist of isolation gown



USE SAFE WORK PRACTICES TO PROTECT YOURSELF AND LIMIT THE SPREAD OF CONTAMINATION

- Keep hands away from face
- Limit surfaces touched
- Change gloves when torn or heavily contaminated
- Perform hand hygiene

CS250672-E

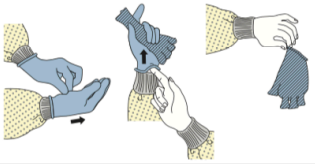
Please follow steps 1-2, 4-5

HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 1

There are a variety of ways to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. Here is one example. **Remove all PPE before exiting the patient room** except a respirator, if worn. Remove the respirator **after** leaving the patient room and closing the door. Remove PPE in the following sequence:

1. GLOVES

- Outside of gloves are contaminated!
- If your hands get contaminated during glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Using a gloved hand, grasp the palm area of the other gloved hand and peel off first glove
- Hold removed glove in gloved hand
- Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove
- Discard gloves in a waste container

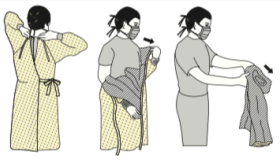


2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band or ear pieces
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container

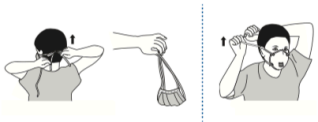
3. GOWN

- Gown front and sleeves are contaminated!
- If your hands get contaminated during gown removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Unfasten gown ties, taking care that sleeves don't contact your body when reaching for ties
- Pull gown away from neck and shoulders, touching inside of gown only
- Turn gown inside out
- Fold or roll into a bundle and discard in a waste container

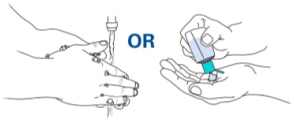


4. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a waste container



5. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE



PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE

CDC

CS250672-E

Appendix 4

PLATOON Data Collection Sheet

Date of data collection:
Barcode ID:
Child's initials:
School:
FIELD DATA INPUT
Teeth Present:

Codes for each tooth:

Upper Right												Upper Left	
		55	54	53	52	51	61	62	63	64	65		
17	16	15	14	13	12	11	21	22	23	24	25	26	27
47	46	45	44	43	42	41	31	32	33	34	35	36	37
		85	84	83	82	81	71	72	73	74	75		
Lower Right												Lower Left	

0 = not present
1 = sound
2 = carious
3 = restored
4 = defective restoration
5 = hypomineralised
6 = hypomineralised and carious
7 = other dental developmental defect

.....

.....

.....

.....

Orthodontic assessment:
Lips: competent, incompetent
Masticatory/speech problems: Yes, N o
Incisor relationship: I, II/I, II/II, III, NA
Right molar relationship: I, II, III, NA
Left molar relationship: I, II, III, NA
Upper permanent canines palpable buccally: right, left, both, no
Upper primary canines mobile: right, left, both, no
Overjet: in mm + or -
Overbite: average, increased, decreased
Centrelines:
Crossbite: posterior, anterior, both, no
Deviation between RCP and ICP: Yes, No
AP skeletal pattern: I, II, III

Images/Moulds:
Images(Photos)
Images were taken? Yes No
If not, why?
……
File name range: From: …… To ……
Moulds:
Upper moulds taken? Yes No
Lower moulds taken? Yes No
Wax bite taken? Yes No

……

……

……

……

Appendix 5

BRADFORD SMILE STUDY

BiB – Bradford Smile Study

Dear Parent/Guardian,

Re- (Child's name)

You kindly agreed for your child to take part in the Bradford Smile study. A brief dental check was undertaken on (insert date).

We noted that your child has

……..

and would benefit from seeing a dentist. If you are registered with a dentist, please make an appointment to see them for a check up. If you are not registered with a dentist please visit the NHS choices website (https://www.nhs.uk/pages/home.aspx) to find local NHS dentists who are accepting new patients.

Kind regards,

Bradford Smile Study Research team

Appendix 3.8b SOP: Orthodontic photography

Orthodontic Photography		
NHS Bradford District Care NHS Foundation Trust / UNIVERSITY OF LEEDS	Author:	Eman Alnuaimi
	Job Title:	PhD student and study coordinator
	Version Number:	2
	Issue date:	01.07.2019
	Date for Review:	-
	Approved by:	Peter Day (Principal Investigator)
	Applicable to:	Dental research examiner, dental nurse
	SOP number	2
	Is this an updated SOP (Y/N)	Y
	If Y what changes have been made:	Updated references, requirements and stages of the process.

Objectives
To ensure dental photographs taken for each child are standardised and consistent.

Scope
This SOP is applicable for children who have been consented to take photographs.

Responsibility
As per delegation log.

Location
Primary schools in Bradford

Requirements

- Consent for photography
- Professional camera (Canon 750D)
- Ring flash (Canon macro ring lite MR-14EX II Ring Flash on ETTL)
- Macro lens (Canon 100mm)
- Two SD cards (one spare)
- Spare batteries for camera and ring flash
- White cardboard sheets (nonreflective) and Blu Tack
- Sterilised photographic kit for each child (cheek retractors, V-shaped retractors, dental photography mirrors) and warm water
- Petroleum jelly

Stages of the process

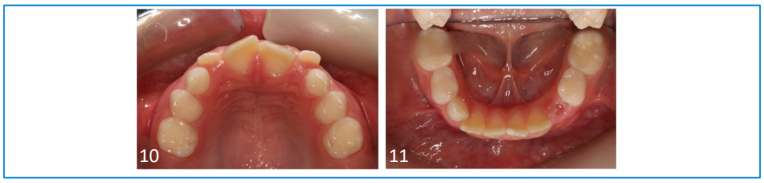
- The photographic kit comes in sets of three, in order to maintain sterility, one sterile kit should be taken out of the pack with sterile drapes before the child enters, cover it again to maintain sterility, take a photograph of the set with the barcode for each child using that kit
- Mount the cardboard sheet on a solid background in an area with good light source (you may need to adjust the height according to the child)
- Check if consent has been given for dental photography
- Explain briefly to the child that photos of their face and mouth will be taken

- Inform the child that if they wish to stop at any time or withdraw, this will be possible
- Take a photograph of the child's consent with the barcode of the kit being used
- Update photography status in the web platform and Daily Checklist (refer to Dental Examination SOP)
- After finishing, transfer the SD card in a padlocked case and upload the photos to the secure at Bradford Institute for Health Research
- Clear the SD card, document in SD Card Clearing Log (Appendix 1)

Views:

F5.6 – 1.10 F5.6 – 1.10 F5.6 – 1.10 F5.6 – 1.10 F5.6 – 1.10 F5.6 – 1.10

F36 – 1.3 F36 – 1.3 F36 – 1.3



F29 – 1.5 F29 – 1.5

1. left lateral profile
2. left lateral oblique
3. frontal smile
4. frontal at rest
5. right lateral oblique
6. right lateral profile

7. left buccal in occlusion
8. anterior in occlusion
9. right buccal in occlusion
10. upper occlusal mirror
11. lower occlusal mirror

SS: 125
ISO: 200
Flash: ETTL
☐ WB Preset D1
☐ WB Preset D2

Extra-oral photos 1-6:

- Turn on the ring flash, ensure it is on ETTL (to change press mode)
- Set the camera aperture to f5.6 with shutter speed set to 125
- Set white balance to pre-set D1
- Ask the child to stand against the white background
- Wherever possible, child's hair needs to be pulled back from their face and neck
- If the child is a female wearing a head scarf, ask her if she's comfortable showing her ears only
- Take the photos at the same height as the patient

Frontal view at rest:

- Ask the child to swallow, no smiling, lips at rest, and look forward
- Align the head in a natural position using Frankfort horizontal plane (Figure 1)
- Take a shot

Frontal view with smile:

- As above
- Ask the child to induce a natural smile (not posed smile)
- Take a shot

Lateral profile view in occlusion (right and left):

- Ask the child to turn 90 degrees with natural head position
- Ask the child to bite on their back teeth and look forward
- Take a shot

Lateral oblique view (3/4 view smiling right and left):

- Ask the child to turn 45 degrees with natural head position and smile
- Take a shot

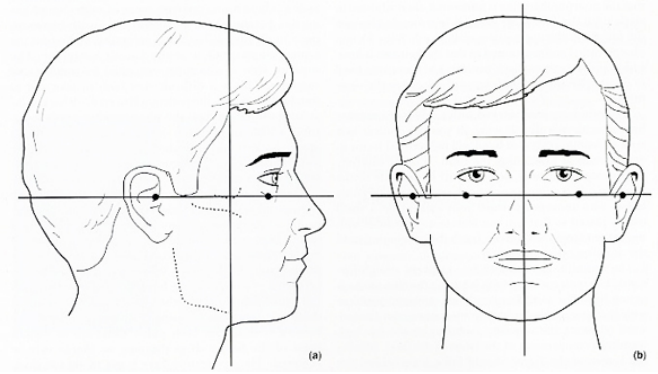


Figure 1: Frankfort horizontal plane

Intra-oral photos 7-9:

- Ensure ring flash is still turned on
- Change camera aperture to f36, shutter speed stays 125
- Set white balance to pre-set D2
- Ensure the child is sitting in a comfortable position (preferably supporting their head against the wall)
- Ensure the child's lips are not dry, if dry apply some petroleum jelly

Anterior in occlusion view:

- Place the large end of the retractor at the corners of the lips, assist the child or ask them to pull as hard as they can without hurting their lips
- Ask the child to bite on their back teeth, making certain that the occlusal plane is horizontal and running through the centre of the view finder (this is easier when the head is in level with Frankfort horizontal plane and the lens axis is in line with the occlusal plane)
- Focus on the lateral incisors
- Ensure you can see all teeth and take anterior shot

Right buccal in occlusion view:

- Ask the child to rotate their head to the left side staying in the same level
- Relax the large retractor on the left corner of the mouth
- Use the small retractor for the right corner of the lip, assist the child or ask them to pull as hard as they can without hurting their lips
- Take a shot at a 90 degrees angle to the primary molars/premolars area at the level of occlusion

Left buccal in occlusion view:

- As above but opposite sides

Intra-oral photos 10-11:

- Change camera aperture to f29, shutter speed stays at 125
- Warm up the mirror using warm water for up to 60 seconds

Upper occlusal mirror view:

- Use the small retractors to retract the lips away from the teeth
- Place the mirror laid on the lower teeth and distal to the last molar, lift odd the mirror to ensure the tooth appears in the photo
- Ask the child to tip back and open their mouth as much as they can
- Endure the photo is at 90 degrees to occlusion and take a shot

Lower occlusal mirror view:

- As above
- Make sure the tongue does not obscure any teeth by asking them to touch the upper palate with the tip of their tongue

References

- Orthodontic Views SOP V1, Leeds Dental Institute
- PLATOON Standardising the Records Process training notes (by Simon Littlewood)
- PLATOON Data Collection Protocol V4 02.08.19
- Bradford Smile Study YouTube Video available at: https://www.youtube.com/watch?v=SR0QASjTDz0
- Dental Examination SOP V3, PLATOON
- http://rps.org/special-interest-groups/medical/blogs/2015/december/standardised-anatomical-alignment-of-the-head-in-a-clinical-photography-studio

Appendix 1

BRADFORD SMILE STUDY

PLATOON SD Card Clearing Log

School:	Date of visit:	SD Card number:	Date cleared:	Signature:

Appendix 3.8c SOP: Dental impressions and bite registration

Dental Impressions and Bite Registration		
NHS Bradford District Care NHS Foundation Trust / UNIVERSITY OF LEEDS	Author:	Eman Alnuaimi
	Job Title:	PhD student and study coordinator
	Version Number:	2
	Issue date:	01.07.2019
	Date for Review:	-
	Approved by:	Peter Day (Principal Investigator)
	Applicable to:	Dental research examiner, dental nurse
	SOP number	3
	Is this an updated SOP (Y/N)	Y
	If Y what changes have been made:	Updated references

Objectives
To ensure dental impressions and bite registration are taken, disinfected, and transported for digitising in a standardised process.

Scope
This SOP is applicable for children who have been consented to take photographs.

Responsibility
As per delegation log.

Location:
Primary schools in Bradford city

Requirements:

- Personal Protective Equipment (PPE)
- Dimensionally stable alginate impression
- Assorted sized of impression trays
- Fixative for trays
- Wax sheets for bite registration
- Water
- Face mirror
- Gauze
- Impression disinfectant and bath
- Lab bags and boxes for transport
- Prescription sheets
- Vomit Spill Kit
- Tissue towels
- Baby wipes

Stages of the process:

- Call Arkive Dental laboratory on 01765698300 in the morning before 12:00pm (to collect on the same day) and inform them to pick up the impressions from Westbourne Green Community Hospital after 15:30pm
- After disinfecting impressions, pack up in boxes and transfer them to Westbourne Green Community Hospital for pick up by the courier, document in Dental Impressions Tracking Log (Appendix 1)
- Update the status in the web application and Daily Checklist (refer to Dental Examination SOP)

Dental impressions:

- Check the consent
- Explain the process to the child briefly including smell/taste of used materials
- To minimise distress: reassure, praise, and coping strategies for gagging
- Ensure the child is in upright position in the chair, head support if possible
- To take a lower impression: stand in front of the child
- To take an upper impression: stand behind the child
- Perform hand hygiene and wear appropriate PPE
- Select appropriate upper and lower trays to try for size, ideally should be approximately 5mm between teeth/gingivae and the inner surface of the tray to allow adequate thickness
- Apply minimal fixative to the tray
- Mix the alginate according to manufacturer's instructions (well mixed, not powder, not too fluid, not too stiff)
- Load on lower tray first
- Ask the child to breathe from their nose
- Rotate in the lower tray and place it symmetrical and covering all teeth
- Manipulate the lips and cheeks, ask the child to move their tongue
- Apply equal pressure (cuspal tips should not contact the trays) on the primary molar/premolar area
- Continue reassuring and distracting the child
- Check the set of the material and lift the tray off the teeth (snap removal) and rotate out
- Inspect the impression for adequacy, if inaccurate, as the child if they can repeat
- Hand to the dental nurse for disinfection according to manufacturer's instructions, do NOT place the tray upside down
- Repeat for the upper, continue distracting and reassuring the child
- Wipe of any excess using baby wipes (extra-orally) and gauze (intra-orally)
- If the child wants to vomit, use vomit bowls and clean any spill using Vomit Spill Kit
- After disinfection, lightly wrap with wet paper towel place into grip seal lab bags and attach a lab card (do not staple) with a barcode
- Place the bags in the lab box (can take up to 20 impressions), should you use another box please tape together
- Prepare for transfer to Westbourne Green Community Hospital for pick up by the courier

Bite registration:

- Practice with the child biting in the intercuspal position
- Warm up the wax in hot water until it softens
- Fold over three layers from the short end of the sheet
- Form into horse-shoe
- Inset the wax while still soft (cool enough for the child) and place it on the occlusal surfaces of lower teeth
- Guide the child's mandible with gentle pressure into intercuspal position and ask them to bite fully
- Wait until the wax is hardened enough not to distort on removal and remove
- Disinfect according to manufacturer's instructions
- Place the wax with in the bag and prepare for transfer to Westbourne Green Community Hospital in the impressions box

References:

- PLATOON Standardising the Records Process notes by Simon Littlewood July 2019
- PLATOON Data Collection Protocol V4 02.08.19
- PLATOON Dental Examination SOP V3

Appendix 1

BRADFORD SMILE STUDY

PLATOON Dental Impressions Tracking Log

School:	Quantity:	Date and time delivered at WBG:	Signature:	Date and time picked up from WBG:	Signature:

Appendix 3.8d SOP: Untoward incident reporting

Untoward Incident Reporting		
NHS Bradford District Care NHS Foundation Trust / UNIVERSITY OF LEEDS	Author:	Eman Alnuaimi
	Job Title:	PhD student
	Version Number:	1
	Issue date:	01.07.2019
	Date for Review:	-
	Approved by:	Peter Day (Principal Investigator)
	Applicable to:	Research team
	SOP number	4
	Is this an updated SOP (Y/N)	N
	If Y what changes have been made:	-

Objectives
To ensure that any untoward incidents are being reported promptly.

Scope
This SOP is applicable for research team members and children who have been consented to take photographs.

Responsibility
NA

Location:
Primary schools in Bradford city

Stages of the process

- Risk assessment has been done to prevent/reduce the occurrence of any untoward incidents
- Any untoward incident (including but not limited to: vomits, falls, scalds, safeguarding, allergic reaction, etc.) should be reported verbally promptly
- Report in written using the Untoward Incident Report Form (Appendix 1) on the same day of the incident to the below as applicable:
  - Headteacher
  - Peter Day (Principal Investigator): p.f.day@leeds.ac.uk
  - Rosie McEachan Born In Bradford Programme Director): Rosie.McEachan@bthft.nhs.uk as applicable
- Do not mention patient identifiable data in the email
- Document in web application and Daily Checklist (refer to Dental Examination SOP)

References:
-N/A

BRADFORD SMILE STUDY

Untoward Incident Report Form

In case of an untoward incident, please fill in the form on the same day of the incident. Report to Peter Day (Principal Investigator) p.f.day@leeds.ac.uk, Headteacher, or Rosie McEachan (Born in Bradford Programme director) Rosie.McEachan@bthft.nhs.uk as applicable.

Incident date: _____ Incident time: _____
School's name: _____ Study number: _____

Details of the incident:

What happened? _____
_____
_____
_____

How it happened? _____
_____
_____
_____

Why it happened? _____
_____
_____
_____

Who was involved? _____
_____
_____
_____

Outcome: _____
_____
_____
_____

Prepared by: _____ Date: _____
Signature: _____
Approved by: _____ Date: _____
Signature: _____

Appendix 3.8e SOP: Withdrawal

Withdrawal		
NHS Bradford District Care NHS Foundation Trust / UNIVERSITY OF LEEDS	Author:	Eman Alnuaimi
	Job Title:	PhD student
	Version Number:	2
	Issue date:	01.07.2019
	Date for Review:	-
	Approved by:	Peter Day (Principal Investigator)
	Applicable to:	Dental
	SOP number	5
	Is this an updated SOP (Y/N)	Y
	If Y what changes have been made:	Updated references and appendix

Objectives
To ensure the child is given the opportunity to withdraw from some or all of the study if they/their parents wish to.

Scope
This SOP is applicable for children who have been consented to take part in the study.

Responsibility
N/A

Location:
Primary schools in Bradford city

Requirements:
None

Stages of the process

- Before dental examination, inform the child that if they wish to stop at any time this will be possible
- Explain to the child that they have the right to withdraw from the study at any time
- If the child/their parent wishes for their child to withdraw, document under status in PLATOON Daily Checklist (Appendix 1)
- Shred all the papers related to the child
- Inform the IT support at BIHR to remove the child's details from the web-based platform

References

- PLATOON Data Collection Protocol V4 02.08.19
- PLATOON Daily Checklist form

Appendix 3.9 General risk assessment form

Risk assessment form

PLATOON/Bradford Smile Study

General Risk Assessment	Number	Issue	Sheet no	Author Source	Approved by	Signature

Health and safety services
General risk assessment

RISK ASSESSMENT FORM -

RISK ASSESSMENT DETAILS		DEGREE OF RISK	RISK RATING MATRIX

Faculty/School/Service	Medicine & Health
Team	School of Dentistry

Risk Assessment Title	PLATOON research team visit to primary schools in Bradford
Risk Assessment Log Reference	
Date	July 2019
Name of Assessors	Sue Keat Jenny Boards
Manager Responsible	Peter Day/Eman Alnuaimi
Location	Primary Schools in Bradford
Details of Activity – PLATOON research team visit to primary schools in Bradford for data collection every Tuesdays, Thursdays, and Fridays from 2nd until 16th July 2019, and 17th July 2019 and ongoing in term time until July 2020.	

Other assessments which might also be required, ✓ if needed:

- Manual Handling ☑ ✓ REF
- COSHH ☑ ✓ REF
- Personal Protective Equipment (PPE) ☑ ✓ REF
- Noise ☐ REF
- Other ☐ REF

REVIEW DATES	
August 2020	

LIKELIHOOD (L)	
5	Inevitable
4	Highly Likely
3	Possible
2	Unlikely
1	Remote Possibility

SEVERITY (S)	
5	Very High -Multiple Deaths
4	High - Death, serious injury, permanent disability
3	Moderate - RIDDOR over 3 days
2	Slight - First Aid treatment
1	Nil - Very Minor

		SEVERITY				
		1	2	3	4	5
LIKELIHOOD	1	1	2	3	4	5
	2	2	4	6	8	10
	3	3	6	9	12	15
	4	4	8	12	16	20
	5	5	10	15	20	25

PERSONS AT RISK

PERSONS AT RISK
Employees
Students
Clients
Contractors
Members of the public
Work Experience students
Other Persons

RISK RATING SCORE	ACTION
1 - 4	Broadly Acceptable - No action required
5 - 9	Moderate - Reduce risks if reasonably practicable
10 -15	High Risk - Priority Action to be undertaken
16 -25	Unacceptable **-Action must be taken IMMEDIATELY**

Health and safety services
General risk assessment

HAZARD AND RELATED ACTIVITIES e.g. trip, falling objects, fire, explosion, noise, violence etc.	**PERSONS AT RISK** e.g. Employees, Customers, Contractors, Members of the public	**POSSIBLE OUTCOME**	**RISK RATING BEFORE CONTROLS (LxS)**	**EXISTING CONTROLS** e.g. Guards, Safe Systems of Work, Training, Instruction, Authorised Users, Competent Persons, Personal Protective Equipment (PPE)	**RISK RATING AFTER CURRENT CONTROLS (LxS)**	**FURTHER CONTROLS REQUIRED?**	**RISK RATING AFTER ADDITIONAL CONTROLS (LxS)**
General Safety (trips/falls)	Research team, students, parents	Accident at school	6 (moderate)	To ensure appropriate number of trained “first-aiders” are available at school.	3 (low)		
Transport of research kit to and from schools	Research team	Spillage of liquids or breakage of instruments. Manual handling considerations. Parking as close to premises as possible.	6	To ensure research staff store the items in boxes and transfer it in a car with business travel insurance. To use manual handling techniques for moving and use trolley provided. Liaise with school regarding local parking availability	4		

Transport of impression materials from schools to dental laboratory	Dental therapist/dental nurse	Cross infection	4	To disinfect impressions according to manufacturer's instructions and by trained and qualified staff. To store impressions in appropriate lab bags and packaging in approved transport boxes for safe transfer. Items to be transported in the boot of the vehicle. Car operator to be covered by appropriate business travel insurance	2		
Patient identifiable data	Pupils	Forms with patient identifiable data are lost	2	To ensure safety and confidentiality of forms with patient identifiable data, these are retained and transported in a specialist sealed/tagged envelope marked “Private and Confidential”	1		

				and addressed to BIHR if found. Data storage and use covered by DREC regulations for the Platoon study.			
Body fluid spill (vomit)	Pupils	Child vomits during taking moulds (impressions) as a result of strong gag reflex	8	To ensure impression trays are not overfilled and use a quick setting impression material To ensure body fluid spill kit is available and staff are trained to use it. Disposal of any body fluid /spill as per DenTCRU clinical waste policy (appropriate PPE / via Trust appropriate and tagged bag)	6		
Child identification	Pupils	Identification of the wrong child	2	To use two verifiers: child's full name and date of birth	1		

Health and safety services
General risk assessment

Medical waste transfer	Dental nurse	Cross infection	4	Using DenTCRU Waste Disposal policy or appropriate Trust policy. Trained staff will use proper handling and transfer of waste in appropriate disposal bags/ tagged and stored in a red transport box	2		
WiFi down	NA	Failure of data entry through the web application	2	Research staff to ensure paper forms are available for data collection	1		
Platform database down	NA	Failure of data entry through the web application	2	Research staff to ensure paper forms are available for data collection	1		
Camera/ring flash not working	NA	Camera/ring flash out of charge	2	To ensure that there are extra charged batteries on the day	1		
Safe transfer of data on camera card	NA	SD memory card lost	2	To ensure the safe transfer of SD memory card in camera. Research staff to be hyper vigilant with camera security at all times.	1		

Health and safety services
General risk assessment

Allergy	Research team, pupils	Pupils develop an allergic reaction as a result of impression materials and equipment	12	A consent is taken and parents/legal guardians are expected to raise any concern of possible allergy. Research staff undertake basic medical emergency training but in this community setting would ring 999 emergency services if required.	6		
Hot/warm water	Research team, pupils	Scalds	6	Research staff to collect hot water in a flask to transport this to clinical area. The flask is kept in a zoned area to ensure correct handling and out of the way of pupils.	4		
Fire alarm	Research team	First degree or minor burns, scalds	10 (high risk if fire)	Liaison with school in advance regarding emergency procedures. To ensure research team are aware of	6 (moderate)		

				evacuation procedures for any room being used for event activities			
Weather conditions – slips, falls, trips	Research team	Adverse weather induced accidents (slips, trips, falls) resulting in injuries such as cuts, bruises or broken bones	6 (moderate)	Liaise with school in advance to ensure first aiders are available at school and contact as appropriate.	3 (low)		
Toilet facilities	Research team	Visitors may be required to use toilet facilities – may slip/trip during use or get lost	4 (Low)	To provide information on the location of toilet facilities on arrival	2 (low)		
Safeguarding (pathology) staff and pupils	Research team, pupils, parents	Child protection guidelines contravened Dental examination raises a safeguarding concern	6 (moderate)	Ensure that one to one contact with protected persons is kept to a minimum and there is always another adult around (university staff or teacher). Research staff instructed to report any allegations or complaints of inappropriate behaviour to the school	3 (low)		

				administration. If staff forsee problems or find themselves in a difficult position on the day to contact Principal or another key member of staff.			
Unfamiliarity with environment/lost visitors	Research staff	May get separated from the research team	4 (low)	To ensure a member of school staff guides the groups on arrival. Research staff to meet together at the reception and a school staff guides them to the activity rooms and out at the end of the visit.	2 (low)		

Health and safety services
General risk assessment

MANAGEMENT AGREED ADDITIONAL CONTROL MEASURES REQUIRED		ACTIONED BY			ACTION COMPLETE	
		POSITION	NAME	DATE	MANAGER SIG	DATE
	Staff briefing/training prior to visits	Lead Researcher	Eman Alnuaimi	3/6/2019		
	Local school liaison in advance of visits to be undertaken by Lead Researcher to identify: Car parking, room access/ hot water access, fire exits, toilet facilities, emergency procedures	Primary School Senior Manager/Lead Researcher	Various school managers/ Eman Alnuaimi	At start of project and ongoing		

COMMUNICATION OF RISK ASSESSMENT FINDINGS TO STAFF				
	METHOD	YES	DATE	COMMENTS
REFERENCE OF FORMAL COMMUNICATION TO STAFF	Copy of risk assessment issued to staff			
	Controls covered in team procedure issued to staff			
	Staff Handbook issued to staff			
	Other -			
ADDITIONAL METHODS OF COMMUNICATION	Induction			
	Toolbox Talk			
	Team Meeting			
	E-mail circulation			
	Other -			

Health and safety services
General risk assessment

COMMENTS AND INFORMATION (Use this section to record any dynamic risk assessment comments and information)
COSHH sheets are available at Westbourne Green Community Health Centre.

Do additional controls adequately lower high risk activities to an acceptable level?	**YES /** If NO explain in comments box above	**SIGNATURE OF MANAGER** "The risks identified in this assessment are controlled so far as is reasonably practicable"	
		Signature:	Date:

DATE OF REASSESSMENT (Every two years minimum)	**ARE THERE ANY CHANGES TO THE ACTIVITY SINCE THE LAST ASSESSMENT?**	**SIGNATURE OF MANAGER**
Not required unless there are changes to protocol procedures or HSE requirement – Study completes July 2020		

LOCATION OF CURRENT SIGNED RISK ASSESSMENT	

Health and safety services
General risk assessment

RISK ASSESSMENT LOG - SAMPLE

RISK ASSESSMENT LOG											
Directorate:						Area:					
Section/Team	Risk Assessment Title	Version No.	Risk Assessment Category	Code /Location	Risk Assessor	Manager responsible for signing off risk assessment	Date assessment signed off	Review Due	Review Date	Outstanding Controls/Actions Yes/No	Comments

Appendix 3.10 Data collection sheet

PLATOON Data Collection Sheet

Date of data collection:

Barcode ID:

Child's initials:

School:

FIELD DATA INPUT

Teeth Present:

Upper Right												Upper Left	
		55	54	53	52	51	61	62	63	64	65		
17	16	15	14	13	12	11	21	22	23	24	25	26	27
47	46	45	44	43	42	41	31	32	33	34	35	36	37
Lower Right		85	84	83	82	81	71	72	73	74	75	Lower Left	

Codes for each tooth:

0 = not present

1 = sound

2 = carious

3 = restored

4 = defective restoration

5 = hypomineralised

6 = hypomineralised and carious

7 = other dental developmental defect

.....

.....

.....

.....

Orthodontic assessment:

Lips: competent, incompetent

Masticatory/speech problems: Yes, N o

Incisor relationship: I, II/I, II/II, III, NA

Right molar relationship: I, II, III, NA

Left molar relationship: I, II, III, NA

Upper permanent canines palpable buccally: right, left, both, no

Upper primary canines mobile: right, left, both, no

Overjet: in mm + or -

Overbite: average, increased, decreased

Centrelines:

Crossbite: posterior, anterior, both, no

Deviation between RCP and ICP: Yes, No

AP skeletal pattern: I, II, III

Images/Moulds:

Images(Photos)

Images were taken? Yes No

If not, why? .....

File name range: From: ..... To .....

Moulds:

Upper moulds taken? Yes No

Lower moulds taken? Yes No

Wax bite taken? Yes No

.....

.....

.....

.....

Appendix 3.11 Letter to parent

BRADFORD SMILE STUDY

We are family BORNINBRADFORD

BiB – Bradford Smile Study

Dear Parent/Guardian,

Re- (Child's name)

You kindly agreed for your child to take part in the Bradford Smile study. A brief dental check was undertaken on (insert date).

We noted that your child has

……

and would benefit from seeing a dentist. If you are registered with a dentist, please make an appointment to see them for a check up. If you are not registered with a dentist please visit the NHS choices website (https://www.nhs.uk/pages/home.aspx) to find local NHS dentists who are accepting new patients.

Kind regards,

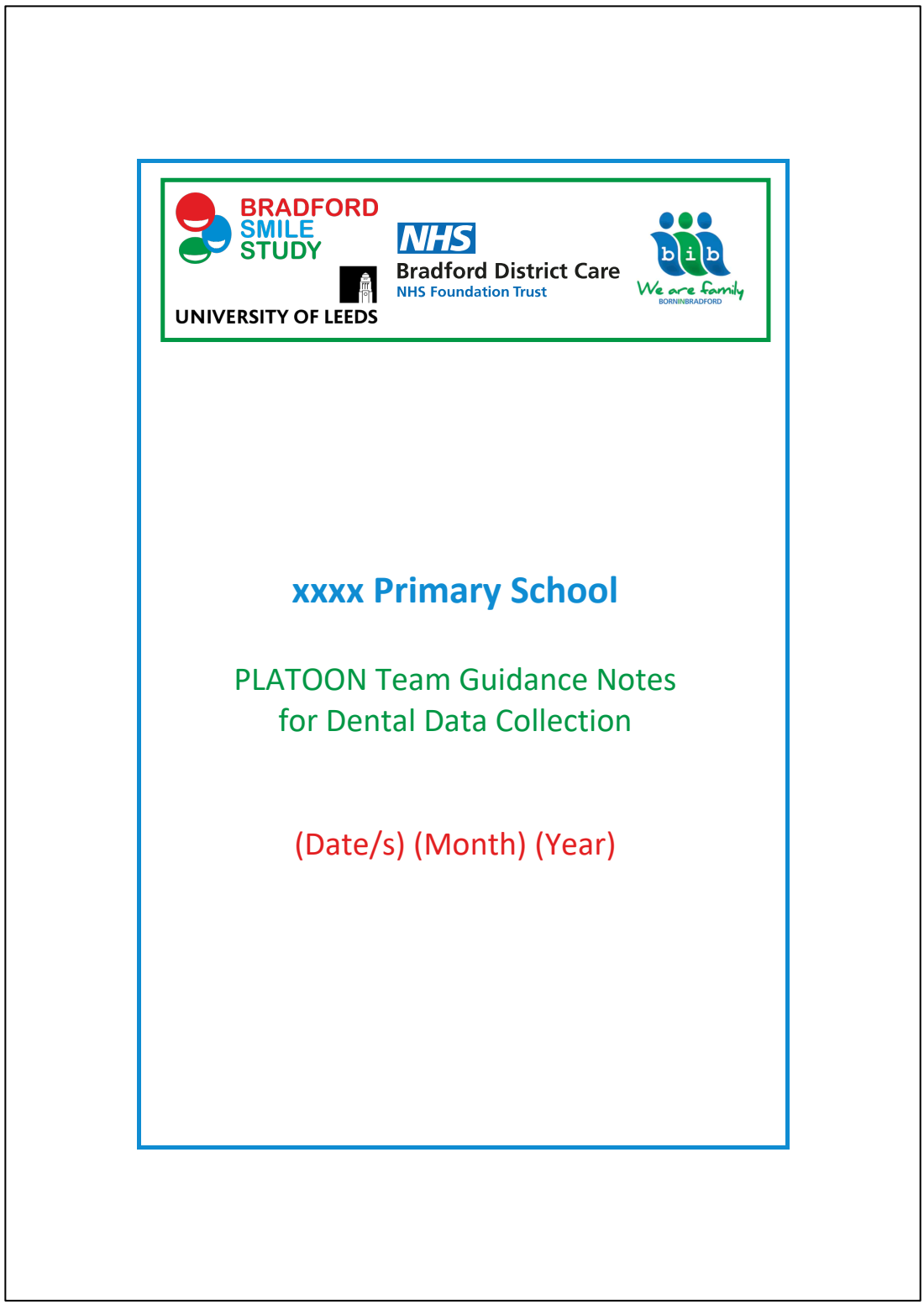
Bradford Smile Study Research team

Bradford District NHS

Bradford Teaching Hospitals NHS NHS Foundation Trust

UNIVERSITY OF LEEDS

Appendix 3.12 Team guidance notes



CONTACT DETAILS:
xxxx Primary School
(Address line)
(Postcode)

School contact:
(Point of contact)
Telephone no.: xxxx
Email: xxxx

PLATOON team contacts:

Name	Designation	Mobile number	E-mail
xxxx	Principal Investigator	xxxx	xxxx
xxxx	Dental Therapist	xxxx	xxxx
xxxx	Research Nurse	xxxx	xxxx
xxxx	PhD Student/ Study Coordinator	xxxx	xxxx
xxxx	DCT3	xxxx	xxxx
xxxx	Clinical Studies Support Assistant	xxxx	xxxx

SCHOOL DAY TIMINGS:
(Hour):(Minute) School starts
(Hour):(Minute) School finishes

RESEARCH TEAM:
xxxx

NUMBER OF EXAMINATIONS:
Number of consented pupils: xx

ACCESS:
- Kit can be transferred to the school in the morning at 8:30am
- Parking spaces available, you can also use the ones on the main road

DENTAL TEAM ID/DBS:
- Please wear a valid photographic ID badge
- Please bring your DBS certificates
- Each member of the team needs to sign in at the reception
- Please wear professional attire or scrubs

STUDENT TIMETABLES:
- School starts: (Hour):(Minute)
- Playtime: (Hour):(Minute)
- Dinner time: (Hour):(Minute)
- School finishes: (Hour):(Minute)

PLAN:
- Duration for each examination including filling out the questionnaire is 30 minutes approximately
- The school will help us fetch the pupils from their classroom
- No fire alarm plans

DENTAL EXAMINATION ROOM AND FACILITIES:
- We have been allocated a room with a sink and we will be guided to it
- We have requested the following:
  - Access to hot water
  - Three tables (two large and one small) and four chairs
  - Privacy screens
  - Bin for general waste disposal
- Please bring your own lunch, drinks, cutlery, mugs, milk, teabags etc.

GIVEAWAYS:
- Each child will be given a toothbrush, a piece of fruit, and a sticker when dental examination has been completed. Inform the child that they have to wash their hands and the fruit before eating.
- Eman will bring apples and ripe bananas (expiry within 3+ days is preferable)

Appendix 3.13 BiB collaboration and information sharing agreement

Bradford Teaching Hospitals NHS
NHS Foundation Trust

Collaboration and Information Sharing Agreement between Bradford Teaching Hospitals NHS Foundation Trust and University of Leeds ("The Investigator's Institution") in relation to Born in Bradford approved study SP391 ("The Study").

i. Background to the Agreement:
Born in Bradford is a family of research studies including three longitudinal multi-ethnic birth cohorts (Born in Bradford; Born in Bradford's Better Start and BiB4All). These cohort studies aim to examine the impact of environmental, psychological and genetic factors as well as specific interventions on maternal and child health and wellbeing. Ethical approval for the data collection was granted by Bradford Research Ethics Committee, as follows:

07/H1302/112	Born in Bradford: A longitudinal cohort study of babies born in Bradford and their mothers and fathers
15/YH/0455	Born in Bradford's Better Start Cohort Study. A cohort study of babies born in Bowling and Barkerend, Bradford Moor and Little Horton areas of Bradford, and their mothers and partners
17/YH/0202	BiB4All: A data linkage cohort study of babies born in Bradford and their mothers

The studies are referred to collectively as "Born in Bradford" or "BiB".

It is critical to the success of the Born in Bradford approved study SP391 PLATOON dental study ("The Study") that the information to which this agreement relates is handled in accordance with relevant UK data protection regulations.

This agreement sets out the roles of each party to the agreement in relation to the information shared and their responsibilities therein.

1. Parties to the Agreement:
Details be included for all agencies which are party to the Agreement:

a) **Professor John Wright, Director of Research**
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
BD9 6RJ

b) **"The Investigator"**
[Investigator individual]
"The Investigator's Institution"
[Investigator institution]

2. Purposes of the Agreement:

This agreement is in place to ensure the protection and security of data shared between Bradford Teaching Hospitals NHS Foundation Trust (BTHFT) and The Investigator's Institution for the purposes of The Study.

3. Information to be shared

Research data from Born in Bradford cohort participants will be shared between the parties. Only data necessary for the Investigator to carry out the Study will be shared ("The Data"), and this will be determined by the Born in Bradford Executive Group. Person identifiable data will not be shared. The Data will be pseudonymised.

Facial photographs ("The Photograph Data") will be made available on a BTHFT SafeXs encrypted memory stick to enable quality control checks to be carried out on The Data.

4. Methods used for sharing:

The Data will be transferred from BTHFT to The Investigator at The Investigator's Institution using the IronPort encrypted email service or the Kiteworks secure filesharing service. If the file size is too big for Ironport or Kiteworks, or there are other barriers to accessing these at The Investigator's Institution, one of two transfer methods will be used:

1. A secure sftp or secure https connection will be provided by The Investigator's Institution to allow BTHFT to upload The Data. The folder to which The Data is uploaded will only be accessible by The Investigator.
2. The Data will be downloaded to a BTHFT SafeXs encrypted memory stick and transferred physically to The Investigator at The Investigator's Institution by a member of BTHFT staff.

The Photograph Data will be downloaded to a BTHFT SafeXs encrypted memory stick. The files may be opened from the memory stick while it is mounted on the Investigator's PC but they must not be removed or transferred.

5. Need to know

For BTHFT:

Prof John Wright, Director of Research, BTHFT

BTHFT staff members in the Born in Bradford Data Team involved in processing The Data.

For The Investigator's Institution:

The Investigator.

6. Supporting processes:

The Investigator has read and will abide by the "Guidance for BiB Collaborators" set out in Appendix 1.

The Investigator has read and will abide by the "Terms and Conditions for Data Transfers" set out in Appendix 2.

7. Information retention issues:

The Investigator will retain all information for as long as necessary to complete The Study. The Investigator will delete The Data and any data items derived from The Data from the Investigator's Institution's information systems at the request of BTHFT or upon completion of The Study, whichever is earlier.

The Photograph Data must not be removed or transferred from the SafeXS encrypted memory stick. The SafeXS memory stick and all Photograph Data contained on it will be returned to BTHFT at the request of BTHFT or upon completion of The Study, whichever is earlier.

Participant data will be held in accordance with the relevant legislation (in particular the Data Protection Act 2018); Records Management: NHS Code of Practice and each agency's relevant policies and procedures.

8. Staff development issues:

Both parties to this agreement will ensure that their staff carry out information governance training appropriate to their role.

All staff at BTHFT complete annual mandatory training in Information Governance procedures. Staff are made aware of their responsibilities under the Data Protection and Freedom of Information Acts, which are laid out in the Trust's DPA and FOI policies and procedures.

9. Consent from service users:

All participants in Born in Bradford give explicit consent for their data to be used for research purposes. The consent forms make clear that they can withdraw their consent at any time by contacting the Born in Bradford office, at which point a member of the Born in Bradford team follows a standard operating procedure to action the withdrawal..

10. Incident Reporting

Incidents are to be reported immediately and in writing to the Director of Research, BTHFT

11. Any other relevant issues

Further information in relation to the Born in Bradford Cohort Study can be obtained by contacting the project office on +441274 364474

This agreement to be reviewed annually.

Approved by (PRINT NAME):

Signature:

Institution: Bradford Teaching Hospitals NHS Foundation Trust

Date:

Approved by (PRINT NAME):

Signature:

Institution: [Investigator institution]

Date:

Copies of this Agreement should be retained by the named persons above and be made available for inspection on request.

A copy should be sent to the DP Officer of each party.

Appendix 1 – Guidance for BiB Collaborators

Use of existing data or existing biological samples

1. Requests for existing data and biological samples will be reviewed, prioritised and authorised by the BiB Executive Group. The Investigator should complete an outline proforma available on the Born in Bradford website (www.borninbradford.nhs.uk) and submit to the BiB Director.
2. Any new data derived from BiB participant data (interview, physical measurements, new variables derived from existing data) must be lodged with the BiB database at the end of the project (or at any time at the request of the BiB Director). The nested study Principal Investigator must supply adequate documentation concerning new variables (including statistical programs) to permit their use in future analyses of the data.
3. The Investigator must notify the BiB Director of any potential errors discovered whilst using BiB data or biological samples.
4. Any residues of biological samples or excess materials must be returned to BTHFT or to the Bristol Bioresource Laboratory, whichever is the originating laboratory, within 6 months of the completion of the research. The expense of transferring both from and back to the BiB site must be met by the applicants.

Collection of new data or new biological samples

In addition to the Guidance for existing data or samples, Investigators collecting new data or samples are expected to adhere to the following Guidance:

1. Full proposals *must* be reviewed by the BiB Executive Group *prior to submission for funding*. The Investigator should complete an outline proforma available on the Born in Bradford website (www.borninbradford.nhs.uk) and submit to the BiB Director.
2. The Investigator should ensure that there is genuine local research partnership and where appropriate a strong link to practitioners to promote translation of findings into practice.
3. The Investigator will be required to meet additional costs (administrative, data management, laboratory etc) that are incurred by the Born in Bradford programme for new data and sample collection. Where a new grant will be submitted to fund the study, the final copy of the grant including the finances must be sent to the BiB Director for approval at least two weeks before the submission date.
4. In addition to the review by an appropriate ethics committee, researchers will be expected to obtain review and advice from relevant patient/public involvement groups, including Born in Bradford's parent governors group. Please contact the BiB Community Engagement Officer for advice on the most appropriate form of public engagement. (borninbradford@bthft.nhs.uk).
5. The Born in Bradford Executive Group will act as data guardians and provide peer review for the scientific merit of research ideas and the use of the collected data and biological samples.

Governance and intellectual property

1. The BiB Director will be responsible for the design and conduct of the Born in Bradford platform study, ethical approval and compliance with research governance requirements. The Investigators will be responsible for the governance of their specific study.
2. Bradford Teaching Hospitals Foundation Trust is the Sponsor of the project.
3. Intellectual Property developed from the Born in Bradford platform study will be owned by Bradford Teaching Hospitals Foundation Trust. We will consider dividing intellectual property rights where collaborators will be making a particular contribution. Any such division must be considered and agreed before the collaboration starts.

Publications and reports

1. We would like to have all work linked to Born in Bradford to be easily identified,

including in electronic searches. We encourage collaborators to include Born in Bradford in article titles e.g. Obesity in a bi-ethnic population: a Born in Bradford study. If this is not possible then authors should include Born in Bradford as a keyword and in the abstract. A protocol and cohort description of the study [1, 2] and BiB 1000 study [3] have been published and should be referred to in all methods sections

2. Authorship on papers must follow standard practice that all authors must have made a substantial contribution to the conception and design of the study, or analysis and interpretation of data, and drafting the paper. In a long running study such as Born in Bradford there are likely to be a number of people whose work makes production of a paper possible but who may not meet authorship criteria. In such cases we encourage the use of the contributorship (see BMJ guidelines).
3. The Investigator should agree authorship guidelines with their team and collaborators at the start of any new research project to avoid later disputes. Studies where **new** data or biological samples will be collected should have a local (Bradford) investigator in the study team.
4. The following acknowledgement must be included in all papers using BiB data:

   "Born in Bradford is only possible because of the enthusiasm and commitment of the Children and Parents in BiB. We are grateful to all the participants, health professionals and researchers who have made Born in Bradford happen."

   For papers using Born in Bradford GP primary care data, the following additional acknowledgement must be included:

   "We gratefully acknowledge the contribution of TPP and the TPP ResearchOne team in completing study participant matching to GP primary care records and in providing ongoing informatics support."
5. When a paper or abstract is ready to be submitted authors will be required to submit a copy (in confidence) to the BiB Director for review by the BiB Executive Group. All papers will be reviewed within two weeks of receipt to check confidentiality is protected; to ensure that the paper will not bring the study into disrepute; to try to identify overlap with other papers published or in preparation. Advice and feedback will be offered to authors where we feel this may be helpful.
6. Born in Bradford is committed to the translation of research into practice. All authors are required to send the BiB Director a summary of key policy and commissioning implications from their analysis upon conclusion of their project.
7. Collaborators must send copies of the final submitted draft and an electronic copy of the final published version to the BiB Director. All press releases on research arising from the study must be approved by the BiB Director.

Contact

Please send all enquiries via email to the Born in Bradford Programme Director (rosie.mceachan@bthft.nhs.uk).

Reference

1. Born in Bradford Collaborative Group. Born in Bradford, a cohort study of babies born in Bradford and their parents: protocol for recruitment phase. BMC Public Health 2008; 8:327 doi:10.1186/1471-2458-8-327
2. Wright, J., Small, N., Raynor, P., Tuffnell, D., Bhopal, R., Cameron, N., Fairley, L., Lawlor, D.A., Parslow, R., Petherick, E.S., Pickett, K.E., Waiblinger, D., & West, J, on behalf of the Born in Bradford Scientific Collaborators Group (2012). Cohort profile: The Born in Bradford multi-ethnic family cohort study. International Journal of Epidemiology. 2012; 1-14 doi:10.1093/ije/dys112
3. Bryant M, Santorelli G, Fairley L, West J, Lawlor DA, Bhopal R, Petherick E, Sahota P, Hill A, Cameron N, Small N, Wright J. Design and characteristics of a new birth cohort, to study the early origins and ethnic variation of childhood obesity: the BiB1000 study Longitudinal and Life Course Studies 2013 4(2) 119-135 doi:10.14301/llcs.v4i2.221

Appendix 2 – Terms and Conditions for Data Transfers

1. The Investigator and other relevant employees of The Investigator's Institution involved in the research have read and will abide by the "Guidance for BiB Collaborators" given in Appendix 1 of this Agremeent.

2. The data remains the property of the Born in Bradford study. This agreement does not restrict the rights of Born in Bradford to distribute the data to other institutions or to publish any document relating to the data.

3. The Investigator will retain The Data and the Photograph Data in a secure location at The Investigator's Institution and will not permit The Data or the Photograph Data or any part of it to come into the possession or control of any other organisation or any individual other than those employees of The Investigator's Institution who are involved in The Study under direct supervision of The Investigator.

4. The Investigator will not transfer The Data or the Photograph Data in whole or in part to third parties without the relevant third party entering into a separate Information Sharing Agreement with Born in Bradford.

5. The Investigator will use the data only to carry out the research described in the proforma relating to The Study as approved by the Born in Bradford Executive Group ("The Proforma"), and only for research that has appropriate ethnical approval. The Investigator will not use The Data or the Photograph Data or any parts thereof for any commercial purposes or any purpose that is subject to consulting or licensing obligations to third parties.

6. The Investigator will use all reasonable endeavours to ensure that The Data and the Photograph Data and any data items derived from The Data or the Photograph Data shall as soon as possible be returned or destroyed upon (i) the request of BTHFT, (ii) on termination of this agreement, (iii) in the event that The Investigator or The Investigator's Institution are in breach of any of the conditions of this agreement or (iv) the withdrawal of consent of a relevant study participant. If The Investigator is required to destroy The Data or the Photograph Data then it will confirm in writing to the Director of Research, BTHFT that it has been destroyed and no further copies of the data are held by The Investigator or The Investigator's Institution.

7. All data and information (including the results of chemical and biological analyses and cleaned or derived variables) relating directly to study participants will be returned to BTHFT upon the request of BTHFT or within 6 months of the completion of The Study, whichever is sooner, for incorporation into the Born in Bradford data warehouse and shall be owned by BTHFT.

8. The Investigator will provide the Director of Research, BTHFT with a fully documented electronic copy of the full results of The Study before its publication in any form or within 6 months of the completion of The Study whichever is sooner.

9. The Investigator will keep the data confidential and will not attempt to identify study participants.

10. The Investigator will not attempt to link The Data or the Photograph Data to other Born in Bradford data held by different individuals or by The Investigator for different projects.

11. The Investigator will not try to link The Data or the Photograph Data to data from other sources other than those that may be set out in The Proforma.

Appendix 3.14 The short form of the Child Oral Health Impact Profile

Hello!

Thank you for helping us with our study. We are doing this study to better understand how children feel about their teeth and themselves.

Please read carefully each statement and choose the answer that best describes you in **the past 3 months** regarding your teeth, mouth, or face. There are no right or wrong answers. We want to know how you really feel.

Example: *During the **past 3 months**, how often have you **felt shy** because of your teeth, mouth, or face?*

If you have felt shy because of your teeth, mouth, or face then choose the appropriate response. If you felt shy for other reasons choose "Never."

Never	***Almost never***	***Sometimes***	***Fairly often***	***Almost all the time***
☐	☐	☐	☐	☐

Some things to keep in mind:

- Answer the questions as honestly as you can.
- Don't talk to anyone about the questions when you are answering them.
- Before you answer, ask yourself:
  Does this happen because of my teeth, mouth, and face?
- Choose the answer that best describes you in the past 3 months.

In the past 3 months, how often have you?

	Never	Almost Never	Some-times	Fairly Often	Almost All the Time
1. Had pain in your teeth/toothache.	☐	☐	☐	☐	☐
2. Had crooked teeth or spaces between your teeth.	☐	☐	☐	☐	☐
3. Had discolored teeth or spots on your teeth.	☐	☐	☐	☐	☐
4. Had bad breath.	☐	☐	☐	☐	☐
5. Had bleeding gums.	☐	☐	☐	☐	☐
6. Been unhappy or sad because of your teeth, mouth, or face.	☐	☐	☐	☐	☐
7. Missed school for any reason because of your teeth, mouth, or face.	☐	☐	☐	☐	☐
8. Been confident because of your teeth, mouth, or face.	☐	☐	☐	☐	☐
9. Had difficulty eating foods you would like to because of your teeth, mouth, or face.	☐	☐	☐	☐	☐

In the past 3 months, how often have you?

10. Felt worried or anxious because of your teeth, mouth, or face.	☐	☐	☐	☐	☐
11. Not wanted to speak/read out loud in class.	☐	☐	☐	☐	☐
12. Avoided smiling or laughing with other children because of your teeth, mouth or face.	☐	☐	☐	☐	☐
13. Had trouble sleeping because of your teeth, mouth, or face.	☐	☐	☐	☐	☐
14. Been teased, bullied or called names by other children because of your teeth, mouth or face.	☐	☐	☐	☐	☐
15. Felt that you were attractive (good looking) because of your teeth, mouth, or face.	☐	☐	☐	☐	☐
16. Felt that you look different because of your mouth, teeth, or face.	☐	☐	☐	☐	☐
17. Had difficulty saying certain words.	☐	☐	☐	☐	☐
18. Had difficulty keeping your teeth clean.	☐	☐	☐	☐	☐
19. Been worried about what other people think about your teeth, mouth or face.	☐	☐	☐	☐	☐
20. Overall, please rate your oral health?	poor	fair	average	good	excellent

Appendix 3.15 Health utilisation data collection sheet

BRADFORD SMILE STUDY

b i b We are family BORNINBRADFORD

BiB – Bradford Smile Study

Description of Dental Care Pathway V3 30.03.19

Have you ever given/taken your child to any of the following (you can tick more than one as applicable) because of toothache or tooth decay.

	No	Yes	If yes, how many times? (example: 1 or 4 times)
Painkiller	☐	☐	
Pharmacist/chemist	☐	☐	
General medical practitioner/GP	☐	☐	
General dental practitioner/family dentist	☐	☐	
Out-of-hours dental service/emergency dentist	☐	☐	
Community Dental Service	☐	☐	
Accident and Emergency (A&E)	☐	☐	
Practice nurse/school nurse	☐	☐	
Health visitor	☐	☐	
Other	☐	☐ Please provide more details:	

If this information is collected at the time of consent, the research team may ask-
Please tell us more about the services you visited as part of your child's dental journey.

.....

.....

.....

.....

Appendix 4.1 Abstract-British Society for Oral and Dental Research Annual Meeting 2019

151

PLATOON: Logistical Challenges, Limitations And Solutions

E. Alnuaimi[1], D. Waiblinger[2], S. Smith[2], T. Yang[2], P. Day[1]

[1]School of Dentistry, University of Leeds, UK; [2]Bradford Institute for Health Research, Bradford, UK.

Objectives: The process of operationalising a research protocol into a large birth cohort study running multiple studies simultaneously has been unexplored. The objective is to describe the challenges, limitations, and solutions of operationalising a school-based data collection protocol, part of PLATOON (Premature Loss of bAby Teeth and its impact On Orthodontic Need) study, into the vibrant Born in Bradford (BiB) birth cohort.

Methods: Two examples from the research protocol will be used to showcase complexities and inter-disciplinary communication needed to enable the effective and efficient delivery of PLATOON study in primary schools.

Results: A pilot study involving seven primary schools and up to n=207 Year Six pupils will be conducted in July-2019. *Identification and Recruitment*: Previous research identified n=1080 BiB children who have had extraction of primary teeth. A matched control group of BiB children with no primary tooth extractions will be recruited based on their school and class. Recruitment, supported by the National Institute for Health Research Clinical Research Network (NIHR CRN), will involve identification of both primary schools and pupils. It is uncertain how many control children may have had extractions at their own dentist, therefore making them eligible for the exposure group. *Data collection and entry*: Data, including intra-oral examination, orthodontic photographs and dental impressions will be collected from each child. The complexity of collecting data in school settings requires management of data confidentiality and logistics for safe transport of clinical waste. Data will be entered through a secure bespoke web-application to enable efficient entry. The suitability of a 4G mobile data dongle will be tested to enable access to the web-application in different schools.

Conclusions: Operationalising a complex project requires consideration of many aspects of participant recruitment, data collection, and data transfer. Pilot study will inform data collection over the remaining ten months of the study and quantify the uncertainties.

Appendix 4.2 Abstract-International Association of Paediatric Dentistry 2020 Virtual Congress

1268

Epidemiology

Infection Prevention and Control in a School-Based Dental Project in Bradford (PLATOON)

Eman Alnuaimi, Bernadette Drummond, Peter Day
Department of Paediatric Dentistry, University of Leeds, Leeds, UK

Background: The Bradford Smile Study/PLATOON is a school-based dental project that aims at understanding the impact of Premature Loss of Primary Teeth On the Orthodontic Need (PLATOON). Children aged 8-12 years taking part in the Born In Bradford study were invited to participate. Data collection took place in primary schools in Bradford and includes dental examination and taking orthodontic records (extra- and intra-oral orthodontic photographs, upper and lower impressions, and bite registration). During data collection, contact with saliva is unavoidable; which may act as a source of infection. Thus, following infection prevention and control (IPC) measures is crucial to prevent cross-infection between participants and the data collection team.

Methods: IPC measures are being followed from local and international health governing bodies. IPC measures in a school-based dental project in Bradford will be illustrated.

Results: All team members have had their occupational health assessment carried out before visiting the schools as per the local guidelines. Risk assessment was performed following the University of Leeds risk assessment form and standard operating procedures covered standard infection control precautions. Also, research team members received induction training in the dental practice where the research kit is being collected, dropped off, and dental instruments being sterilised.

Conclusion: Following meticulous IPC measures in a school-based dental project is crucial for the safety of the data collection team and research participants.

Appendix 4.3 Abstract-International Association of Dental Research General Session (Virtual Experience) 2021

IADR Abstract Archives

Premature Loss of Primary Teeth Increases Future Orthodontic Need

Objectives: To investigate the impact of premature primary tooth loss due to dental caries on orthodontic treatment need of children.
Methods: This is a cross-sectional study that recruited children aged 6-12 years from the Born In Bradford (BiB) birth cohort study in the UK. A dental data linkage feasibility study identified BiB children who received extraction of primary teeth under general anaesthesic (exposures); these were matched with children who did not have premature extraction of primary teeth (controls). Trained examiners collected data during visits to schools who were invited and consented to take part. Data collected included a dental examination, clinical photographs (extraoral and intraoral) and alginate impressions. Standard operating procedures were developed for efficient data collection. A blinded expert panel, consisting of three specialist orthodontists, independently assessed the records for orthodontic treatment need. A consensus decision was made as to the Index of Orthodontic Treatment Need Dental Health Component (IOTN DHC) grade and timing of treatment (immediate or in the permanent dentition). The proportion of children judged to be in need of orthodontic treatment and the risk ratio were calculated.
Results: 333 BiB participants, attending 15 primary schools, consented to take part. Data were collected between July 2019 and March 2020. Complete records were obtained for 324 participants (97%, 74 exposures and 250 controls). 54 children in the exposure group (73%) were assessed to be in need of orthodontic treatment (IOTN DHC 4 or 5) compared to 101 in the control group (40.4%). Children in the exposure group were more likely to have an increased need of orthodontic treatment (RR 1.84, 95% CI=1.51-2.25, P<0.0001).
Conclusions: Premature loss of primary teeth leads to an increased need for orthodontic treatment.

Division:
Meeting: 2021 IADR/AADR/CADR General Session (Virtual Experience)
Location:
Year: 2021
Final Presentation ID: 2538
Abstract Category|Abstract Category(s): Orthodontics Research

Authors
- Alnuaimi, Eman (University of Leeds , Leeds , United Kingdom)
- Benson, Philip (University of Sheffield , Sheffield , United Kingdom)
- Yang, Tiffany (Bradford Institute for Health Research , Bradford , United Kingdom)

Appendix 4.4 Amendments to the protocol

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
PLATOON-Premature Loss of bAby Teeth & its impact On Orthodontic Need

1. Is your project research?

(•) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

(•) Other study

2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (•) No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (•) No

b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (•) No

c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (•) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

- [x] England
- [ ] Scotland
- [ ] Wales
- [ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (•) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which applications do you require?

- [x] IRAS Form
- [ ] Confidentiality Advisory Group (CAG)
- [ ] Her Majesty's Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

( ) Yes (•) No

5. Will any research sites in this study be NHS organisations?

(•) Yes ( ) No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative in all study sites?

Please see information button for further details.

( ) Yes (•) No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

(•) Yes ( ) No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

(•) Yes ( ) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

( ) Yes (•) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

( ) Yes (•) No

9. Is the study or any part of it being undertaken as an educational project?

( ) Yes (•) No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

( ) Yes (•) No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

( ) Yes (•) No

NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Mr	Peter	Day
Work Address	School of Dentistry, Level 6, Worsley Building		
	Clarendon Way		
	Leeds		
PostCode	LS2 9JT		
Email	p.f.day@leeds.ac.uk		
Telephone	01133436139		
Fax			

For guidance on this section of the form refer to the guidance

Full title of study:	The impact of premature extraction of primary teeth on orthodontic treatment need in a longitudinal birth cohort. In patient facing documents the PLATOON research study will be called the Bradford Smile Study.
Lead sponsor:	University of Leeds
Name of REC:	Yorkshire & the Humber - Bradford Leeds Research Ethics Committtee
REC reference number:	18/YH/0440

International Standard Randomised Controlled Trial Number (ISRCTN):	
ClinicalTrials.gov Identifier (NCT number):	

Additional reference number(s):

Ref.Number Description	Reference Number

Name of lead R&D office:	Bradford Teaching Hospitals NHS Foundation Trust
Date study commenced:	17.05.2019
Protocol reference (if applicable), current version and date:	V2

Amendment number and date: V3 29.07.19

Type of amendment

(a) Amendment to information previously given in IRAS

(•) Yes ( ) No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

Please see below:
Explanation is provided in summary of changes below.

(b) Amendment to the protocol

(•) Yes ( ) No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

Please see below:
"Protocol and recruitment strategy"
Explanation is provided in summary of changes below.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

(•) Yes ( ) No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Please see:
Information for Parents and Carers
Child Participant Information
Consent Form For Parents and Carers
Consent Form For Headteachers
Information for BiB Parents Re Dental Decay
Health Economist Questions
Data Collection Protocol
Explanation is provided in summary of changes below.

Is this a modified version of an amendment previously notified and not approved?

( ) Yes (•) No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.
If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

Following ethical approval and research permissions, we undertook data collection between 02.07.19 to 17.07.19. We recruited 49 participants. We've learnt a number of important lessons from this and would like to make the following changes to the project to maximise recruitment.
Please can you consider the following changes:

1. Information for Parents and Carers:
We have made minor changes to the information sheets. These include corrections of spelling mistakes, updating the URL addresses and contact email address, adding a QR code, and changing contact telephone number. We will also provide a new additional QR code and URL address when our YouTube video is translated into Urdu/Murpuri. These changes are outlined in "Information for Parents and Carers V6 29.07.19".

2. Child Participant Information:
We have made minor changes to the information sheet. These include corrections of spelling mistakes and updating the URL address. We will also provide a new URL address when our YouTube video is translated into Urdu/Murpuir. These changes are outlined in "Child participant information V2 29.07.19".

3. Consent Form for Parents or Carers:
After recruitment of the 49 participants, we noted that more than 50% of the parents have filled in their details to attend data collection with their child. However, after contacting them, they were not interested in attending. We therefore rephrased the questions. We have also included corrections of spelling mistakes, updated the contact details (email and phone), and a section about child's history of allergy. These changes are outlined in "Child participant information V6 05.08.19".

4. Consent form for Headteachers:
Updated contact details outlined in "Consent form for Headteachers V2a 02.08.19".

5. Information for BiB Parents Re Dental Decay:
We noted that some children had problems other than tooth decay such as gum disease and malocclusion. We therefore included a line for free text so that our dental team can write in what the problem is. These changes are outlined in "Child participant information V2 29.07.19".

6. Protocol and primary recruitment strategy
The children participating in the birth cohort are slowly getting older (recruitment to the Born in Bradford cohort started in April 2007) and therefore we have changed the upper age range to 12 years old to reflect this.

From our past recruitment experience, we only received 5 letters back out of 207 letters that have been sent via second class mail to the home addresses of BiB parents. Our recruitment team explored the option of sending the letters via school in the child's book bag and we received a further 44 consents returned. We have also corrected spelling mistakes. These changes are outlined in "Research Protocol V3 29.07.19".

7. Health economist questions. Following discussion with the health economist, for children who have had premature extraction of primary teeth, we need to learn more about their dental journey in greater detail. We, therefore, propose to collect the following data about their dental journey. These questions are included in "Description of Dental Care Pathway V3 30.03.2019". A researcher will collect this information either by telephone or by a face to face interview with the parent at the time of taking consent or after dental data has been collected. We have added information to the Parent Information Sheet ("Information for Parents and Carers V6 29.07.19") to reflect that they may be asked about their child's dental journey.

8. Data Collection Protocol
During the pilot study, we found a gauze tissue to be more effective at removing plaque than asking the child to brush their teeth. Once the plaque was removed we could then see the teeth and undertake the dental examination. The changes are outlined in "Data Collection Protocol V4 02.08.19".

9. Adverts
A pull-up banner or poster that describes the study will be used in schools and during community events. This will advertise the study to parents a few days or weeks before the dental data collection is due to take place.

10. Text or email messages to parents
Some school are happy to send out a brief reminder about the study to parents through the school website, social media, email or school-based text messaging service. From experience it is very difficult to exactly specify the content of the message. However, we will ensure that any message is factual (for example "The Bradford Smiles study is coming to school next week. For further information ....."). The message will refer the parents to the URL address for participant information video on youtube video and who to contact for further information about the study.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

None

List of enclosed documents

Document	*Version*	*Date*

Information for Parents and Carers	7	20/08/2019
Child Participant Information	2	29/07/2019
Consent Form for Parents or Carers	7	20/08/2019
Consent form for Headteachers	2	02/08/2019
Information for BiB Parents Re Dental Decay	3	02/08/2019
Research Protocol	4	20/08/2019
Dental Care Pathway	3	30/03/2019
Data Collection Protocol	4	02/08/2019
Pull-up banner	1	09/08/2019

Declaration by Chief Investigator

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I consider that it would be reasonable for the proposed amendment to be implemented.*

This section was signed electronically by peter day on 21/08/2019 09:08.

Job Title/Post:

Organisation:

Email:

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by Mrs Clare Skinner on 21/08/2019 09:42.

Job Title/Post:	Head of Research Integrity and Governance
Organisation:	University of Leeds
Email:	governance-ethics@leeds.ac.uk

Appendix 5.1 Abstract-British Society of Paediatric Dentistry 2021

R3 | Premature extraction, orthodontic need and Quality of Life in Bradford Children

Eman Alnuaimi[1]; Bernadette Drummond[1]; Tiffany Yang[2]; Philip Benson[3]; Peter Day[1]
[1]*University of Leeds, Leeds, United Kingdom;* [2]*Bradford Institute for Health Research, Bradford, United Kingdom;* [3]*University of Sheffield, Sheffield, United Kingdom*

Background: Premature extraction of primary teeth and orthodontic need may influence children's oral health-related quality of life (OHRQoL).
Aim: To investigate the relationship between premature primary tooth extraction, orthodontic need and OHRQoL in children from a multi-ethnic and deprived community.
Methods: Children aged 6–12 years from Born in Bradford birth cohort participating in PLATOON (Premature Loss of rimary Teeth and its impact On the Orthodontic Need) study were identified in one of two groups: Exposure group, who had had premature primary tooth extraction; and Control group, no extractions. Study models and photographs were obtained at school visits and participants completed the COHIP-SF 19. An expert panel of three specialist orthodontists assessed the records for orthodontic need, using the Index of Orthodontic Treatment Need. Differences in COHIP-SF 19 scores by group and orthodontic need were assessed using the Mann-Whitney *U* test.
Results: Complete records for 311 children were assessed ($N = 78$ Exposure group; $N = 233$ Control group) and half ($N = 58$ Exposure group; $N = 98$ Control group) were judged in need of orthodontic treatment. Median COHIP-SF 19 scores were significantly higher for those judged in orthodontic need (17; IQR 12–24) compared to those without need (14; IQR 9–21) ($p < 0.01$). The median COHIP-SF 19 scores were higher in the Exposure group (17; IQR 13–21) compared with Control group (15; IQR 9–22), but this was not significant ($p = 0.09$).
Conclusion: The need for orthodontic treatment may influence children's OHRQoL. Future work should consider whether these relationships differ by sociodemographic groups or gender.
Funding body: British Orthodontic Society Foundation.

R4 | Dental students' perception of online paediatric dentistry and orthodontics education during COVID-19

Alice Bradley; Caryl Wilson-Nagrani; Shannu Bhatia
University Dental Hospital, Cardiff, United Kingdom

Background: The COVID-19 pandemic posed many challenges for the delivery of dental education. Cardiff University had to suspend face-to-face teaching in March 2020. This necessitated the development and delivery of online teaching for our dental students. It is important to evaluate the students' perception of this transition to online teaching and learning.
Aim: This study aims to assess the dental students' perception of the transition to online teaching and learning within Paediatric Dentistry and Orthodontics (PDO).
Method: Year 3, 4 and 5 undergraduate dental students ($N = 215$) at Cardiff University were invited to complete an online questionnaire related to delivery, benefit and engagement with online teaching and learning in PDO. Their views on the impact of COVID-19 on their education, and on continuation of online learning to supplement clinical teaching post-pandemic, were determined.
Results: Data analysis is currently ongoing. A pilot study has shown that 100% of students felt COVID-19 had negatively impacted their educational experience. The majority of students (66.7%) agreed that online seminars were a good alternative to face-to-face lectures; all 100% felt that online learning was necessary to minimise disruption to their education. The complete results of this study will be presented once finalised.
Conclusion: Our student-centred teaching philosophy gives importance to the students' views that will influence future delivery of teaching in PDO. The pilot study revealed that students appreciate the role of online teaching in the continuation of their education; going forward, they would prefer a combination of face-to-face teaching and online teaching.