Families learning about toothbrushing: developing a scalable intervention

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Abstract

Background: Dental caries in children is a preventable condition. In Pakistan, despite high prevalence, there have been minimal efforts to address this public health problem.

Aim: To develop and test feasibility of a behavioural intervention aimed at parents, delivered by Lady Health Workers (LHWs) for oral health promotion of children in Pakistan.

Methods: The PhD used mixed methods approach following MRC guidance on developing and evaluating complex health interventions. The theoretical domains framework (TDF) provided theoretical underpinnings and COM-B model helped analyse drivers for behaviour change. Study 1: systematic review and meta-analysis for effectiveness of behaviour change interventions delivered by non-dental health workers for children's oral health promotion, to identify behaviour change techniques (BCTs). Study 2: focus groups to identify barriers & facilitators for children's toothbrushing and oral health promotion. Study 3: compilation and finalisation of intervention through identification of modifiable behavioural determinants, and patient and public involvement (PPI) to finalise the intervention materials. Study 4: feasibility study for feasibility assessment of intervention (LHW training, intervention delivery and fidelity), and evaluation methods (recruitment strategy, and data collection). Acceptability of intervention and perceived impact/sustainability explored using semi-structured interviews.

Results: Systematic review identified 23 effective studies from which 18 individual BCTs were finalised to form the PROviding Support to Parents for Engaging in their Children's Toothbrushing (PROSPECT) intervention. The feasibility study recruited 7 LHWs and 34 mothers (>100% recruitment), and trained all LHWs who then delivered the intervention during home visits (n=34) with high fidelity. The data collection showed 91% response rate. An overall positive response reported by mothers and LHWs regarding intervention's acceptability, and perceived impact/sustainability.

Conclusion: The results suggest incorporating toothbrushing advice as part of LHWs routine home visits as feasible and acceptable means to promote children's oral health in Pakistan. A definitive trial is needed to test intervention's effectiveness.

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List of Abbreviations

BCTs	Behaviour change techniques
BCW	Behaviour change wheel
BCTTv1	Behaviour change technique taxonomy version 1
CI	Confidence interval
COM-B	Capability opportunity motivation of behaviour
dmfs	decayed, missing, filled surfaces
dmft	decayed, missing, filled teeth
ECC	Early childhood caries
FDI	Fédération Dentaire Internationale or World Dental Federation
FGDs	Focus group discussions
FP&PHC	Programme for family planning and primary health care
GBP	Great Britain Pound
HR	Hazard Ratio
LHS	Lady Health Supervisor
LHW	Lady Health Worker
LHWP	Lady Health Worker Programme
LMICs	Low- and middle-income countries
MMR	Mixed methods research
MoA	Mechanism of action
MRC	Medical Research Council
NIHR	National Institute for Health Research
NRSI	Non-randomised study of intervention

OR	Odds ratio
PI	Predictive interval
PKR	Pakistani Rupee
PPI	Patient and public involvement
RCT	Randomised controlled trial
RR	Relative risk
RRR	Relative risk reduction
SES	Socioeconomic status
SMD	Standardised mean difference
TaT	Theory and techniques tool
TDF	Theoretical domains framework
WHO	World Health Organization

Declaration

I declare that this thesis is a presentation of original work and I am the sole author. This work has not previously been presented for an award at this, or any other, University. All sources are acknowledged as References.

The thesis has partly been disseminated through the following:

Journal article

1. Faisal MR, Mishu MP, Jahangir F, Younes S, Dogar O, Siddiqi K, Torgerson D. The effectiveness of behaviour change interventions delivered by non-dental health workers in promoting children's oral health: A systematic review and meta-analysis. PLoS One. 2022 Jan 11;17(1):e0262118.

Conference abstracts

1. Abstract accepted for poster presentation at British Association for Study of Community Dentistry (BASCD) Spring Scientific meeting 2-3rd April 2020 in Cardiff, Wales. Systematic review of interventions delivered through non-dental primary care professionals and health workers for children's oral health promotion.

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2. Conference presentation through virtual interactive talk at International Association for Dental Research (IADR) General Session and Exhibition virtual conference 22nd June 2022. Promoting Children's Toothbrushing in Pakistan: Feasibility of PROSPECT Intervention.

3. Poster presentation at the University of York Health Sciences Research Showcase 13th July 2022. Development of PROSPECT (PROViding support to parents for engaging in their children's toothbrushing) intervention.

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Section 1: Background

Chapter 1: Overview of the public health problem

1.1 Chapter overview

This chapter comprises of literature review related to children's oral health. Although oral health is a broad term, the focus will be on dental caries, commonly known as dental or tooth decay.

The chapter starts with (Part A) defining the problem through a look at oral health and focusing on dental caries, its epidemiology and impact. It then moves to highlight oral health inequalities in relation to dental caries. Next presented (Part B) are the possible ways of tackling the problem with presentation of evidence regarding key oral health preventive behaviours and interventions focusing on these behaviours for promoting children's oral health. It then moves to describe parental/family level influences on children's oral health behaviours that can influence adoption of healthy oral health behaviours. The final part of this chapter (Part C) is an overview of oral health promotion challenges and how these can be met specifically looking at Pakistan. The chapter ends with a review of frameworks for development of interventions for health promotion and how a development of a theory-based intervention will address the identified challenges.

Part A: The problem

1.2 Children's oral health and problems

Oral health is an integral part of every child's health and wellbeing. Oral diseases have often been referred to as a 'worldwide epidemic' which pose a major public health problem (Jin, Lamster et al., 2016). Despite being largely preventable, oral diseases are highly prevalent and affect almost every person throughout their life course, with negative impacts extending beyond the individual to the community and wider society level (Jin, Lamster et al., 2016, Peres, Macpherson et al., 2019). In order to alleviate the health and economic burden, oral diseases require urgent attention for improving health outcomes and quality of life of the individuals and the families.

Oral diseases comprise of chronic clinical conditions of the teeth, gums and mouth such as dental caries, periodontal (gum) diseases and oral cancers (Heilmann, Tsakos et al., 2015, Peres, Macpherson et al., 2019). The most common oral health condition found in children is tooth decay with periodontal disease and oral cancers affecting older age groups.

The link between oral health and general health has long been a topic of research. Although the oral manifestations of systemic diseases were established very early on, there is an ever growing body of evidence reporting the inextricable relationship between oral and general health (Sabbah, Folayan et al., 2019). For example: a number of studies have reported associations between periodontal diseases and cardiovascular diseases (Joshy, Arora et al., 2016), diabetes (Bascones-Martinez, Matesanz-Perez et al., 2011, Preshaw, Alba et al., 2012), respiratory conditions (Bansal, Khatri et al., 2013) and dementia (Pazos, Leira et al., 2018). Although the causal relationship is not yet clear, the links between oral and general health signify the importance of considering oral health as a part of overall health and general wellbeing.

1.3 Dental caries

1.3.1 Epidemiology

Dental caries refers to demineralisation of the dental hard tissue as a result of acid produced due to bacterial fermentation of dietary carbohydrates (Selwitz, Ismail et al., 2007). These bacteria are present in the plaque which is a biofilm that covers the tooth surface. Dental caries is a multifactorial disease and is a result of complex interplay over time between genetic, behavioural and environmental factors such as salivary

composition and flow, consumption of diets high in sugar and oral hygiene measures such as toothbrushing and exposure to fluorides. (Pitts, Zero et al., 2017, Selwitz, Ismail et al., 2007).

Dental caries is one of the most common chronic disease worldwide. According to the Global Burden of Disease study, which systematically appraised oral conditions data globally in order to produce reliable estimates to enable policy planning and evaluation, untreated dental caries of the primary dentition affects 532 million children worldwide. Upon analysis of trends between 1990-2017, the study also reported an increase in percent change in number of prevalent cases in lower-middle- and low-income countries 15 (95% uncertainty 12.7, 17.6) whereas it decreased in high −12.9 (95% uncertainty −16.3 to −9.6) and upper-middle-income countries −26.6 (95% uncertainty −29.5 to −24.7) (Bernabe, Marcenes et al., 2020).

The research reported on as part of this PhD for oral health promotion of children was carried out in Pakistan which is low-middle-income country (World Bank, 2021). There is a high disease burden of both communicable and non-communicable diseases such as tuberculosis, diabetes, cancers, mental disorders, cardiovascular and respiratory diseases (Jafar, Haaland et al., 2013, Tahseen, Khanzada et al., 2020), with low priority given to oral and dental diseases despite their high prevalence in the country. There is no national epidemiological survey to identify the prevalence of oral conditions in young children and although the data on dental status of young children in Pakistan is limited, but what is available, points to a high prevalence of dental caries. A study by Dawani et al (2012) reported caries prevalence of 51% in children aged 3-6 years residing in the city of Karachi (Dawani, Nisar et al., 2012). Studies in other cities of Pakistan also reported similar high caries prevalence of 40.5% in 3-5 year old children in Lahore (Sufia, Chaudhry et al., 2011), 49% in 3-5 year old children in Islamabad (Masoud, Qazi et al., 2020), 50.9% in 5-6 year old children in Rawalpindi (Mehmood, Faisal et al., 2017). A systematic review and meta-analysis on caries prevalence reported that nearly 60% of population in Pakistan has dental caries (Siddiqui, Alshammary et al., 2020). Although the studies included were of low quality and the prevalence reported is for all age groups, it provides an idea of how prevalent the problem is in Pakistan.

1.3.2 Impacts

The term Early Childhood Caries (ECC) was first introduced in 1999 to facilitate identification and reporting of dental caries of primary dentition in children 5 years of age and younger (Dye, Hsu et al., 2015). ECC is known to develop early in life with rapid progression leading to discomfort and pain, and is often left untreated (Colak, Dülgergil

et al., 2013). Due to their high prevalence and deleterious effect on overall health and oral health related quality of life (OHRQoL) (Filstrup, Briskie et al., 2003), dental caries are a public health problem. Discomfort and pain caused due to untreated decay can result in difficulty eating and chewing, irritability and disturbed sleep, which in turn can negatively impact a child's nutritional intake and body weight (Alkarimi, Watt et al., 2014, Sheiham, 2006). Child's social interaction can be limited due to difficulty talking and smiling and may even result in school absenteeism impacting their ability to learn (Jackson, Vann et al., 2011). Furthermore, the economic burden for treating caries can extend well beyond the immediate family such as parents' taking time off from work to care and provide dental treatment for their child, cost of hospitalisation and treating the child under general anaesthesia (Colak, Dülgergil et al., 2013).

The more severe the caries, the poorer the quality of life has been reported to be (Abanto, Carvalho et al., 2011). Abed and colleagues studied the family impacts of severe dental caries in children from the data of 3859 children aged 5, 8, 12 and 15-years, who participated in the UK's Children's Dental Health Survey 2013. Parents of children who suffered from severe dental caries showed significant negative impacts on family life which were independent of child's or family's sociodemographic characteristics. These included disruption to sleep and normal activities, feeling stressed and guilty, the child needing more attention and having to take time off work (Abed, Bernabe et al., 2019).

Furthermore, a study conducted to examine the changes in OHRQoL of children and their carers after tooth decay in children was treated, showed a significant improvement in both child and parental reports of oral health as well as overall health status (BaniHani, Deery et al., 2018).

1.4 Oral health inequalities

Traditionally, there has been a focus on separating the mouth from the body and considering oral health to be a separate entity from the general health. However, this thought process has evolved over the years and oral health is now considered a "fundamental component of health and physical and mental wellbeing." (Glick, Williams et al., 2017). Furthermore, in the editorial by Glick and colleagues (2017), they summarise the World Dental Federation's (FDI) oral health definition to say that "it exists along the continuum influenced by the values and attitudes of people and communities." (Glick, Williams et al., 2017). This clearly highlights the broader determinants such as physiological, psychosocial, economic and environmental factors at play that can influence a person's oral health.

This multi-level influence is the reason why despite numerous efforts to improve oral health in communities, inequalities still exist. Dental caries has often been dubbed as "disease of deprivation" because of its increased occurrence in socially disadvantaged populations (Masood, Mnatzaganian et al., 2019, Schwendicke, Dörfer et al., 2015).

In a recent study conducted in China to examine whether inequalities related to dental caries are greater due to experience of disease or in its treatment (Qin, Chen et al., 2021), the study reported that there was greater inequality related to treatment of dental caries as compared to experience of the disease. Despite the availability of medical insurance systems in the province, they had not been applied to dental treatments to cover the costs.

On the other hand, a study conducted in the UK reported that despite equal access to dental care in England, there was apparent widening of inequalities in child dental caries (Ravaghi, Hargreaves et al., 2020). This can be explained through the findings of a systematic review and meta-analysis on socioeconomic inequality and caries, which reported that lower socioeconomic position was associated with higher caries experience with findings suggesting stronger association in developed countries (Schwendicke, Dörfer et al., 2015). Although the evidence was graded of low or very low quality, these results are supported by other recent studies. A cross-sectional survey of a population-based birth cohort study in the Netherlands indicated increased prevalence of caries in 6-year old children from low socioeconomic position (van der Tas, Kragt et al., 2017).

Conversely, a cross-sectional study examining the association of child's place of residence and family income with caries experience in pre-school children aged 2-5 years of age residing in an urban city of Lahore, Pakistan, reported that children from upper socioeconomic status had more caries experience as compared to those from lower socioeconomic status (Sufia, Chaudhry et al., 2011).

These results are supported by another study which examined the relationship between socioeconomic status and oral hygiene indicators of school children (2-18 years) attending private and public (state) schools in Pakistan (as an indication of high and low socioeconomic status), which reported no statistically significant difference between caries experience of children attending private and public schools (Khalid, Mahdi et al., 2020).

The reason for this can be attributed to the fact that unlike developed countries, there is no dental health coverage for children in low-and middle-income countries (LMICs) for which reason there is not a disparity seen in accessing services (including preventive

services) between those from lower and higher socioeconomic position. Another explanation is that children belonging to families of higher socioeconomic position, may indulge in a higher sugar diet including consumption of carbonated drinks because of their ability to afford these products (Khalid, Mahdi et al., 2020).

Furthermore, the study by Sufia et al (2011) also reported that the major portion of caries experience was untreated decay with only minimal numbers with filled teeth (0.3% out of total 601 examined). The majority of children (85%) were reported to have cleaned their teeth once daily. Similar findings have been reported by another study examining the feeding and oral hygiene habits of 435 children aged 12-15 months in Pakistan, in which 54% mothers reported having never brushed their children's teeth and 35.9% reported brushing once a day. Moreover, 80.9% reported not brushing their children's teeth at night (Awais, Naheed et al., 2019).

Watt (2007) in his paper, states that individual behaviours are not freely chosen but are determined and conditioned by the social environments in which people live and work. Thus, focusing on social determinants at the structural (public policy) level also termed as the upstream approach, has the most potential for creating social environments needed for adoption and maintenance of good oral health behaviours, rather than the downstream approach which pivots on individual risk factors and behaviours (Watt, 2007). Although a rational argument, backed by evidence and many theories which link social determinants to health outcomes (Marmot and Wilkinson, 2005; Braveman et al., 2011; Marmot and Ellen, 2014), it is at large, easier said than done. The breadth of change required can take considerable amount of time to happen (O'Malley, 2013), especially in developing countries with limited resources.

Furthermore, there is now a growing international consensus on the need for a shift from a high risk approach which focuses solely on high risk groups identified through measures such as screening, towards a combination of high risk approach and population based measures which take into account the social and economic factors at the population level (Burt, 2005, Watt, 2007). Thus, moving towards health promotion research involving public health interventions that support adoption of 'health-enhancing' behaviours and discourages 'health-compromising' behaviours (Sheiham, Alexander et al., 2011). However, in order to produce changes at the structural level through public policy changes which is a complex process (Pollack Porter, Rutkow et al., 2018), it is important to continue to support individuals to adopt healthy behaviours in order to improve their health outcomes.

This section presented literature on high prevalence of dental caries in children and its far- reaching negative effects. There is a clear need to tackle this public health problem. The next section provides evidence on caries preventive behaviours and the multiple level of influences on children's oral health that need to be considered to be able to effectively address the problem.

Part B: The potential solution and influencing factors

1.5 Preventive oral health behaviours

Although dental caries is one of the most chronic childhood conditions with long lasting negative consequences, the crux of the matter is that it is largely preventable. In spite of it being nearly two decades that the FDI called for a shift in focus from a restorative approach to a more preventive one for the management of dental caries (Pitts and Zero, 2016), the translation of this into practice has been slow and even insignificant in low- and middle-income countries.

The 3 key behaviours that have been attributed to dental caries prevention include: regular toothbrushing with fluoride toothpaste, limiting consumption of diets high in sugars and regular dental attendance (Albino and Tiwari, 2016, Marinho, Higgins et al., 2003, Marinho, Worthington et al., 2015, Twetman, 2018).

A systematic review by Harris and colleagues (2004) examining the risk factors for dental caries in young children, reported that good oral hygiene and non-cariogenic diet play an important role in development of dental caries. They also indicated that a balance between 'good habits' such as adequate plaque control and 'bad habits' such as cariogenic diet may still be able to control caries (Harris, Nicoll et al., 2004). Similar findings were reported by Ruxton el at (2010) in which they systematically reviewed studies published between 1995-2006, and reported that caries risk was more reliably predicted by a combination of sugars (amount/frequency), fluoride exposure and food adhesiveness as compared to amount of sugars alone (Ruxton, Gardner et al., 2010).

However, Sheiham and colleagues present a very contrasting viewpoint indicating that sugars are the main cause of caries formation and modifying factors such as fluorides and dental hygiene wouldn't even be needed if this single cause could be tackled, and call for stricter legislation around availability and marketing of sugars (Sheiham and James, 2015).

Interestingly, changing toothbrushing and sugar consumption behaviours can be said to be akin to what has been defined as positive and negative reinforcement as part of operant conditioning theory (Staddon and Cerutti, 2003). As most of the times people already perform some sort of toothbrushing, and in order to achieve the desired behaviour, they would need to add to it. Conversely, to reduce sugar consumption, a person would be required to cut down on a behaviour that they are already enacting.

Although there are conflicting views on which is the most significant risk factor between the two, there is however, a general consensus in the dental community world over about the vital role of toothbrushing, fluorides and dietary sugars in dental caries formation.

In the following sub-sections, I present the evidence for each of these three preventive behaviours: toothbrushing with fluoride toothpaste, dietary and dental visiting behaviour.

1.5.1 Toothbrushing for caries prevention

Toothbrushing with a fluoride toothpaste provides mechanical removal of plaque bio-film which hosts the cariogenic bacteria and availability of fluoride helps strengthen the tooth structure against carious attack. The role of twice daily toothbrushing with a fluoride toothpaste in caries prevention is well established. The Cochrane systematic review and meta-analysis on effectiveness of fluoride toothpaste for preventing caries in children adolescents provided clear evidence of effectiveness of fluoride toothpaste in reduction in development of caries by 24% on average, which was independent of effect of water fluoridation. The review included 74 trials (70 in meta-analysis) which included children up to 16 years of age. It was also reported that higher frequency of use, fluoride concentration and supervised toothbrushing resulted in increased effect of the fluoride toothpaste on caries increment (Marinho, Higgins et al., 2003). Although the review provided little information regarding the effect on deciduous dentition, the included studies were relatively of high quality to provide clear indication of the beneficial effect of toothbrushing with fluoride toothpaste on caries prevention.

Another Cochrane review on fluoride toothpaste of different concentrations for preventing dental caries, reported high certainty of evidence for 1000-1250 parts per million (ppm) fluoride containing toothpaste to be more effective in preventing caries in children and adolescents than a non-fluoride containing toothpaste (Walsh, Worthington et al., 2019).

For younger children, it has been recommended for their parents or caregivers to supervise their toothbrushing until the time they are well capable of managing adequate toothbrushing on their own. Supervised toothbrushing refers to an adult brushing their child's teeth or supervising the child whilst they brush their teeth (Dos Santos, de Oliveira et al., 2018). Similarly, parental supervised toothbrushing has been defined as a dyadic process which involves the parent-child dyad, and entails parent actively brushing their child's teeth with the child allowing his/her teeth to be brushed (Aliakbari, Gray-Burrows et al., 2021a, Elison, Norgate et al., 2014).

Children's supervised toothbrushing can have many direct and indirect advantages which include: making sure children are sufficiently exposed to fluorides daily; are brushing adequately in terms of frequency and duration; develop adequate toothbrushing skills which may translate into adoption of healthy oral health habits; do a better job of toothbrushing knowing that they are being observed and also prevents incidents of children eating or licking toothpaste (Aliakbari, Gray-Burrows et al., 2021a, Dos Santos, de Oliveira et al., 2018).

Many studies have evaluated the results of incorporating supervised toothbrushing programmes as a means to prevent caries in children. In a randomised controlled trial by Curnow et al (2002) conducted in high caries risk 5-year old children in Scotland, to determine the effectiveness of supervised toothbrushing at school- once daily with 1000 ppm fluoride toothpaste and a home support package for reduction in caries on two years' followup, the authors reported high caries risk children showed significant reduction in caries after participating in a supervised toothbrushing programme (Curnow, Pine et al., 2002). In a follow-up study conducted 54 months later of the same trial when children were aged 12 years on average, the authors reported prolonged caries preventive benefits in children belonging to the intervention group (Pine, Curnow et al., 2007). Although the trial reported successful results, they mostly related to caries in permanent dentition- first permanent molars. This was because children already had caries in their primary dentition when they entered the study and for this reason in order to prevent caries in the primary dentition, interventions would need to focus from a younger age of the child.

Furthermore, analysis of the national supervised toothbrushing programme in nurseries of Scotland with provision of home support package revealed an improvement in dental health of 5-year old children which was associated with the nursery toothbrushing programme (Macpherson, Anopa et al., 2013). Although this study did not report individual level data, there was a significant correlation seen in decline of caries experience with uptake of toothbrushing.

Similar significant results have been reported for school-based supervised toothbrushing in a study by Rong et al (2003) in 3-year old children in China (Rong, Bian et al., 2003) and Jackson et al (2005) in 5 year old children in Boroughs of London (Jackson, Newman et al., 2005). However, it is important to note that the study by Jackson et al (2005) was conducted in a deprived community with one of the highest levels of caries in the country, for which reason the results may have limited generalisability to other populations or settings. Also, the authors in study by Rong et al (2003) in China declared

receiving funding from Procter & Gamble company (well-established producer of different toothpaste brands) for their study, hence, potential risk for conflict of interest cannot be eliminated.

Furthermore, recent evidence syntheses regarding the role of supervised toothbrushing in prevention of dental caries in children have presented differing results. A systematic review by Santos et al (2018) evaluating the effects on caries incidence of supervised toothbrushing in children up to 16-years of age, reviewed four studies of supervised toothbrushing that were included in their review, and all were conducted in schools. They reported that due to lack of high quality of evidence, a definitive conclusion regarding the effectiveness of supervised toothbrushing could not be reached (Dos Santos, de Oliveira et al., 2018). The review only included randomised or quasi-randomised controlled trials in which the control group did not receive supervised toothbrushing but was exposed to fluoride toothpaste of the same concentration as the intervention group. Thus, strictly assessing studies on the element of 'supervising' children's toothbrushing at school and whether it showed any difference in caries level between the intervention and control groups.

Lack of strong evidence suggesting caries preventive effect of school-based toothbrushing in children could also be attributed to the fact that it does not consider the home-based practices and parental influence on their children's toothbrushing. Children spend major part of their day at home and this duration is further increased during the school holidays. Furthermore, in the context of current research's study setting where majority of children brush in the morning, usually before going to school, only provision of supervised toothbrushing at school may not prove to be as beneficial.

Another systematic review appraising the studies of home-based, parental supervised toothbrushing interventions for caries prevention in young children (< 8 years of age), reported mixed results of the interventions on children's caries experience. The authors reported that most of the studies (26 out of the 46 included) predominantly involved health practitioner delivering one-to-one sessions aimed at improving knowledge and skills, and only 18 studies reported a theoretical basis for their intervention (Aliakbari, Gray-Burrows et al., 2021b). Health information sessions delivered in a didactic manner have been hardly known to improve health behaviours. Furthermore, just focusing on improving knowledge and skills is not enough to translate this into behaviour change without provision of further support.

Given the evidence of limited impact of school-based toothbrushing in preventing dental caries in the primary dentition, it is important to provide support in the very early years of

a child's life to prevent incidence of caries in the primary dentition. Parenting support groups/network that provide peer-to-peer, non-didactic form of support have been reported as an invaluable resource by parents for receiving child-rearing advice (Elison, Norgate et al., 2014), and have the potential to prevent caries in children's primary dentition (Faisal, Mishu et al., 2022)

Furthermore, the inconclusive evidence for effectiveness of both school-based and home-based supervised toothbrushing interventions in caries prevention can be attributed to low methodological quality of existing studies and lack of theoretical underpinnings of the interventions tested. Future interventions with robust study design and theoretical underpinnings are needed to provide more conclusive results.

1.5.2 Dietary behaviours

Low sugary food intake has been linked to prevention of dental caries as it limits the required substrate for the cariogenic bacteria to ferment and produce acids that can perpetuate tooth decay (Sheiham and James, 2015). Along with the debate of only a very weak association of sugars with caries in the presence of twice daily toothbrushing with fluorides, there are also arguments whether it is the amount or the frequency of sugar intake that can be considered more harmful, with studies supporting each of the reasoning.

Although given the biological model of caries development, the frequency of sugar intake makes sense as repeated exposure to sugars may cause repeated drop in pH resulting in enamel demineralisation. However, studies have suggested that not all separate eating events within a 30-45 minute interval of initial exposure to sugars and drop in pH, necessarily contribute to caries formation (van Loveren, 2019).

On the other hand, a systematic review to inform WHO policy guidelines suggested dose-effect relationship of the dietary sugars on caries formation. It reported moderate quality of evidence when sugar consumption is <10% of energy (E) intake and a significant relationship if intake was reduced to <5% E (Moynihan and Kelly, 2014). However, the evidence for <5% energy intake was judged to be of very low quality mostly based on population studies which can include bias related to difference in prognosis for exposed and unexposed groups and also the different time periods over which data was gathered (ranging from 1950 to 2010) (Freeman, 2014).

The effect of amount or frequency of dietary sugars in caries formation is hard to unpick as there exists a high correlation between the two, such as even if small amounts of sugars are consumed frequently, they can add up to large amounts while it is quite

possible that large amounts are consumed quite frequently (van Loveren, 2019). Furthermore, information regarding dietary intake is invariably collected through self-report measures which are at a high risk of self-report bias.

A recent Cochrane systematic review and meta-analysis on effectiveness of interventions with pregnant women, mothers and other primary caregivers for preventing ECC reported moderate quality of evidence for providing dietary and feeding advice to caregivers of children up to one year of age in slightly reduced risk of ECC. Also, there was insufficient evidence to draw conclusions regarding the effective intervention features that may be effective in preventing ECC (Riggs, Kilpatrick et al., 2019).

Although there is high uncertainty regarding the effect of dietary sugars in caries development, it nevertheless acts as a common risk factor for other systemic diseases such as childhood obesity, diabetes and risk of cardiovascular diseases (Sheiham and Watt, 2000). Thus, depending on the context and practicality, in addition to focusing on toothbrushing with fluoride toothpaste, dietary advice may form part of oral health promotion efforts, in relation to the common risk factor approach.

1.5.3 Dental visits

Regular dental visits provide an opportunity for diagnosis and management of initial problems before they progress to secondary stages and also serves as a platform to provide professional, tailored advice according to an individual's needs (Beil, Rozier et al., 2014).

So far, there has been no strong evidence to link regular dental attendance with better dental health in children with studies suggesting an association both for and against it (Cianetti, Lombardo et al., 2017, Tickle, Williams et al., 1999). Furthermore, despite recommendations for first dental visit to be around child's first birthday, there is no strong evidence to support the age of first dental visit could influence caries outcome in children (Beil, Rozier et al., 2014). Ismail and colleagues investigated caries experience in 1,271 first grade children in Nova Scotia, Canada who had universal access to dental care and concluded that despite having this universal access since birth there were disparities still evident in dental service uptake (Ismail and Sohn, 2001).

The existence of these inequalities in dental service utilisation despite availability of free dental services for children in many developed nations suggests that although an important aspect, however, it is not just mere availability of services that determines regular dental visiting but also the social and cultural influences that moderate the health seeking behaviour of the individuals and families. This can be referred to as the inverse

care law (Hart, 1971), implying that even after removing financial and cost barriers for accessing care, existence of health inequalities means there are other wider social and environmental factors at play (Marmot, 2018, Watt, 2002)

It is not so surprising then that in low-and middle-income countries where there is no availability of universal dental coverage, symptomatic dental visiting is a norm. Reviewing the evidence presented, interventions for improving children's oral health outcomes in these countries may focus on two most significant preventive oral health behaviours: regular toothbrushing with fluoride toothpaste and dietary (limiting sugar intake) advice.

1.6 Parental/family level influences on children's oral health

Children's oral health and behaviours are influenced by "complex interplay of causal factors" (Fisher-Owens, Gansky et al., 2007). The conceptual model of influences on child's oral health produced by Fisher-Owens and colleagues (2007), describe how individual, family and community level influences are at play, categorising them into 5 determinants: genetic and biological factors, health behaviours, social environment, physical environment and dental and medical care. Presented below (Figure 1.1) is an adapted version of the Fisher Owen's conceptual model with child, family and community

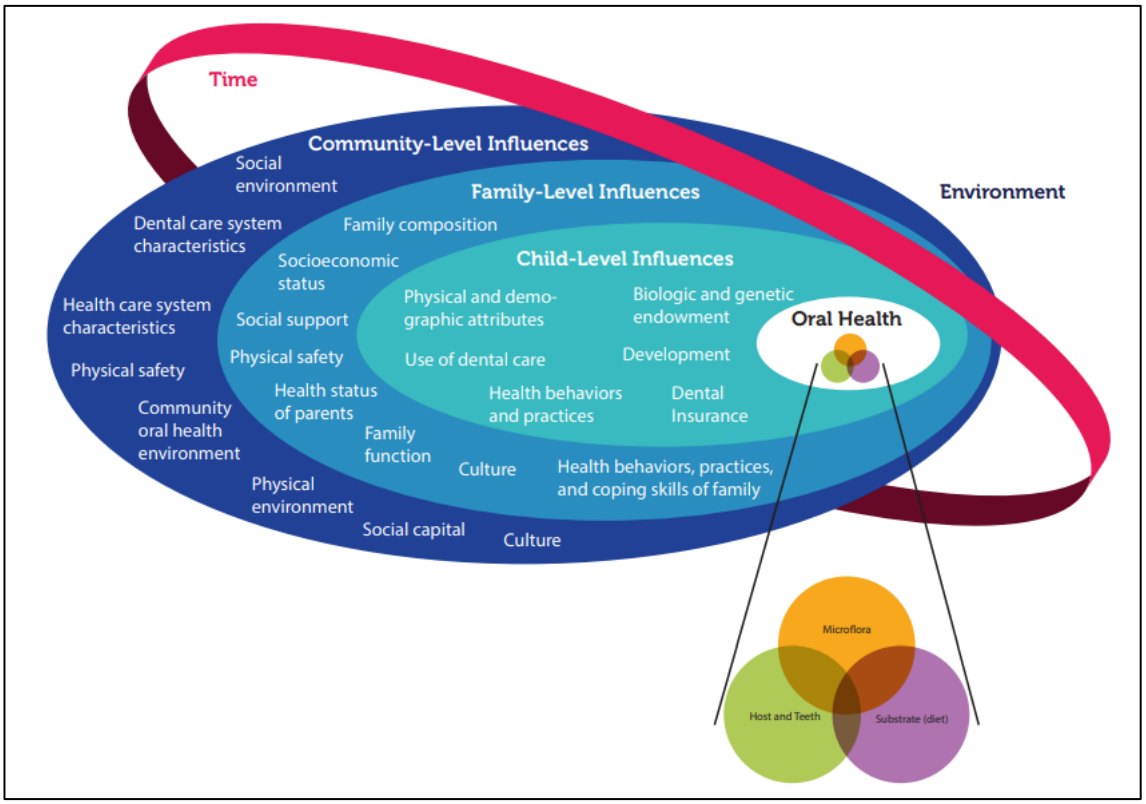


Figure 1.1 Fisher Owens conceptual model of influences on children's oral health. Adapted from WHO Ending Childhood Dental Caries Implementation Manual 2020

level influences (taken from WHO Ending Childhood Dental Caries Implementation manual, 2020) (World Health Organization, 2020).

Between the proximal individual level factors and distal community and environmental level ones, there is a very significant intermediary role played by the parents and family level influences on child's oral health (Duijster, Verrips et al., 2014). Young children are dependent on their parents or caregivers for their developmental and daily needs (Hooley, Skouteris et al., 2012) and so the parental related factors can have a significant effect on their children's oral health and related behaviours. Below I present these different influences on children's oral health, starting with socioeconomic factors, followed by psychosocial factors and parental behaviour and practices.

1.6.1 Socioeconomic factors

The socioeconomic status (SES) is a composite measure of an individual's social standing calculated by using proxy measures such as education, occupation and income level (Baker, 2014). The psychosocial factors include those "mental states, psychological traits, or aspects of the social environment" that can influence health behaviours (Macleod and Davey Smith, 2003). Like many other diseases, oral disease follows a social gradient with people at the top enjoying better health outcomes than those immediately below with the sequence continuing down the social scale (Watt, 2007).

Hamasha and colleagues (2006) in their prospective longitudinal study compared oral health behaviours such as consumption of sugar/soda-based drinks, tooth brushing frequency and dental visits in 6-108 months old children from low and high SES based on family's income and mother's educational level. They reported that children belonging from the low SES had a higher mean score of decayed and filled teeth and higher consumption of sugar/soda based drinks, as compared to those from the higher SES (Hamasha, Warren et al., 2006). Similar results were reported by Saldūnaitė et al (2014) in their study assessing impact of parental SES in dental caries prevention in children aged 7, 9 and 12 years old. Parents belonging from higher SES based on income and educational level were found to be more engaged in their children's preventive oral health behaviours such as twice daily toothbrushing and also scored their children's oral heath better than their counterparts from the low SES group (Saldūnaitė, Bendoraitienė et al., 2014).

There have been studies conducted based on the life course approach which states "various biological and social factors throughout life independently, cumulatively and

interactively influence health and disease in adult life" (Kuh, Ben-Shlomo et al., 2003) to understand how social influences during early life and overtime can influence an individual's oral health status during later age. Poulton et al (2002) reported significant differences in periodontal health status and caries level in adults based on their childhood SES with those from the low SES group doing poorly in these dental measures (Poulton, Caspi et al., 2002). Similarly, tooth loss during adulthood was also significantly associated with low SES during childhood (Celeste, Eyjólfsdóttir et al., 2020, Listl, Broadbent et al., 2018).

1.6.2 Psychosocial factors

Psychosocial factors is an umbrella term which relates to the correlation between the social factors and an individual's mind that influences their health behaviours and wellbeing (da Silva, Alvares de Lima et al., 2018). Examples include maternal stress, depression, sense of coherence, locus of control and self-efficacy that have also been reported to have a profound effect on children's oral health and related behaviours.

The concept of sense of coherence is central to the salutogenic model with other protective psychosocial factors such as locus of control, self-esteem and self-efficacy also related to it (da Silva, Alvares de Lima et al., 2018, Eriksson and Lindström, 2010). The salutogenic model posits that experiences of life help shape one's global orientation viewing life as comprehensible, meaningful and manageable (Mittelmark and Bauer, 2017). It refers to a person's ability to cope with stressors by mobilising resources at their disposal.

The sense of coherence (SoC) concept was first presented by Antonovsky (1987) and refers to the degree to which individuals view life as comprehensive, manageable and meaningful. A stronger sense of SoC leads one to perceive their environment as less chaotic and facilitates the adoption of good health behaviours (Qiu, Wong et al., 2013). The concept of Locus of control (LoC) was first suggested by Rotter in 1954 which refers to an individual's perception of control that they have over things that happen to them (Goddard, 2012). People having an internal LoC means they believe that ability and effort can produce an effect on the things that happen to them, as opposed to an external LoC which refers to the belief that luck or fate is the reason for things happening to them (Kent, Matthews et al., 1984). Self-efficacy refers to one's belief in their ability to perform an action (Zhou, Sun et al., 2015) and is an important construct of many health behaviour theories (Williams and Rhodes, 2016) such as social cognitive theory (Bandura, 1986), protection motivation theory (Rogers and Prentice-Dunn, 1997), health belief model

(Rosenstock, Strecher et al., 1988) and transtheoretical model (Prochaska and DiClemente, 1982).

In a systematic review and meta-analysis on protective psychosocial factors related to dental caries in children and adolescents, da Silva et al (2018) reported mother's high sense of coherence to be protective against dental caries in children whereas low internal parental locus of control was associated with development of dental caries in their children (da Silva, Alvares de Lima et al., 2018). Higher parental self-efficacy was also reported to be associated with their children's preventive oral health behaviours such as toothbrushing and regular dental visits (de Silva-Sanigorski, Ashbolt et al., 2013).

Furthermore, social support, which can be defined as "support accessible to an individual through social ties to other individuals, groups, and the larger community" (Lin, Ensel et al., 1979), has been analysed in many studies undertaken to examine the relationship between social support and oral health. Although the exact mechanism is not yet clear, a number of possible theoretical explanations have been offered. It may act by shaping social norms through spread of information (for example people in the neighbourhood discussing preventive health behaviours), or accessing services through a collective effort, and it has also been theorised as akin to the coping mechanism and may act through the behavioural, psychological and physiological pathways in a downstream manner, to alleviate the effects of stress on health or even as a main factor influencing health behaviours (Brennan and Spencer, 2012, Lin, Ensel et al., 1979, Reynolds, Damiano et al., 2015).

Social support has been found to be negatively associated with dental caries in older children or adolescents independent of socioeconomic status (Bernabé, Stansfeld et al., 2011, Fontanini, Marshman et al., 2015). Nelson et al (2012) studied the mediating effect of the maternal psychosocial factors (stress, coping and social support) in the pathway between early maternal enabling factors (education, cognitive abilities, psychological distress) with caries in their children at the age of 14 years. They reported that greater social support at 3 years of child's age was directly associated with lower caries experience at adolescence (Nelson, Lee et al., 2012).

1.6.3 Behaviour, attitudes and practices

Although the links between socioeconomic conditions and psychosocial factors with children's oral health are well established (Finlayson, Siefert et al., 2007, Reisine and Psoter, 2001), there are other parental and family related factors that have be reported to be significant predictors of children's oral health. These include factors such as

parental attitudes and behaviour regarding their children's oral health, and oral health practices influenced by family structure, functioning and social support.

Adair et al (2004) in their large international study involving 2822 children aged 3-4 years from 17 different countries reported that parental attitudes significantly affect the establishment of healthy oral health habits with cultural and ethnic diversity playing an important role (Adair, Pine et al., 2004).. Similarly, Albino et al (2018) investigated the caries protective parental factors in an indigenous community with high caries prevalence by studying parental factors in caries free children. Parents who were more engaged in their children's preventive oral health behaviours such as regular supervised toothbrushing with fluoride toothpaste and low consumption of sugary food and drinks, these parents believed they had the attitude and ability to positively influence their children's oral health (Albino, Tiwari et al., 2018).

Many other studies have also reported the association between parental oral health attitudes or perceptions with their preschool aged children's oral health behaviours (Bozorgmehr, Hajizamani et al., 2013, Clarke and Shaw-Ridley, 2019, Finlayson, Cabudol et al., 2019).

Some studies have also reported on association of family structure with that of young children's oral health (Hooley, Skouteris et al., 2012). Single parent families, higher birth order and family size were directly proportional to preschool aged children's caries experience (Duijster, Verrips et al., 2014, Julihn, Soares et al., 2020, Sujlana and Pannu, 2015, Wellappuli and Amarasena, 2012). Furthermore, Morita et al (2019) studied whether other family members' such as grandparent's co-residence was linked to pre-schooler's caries experience in Japan. They reported no significant association of grandparents' co-residence with children's caries experience when controlled for socioeconomic status (Morita, Matsuyama et al., 2019). In addition, findings reported by Williams et al (2021) suggest that grandparents' oral health related knowledge, when acting as the primary caregiver, can positively influence their grandchildren's oral health (Williams, Rainchuso et al., 2021). Qiu et al (2013) for their study conducted in China, reported a significant association between lower consumption of sugary foods in children whose primary caregivers were grandparents with a strong sense of coherence (Pitchon, Gomes et al., 2021, Qiu, Wong et al., 2013).

Family functioning has also been found to play a key role in influencing children's oral health. Poor functioning families based on responsiveness, communication and organisation were increasingly associated with engaging in less favourable oral hygiene

behaviours and their children had higher caries experience (Duijster, Verrips et al., 2014).

Furthermore, Stormon and colleagues (2020) in their study using data from a large cross-sequential dual cohort in Australia which recruited 10,090 children, reported consistent parenting styles to be protective of caries in their children (Stormon, Ford et al., 2020).

The importance of consistency and routine has also been evidenced from the international study by Pine, Adair and colleagues (2004) in which they analysed the effect of familial and cultural perceptions, beliefs and oral health behaviour on children's caries experience. After analysing data from 17 countries, the most important predictor reported for children's caries experience which even persisted in children from disadvantaged communities, was parents' ability to incorporate child's toothbrushing in their daily routine (Pine, Adair et al., 2004).

In addition, children's behaviour management issues have also been identified as a significant barrier to implementation of positive oral health behaviours. An online survey-based study of 239 families of 0 to 4-year-old children in Australia examined the barriers for regular toothbrushing of children. The study reported parental oral health knowledge and use of routine as the most important predictors of toothbrushing frequency, whereas most important predictors of difficulty in implementing regular toothbrushing were resistant child behaviour and household organisation (Berzinski, Morawska et al., 2020). Similarly, another study conducted in Australia reporting on development and validity testing of a comprehensive parenting and childhood toothbrushing assessment (PACTA) questionnaire indicated that children were more likely to brush twice a day when parents reported less behaviour problems with use of effective parenting strategies and having better oral health related attitudes and knowledge (Tadakamadla, Mitchell et al., 2021).

The findings suggest that in addition to increased knowledge regarding children's oral health behaviours, parents also need support in managing difficult child behaviour through learning the use of effective parenting strategies which would enable them to better organise and implement a toothbrushing routine for their child(ren).

Moreover, as previously stated, caries experience in the primary dentition has been linked to development of future caries in the permanent dentition (Li and Wang, 2002, Skeie, Raadal et al., 2006) and for this reason it is important to develop preventive oral health behaviours early in an individual's life. Although this would be an ideal situation, in reality there may be existence of various barriers due to the multiple influences at play at the individual, family, social and environmental level. Duijster and colleagues (2015)

qualitatively explored parental views on barriers and facilitators for establishing oral health promoting behaviours in their children to provide an understanding of how they can be better supported (Duijster, de Jong-Lenters et al., 2015). The study reported that children's toothbrushing behaviours were mainly influenced by direct family environment such as: parental related factors (knowledge, perceived importance, confidence and locus of control, role modelling and supervision) and parenting strategy and toothbrushing habits and routines. Consumption of sugary foods was found to be influenced by both direct family related factors and also the social and environment such as schools, media advertisements and affordability of products (Duijster, de Jong-Lenters et al., 2015).

Furthermore, in a study that investigated child's oral health behaviours that prospective mothers intended to implement versus those that they actually implemented, the authors reported that mothers were actually able to implement only some of the child oral health behaviours that they had formerly intended to (Alvey, Divaris et al., 2020). This again suggests that although parents intend to adopt best oral health behaviours for their children, failure to do so indicates a clear need for additional support to help with this.

Thus, based on the evidence of importance of parents implementing a consistent routine to establish favourable oral health behaviours for their children, it is crucial to provide support to families and parents through effective parenting and child behaviour management strategies to help them establish good oral health behaviours for their children, as a way to ensure positive oral health outcomes.

This section presented evidence on caries preventive behaviours and the parent related level of influences that need to be considered when developing interventions to promote children's oral health. In the next section, I present about the oral health promotion efforts and make a case of how oral health promotion largely remains neglected as part of general health promotion in Pakistan. The section then ends with a discussion on importance of theory for developing interventions and how the problems identified can be addressed through this.

Part C: The context for the potential solution

1.7 Oral health promotion and challenges

Given the high prevalence of ECC globally, there have been recommendations put forth to tackle this global burden of disease. In a 3-day WHO global consultation on public health interventions against ECC, specific recommendations were agreed and reported (Phantumvanit, Makino et al., 2018). Some of the key focus areas that were highlighted are:

1. Integration of ECC preventative strategies and initiatives into the existing primary health care systems.

2. Behaviour modifying initiatives should focus on families and communities.

3. Fluoride administration both at the individual and population-level for prevention of ECC.

However, a recent review on oral health policies to tackle the burden of ECC in 14 countries/regions reported that translation of ECC preventive recommendations has been slow or even non-existent in some regions (Chen, Duangthip et al., 2021). The focus of this review was on 14 countries: Australia, Brazil, Cambodia, China, Hong Kong, Egypt, India, Indonesia, Japan, Nigeria, Thailand, UK, USA, and Venezuela. Out of these, three countries (Cambodia, India and Venezuela) did not have any national oral health policy and four countries (Cambodia, China, India and Venezuela) were reported to have no publicly funded dental care programme for young children (Chen, Duangthip et al., 2021). This is similar to the oral health care scenario in Pakistan where there is no national oral health policy along with lack of availability of publicly funded dental care programs for young children (Niaz, Naseem et al., 2013).

Thus, it can be deduced that ECC preventative programs are not yet prioritised in many countries/regions and ECC remains a public health challenge which is further compounded by lack of dental workforce.

The shortage of adequate skilled workforce is one of the grave challenges facing oral health promotion efforts around the globe. In 2008, the WHO published guidelines and recommendations for task shifting. Task shifting is defined as "rational redistribution of tasks among health workforce teams". This implies using the available health workforce efficiently through delegation of tasks from specialist workforce to non-specialist health workers who may have shorter training and fewer qualifications (World Health

Organization, 2008). Although this urgent call was primarily focused on dealing with the rise in HIV/AIDS through increasing access to related health services, the guidance sets out recommendations to increase access to other health services as well.

More recently, in the WHO implementation manual for ending childhood caries, there has been an strong emphasis on involving community health workers to help with the efforts of caries prevention by promoting adoption of positive oral health behaviours for children (World Health Organization, 2020). This seems a rational approach that has the potential to address the limitations created by shortage of dental specialist workforce and also provides an opportunity to focus on early prevention of the disease by intervening early in the life course.

1.7.1 Healthcare delivery system in Pakistan

The healthcare delivery system in Pakistan consists of both public and private sectors which deliver healthcare to the majority of the population. Some government and semi-government institutions such as the armed forces, railways etc also provide healthcare to their employees but this only amounts to 10% of the population (WHO EMRO).

The federal and provincial governments have been jointly responsible for the administration of healthcare whilst the actual delivery of healthcare is mainly implemented at the district level. The healthcare delivery (Figure 1.2) is organised through a three-tiered health delivery system: (1) the primary care facilities provide preventive and promotive health services, while the (2) secondary care, and (3) tertiary care facilities are responsible for provision of curative and rehabilitative services (Hassan, Mahmood et al., 2017).

The primary care is set up to provide services through the Basic Health Units (BHU) which serve a catchment population of up to 25,000 and the Rural Health Centres for catchment area of 100,000 people (Hassan, Mahmood et al., 2017).

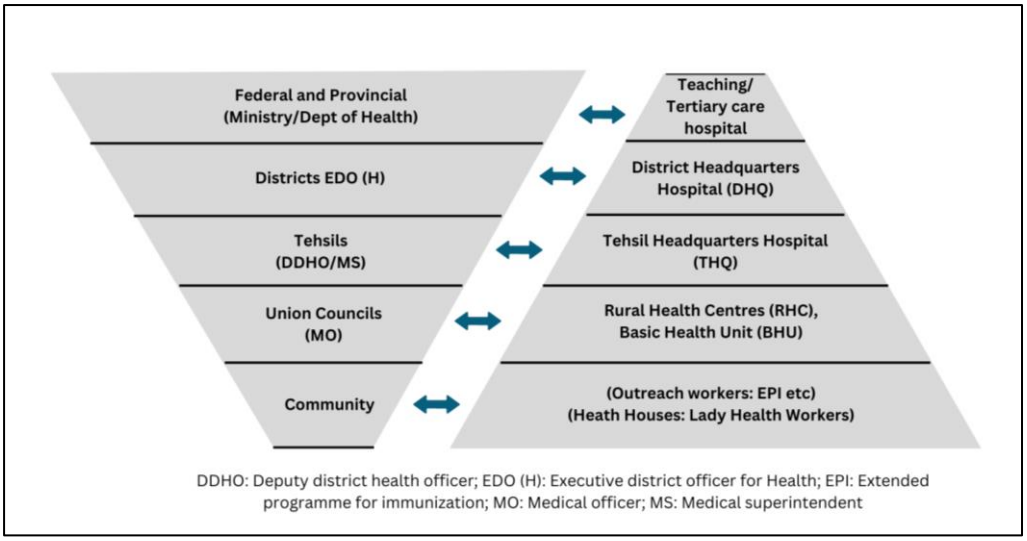


Figure 1.2 Healthcare delivery system in Pakistan (WHO EMRO) (Chaudhry, 2019)

1.7.2 The Lady Health Worker Programme

In Pakistan, under the Ministry of Health Planning Commission, Pakistan (2003), provisions were made to support two community health promotion initiatives: a communication strategy with (1) media focus on behaviour change communication and (2) utilising Lady Health Workers (LHWs) of the National Program for Family Planning and Primary Healthcare (FP&PHC), at the grass root level (Ronis and Nishtar, 2007).

The National Program for Family Planning and Primary Healthcare also commonly known as the Lady Health Worker Programme (LHWP) was established in 1994 as a result of Pakistan's commitment to being a signatory of the Alma-Ata declaration (1978). This declaration was the birth of modern-day Primary Health Care (PHC). According to the Alma-Ata declaration, PHC was defined as "essential healthcare made universally accessible to individuals and families in the community by means acceptable to them, through their full participation and at a cost that the community and country can afford." (Okoro, 2008, World Health Organization, 1978) which has been used synonymously with 'health for all' slogan.

Since its inception, the LHWP has been gradually expanded and scaled up to cover the whole country for delivery of essential primary healthcare. The LHWs link communities with the health services and provide basic preventive and curative services in their community with the main focus on maternal and child health. Some of their main duties include promoting health, hygiene, sanitation, family planning and healthy pregnancy; and provision of essential drugs for minor ailments such as fever, diarrhoea, acute respiratory tract infections and contraceptive materials (Jalal, 2011). They are also involved in implementation of the Extended Programme for Immunization (EPI) including

polio eradication efforts, and awareness for prevention of seasonal diseases such as dengue and malaria, and being forerunners in polio eradication efforts (Chaudhry, 2019).

LHWs are recruited based on stringent criteria of having had minimum 8 years of formal education, being over 18 years of age and resident of the community and preferably married (to avoid staff turn overs as in Pakistan it is quite common for women to move away from their local area to live with her husband after getting married). Each LHW is linked to a health facility- the BHU and the RHC, where she receives her training (15 months basic training and refresher training subsequently), stipend and medical supplies (Nina Zhu, Allen et al., 2014). They mostly work in the rural and semi-urban areas and each LHW serves around 200 houses or a population of 1000-1500 individuals in her catchment area. The LHWs have their office in their home which is called the Health House, from where they provide health services to their community (such as children's vaccinations), in addition to the routine home visits which they conduct on a regular basis (visiting a household every one or two months).

There is a well-established supervisory network that helps manage the quality of work that is being delivered by the LHWs in their community (Hafeez, Mohamud et al., 2011). These include the Lady Health Supervisors (LHS) who routinely oversee the work of 20-25 LHWs, and are attached to the BHU and/or the RHC. At the district level, the District Programme Implementation unit supervises and organises the work of all the LHWs and the LHS in the district (Bechange, Schmidt et al., 2021).

Over more than two decades that the LHWP has been operational, it has undergone several evaluations in order to provide an understanding of system level issues related to its operation, such as the management and supervisory aspects, whilst also focussing on the health outcomes and the processes involved. In the most recent evaluation (Oxford Policy Management, 2019), the level of supervision of LHWs by the LHS was found to meet targets set for most regions of Pakistan, however, a mixed achievement level across various health outcome domains throughout Pakistan has been reported. Strongest impacts were found to be in family planning and maternal care (e.g. proportion of women using modern contraceptive methods, uptake of tetanus injections and use of iron tablets during pregnancy). Comparison with previous levels analysed through demographic health survey (DHS) of Pakistan (2006/07 and 2012/13), the evaluation reported little impact of the LHWP on infant and young childcare, including immunisation rates but a positive impact in polio immunisation was reported. Furthermore, the evaluation report also states that although LHWP misses many marginalised

communities, it does have a strong impact for long term health outcomes for the poorer households that it reaches (Oxford Policy Management, 2019).

The programme has faced systemic challenges such as funding deficits which have resulted in shortage of equipment and supplies, and a decrease in regular trainings offered to the LHWs (Oxford Policy Management, 2019). Additional challenges included cease in LHW recruitment following their regularisation (being a government employee earning a pensionable salary) and increased work responsibilities (such as during polio programmes), leading to shortage of adequately trained staff to work in the communities. Despite these politically influenced systemic issues, the evaluation reported that the stakeholders (both in and out of the government) believe the programme to be a "highly effective and appropriate instrument" when properly managed with appropriate resources (Oxford Policy Management, 2019).

In a systematic review on contextual level influences on performance of community health workers (CHW) in low-and middle-income countries, the authors reported favourable performance in programmes in which CHWs being trusted members of the community, better reflected the cultural diversity of the people in their communities that they served (Kok, Kane et al., 2015). As the LHWs are members of the same community that they serve, their socio-cultural embeddedness places them in a unique position to understand how health and healthcare use is socially and/or culturally influenced within their communities. Furthermore, studies exploring LHWs perspectives about their role in the LHWP reported that belonging from the same community also contributes to high level of trust and acceptability of the LHWs (Afsar and Younus, 2005). Majority of women in Pakistan rely on primary care services for their healthcare needs, to which they may not always have access either due to travelling distance or costs, to nearest primary care centre, or because of women's limited mobility outside the house/community in the rural areas (Chaudhry, 2019). Therefore, LHW's work of delivering door-to-door preventive and curative primary care services helps improve access of women to these services, and for this reason, many women and community members regard the LHWs like a member of their family (Kinshella, Sheikh et al., 2021). Unlike a health professional from outside the community, the comfort level and the rapport that the LHWs share with the people (Tariq and Durrani, 2018), allows them to become agents of change for their communities.

Although the LHWs 'peer relationship', and understanding of the cultural milieu and broader context of people's lives through interaction within their communities, places them in a unique position to improve health outcomes, they themselves need to feel

empowered and supported to do so. For example, they should have the knowledge of the diseases and health conditions, and be also well equipped in softer skills such as communication and problem-solving (Chaudhry, 2019, Redick and Hs, 2014) through provision of adequate training.

A qualitative study based on focus groups and self-report questionnaire methods to explore the knowledge and communication needs of the LHWs and LHS in Pakistan, reported that out of 105 participants recruited, four-fifths of the respondents described their communication skills as moderately sufficient. The workers also reported possessing sufficient level of knowledge on topics of family planning, maternal, newborn and child health, nutrition and EPI. Similar findings have been reported by another qualitative study exploring LHWs (n=62) experiences, in implementing an mHealth application as part of cluster randomised trial for identification and management of women at risk of adverse outcomes from pre-eclampsia in rural Pakistan (Kinshella, Sheikh et al., 2021). The study reported LHWs views on being able to provide better counselling because of increased knowledge and recommendations on the topic after being trained about this as a result of their participation in the study.

In the study by Haq et al (2009), the participants reported use of various techniques to communicate and counsel people in their communities for behaviour change. These included explaining about how better child health leads to better family prospects, tying in the messages with those of religious teachings and even seeking help of other community members such as teachers and counsellors. However, they expressed their wish to be provided with refresher trainings and an opportunity to build their knowledge about other health conditions and diseases which were not part of their curriculum (Haq and Hafeez, 2009), as having sufficient knowledge increased their confidence to provide counselling to the people on the topic. Provision of regular refresher trainings and adequate supervision have been identified as important elements to increase LHW motivation and performance through problem-solving, cross-learning, skill sharing and team work (Aftab, Piryani et al., 2021, Bhutta, Lassi et al., 2010).

Due to the success of the programme in improving health indicators and their widespread reach in almost every house in the community, there has been a growing interest in utilising them to deliver health interventions to provide evidence to support lobbying for health policy changes.

Keeping in view their work focus on maternal and child health, there have been studies conducted to assess the effectiveness of delivery of behavioural interventions such as those for promoting healthy and safe practices during pregnancy (Omer, Mhatre et al.,

2008), providing support to combat maternal depression (Rahman, Malik et al., 2008), improving mother and child nutritional intake (Lhussier, Bangash et al., 2012). These studies concluded that LHWs for promoting health outcomes is a promising avenue especially in resource constrained settings. This not only allows for spreading knowledge in the community but also fosters trust and capacity building and encourages community participation.

The United Nations sustainable development goals (SGDs) 2015-2030, is a global call for action to end poverty and chart a new era of development. The universal health coverage (UHC) which is one of the targets of the sustainable development goals (SGDs), refers to individuals and communities receiving the health services needed without financial hardship (United Nations, 2015). To achieve the target of UHC, the government of Pakistan has developed a UHC benefit package of Pakistan which consists of essential package of health services (EPHS) as a major component (Ministry of National Health Services, 2020). The EPHS laid out 28 interventions to be provided at the community level through the LHWs. However, a recent study by Sohail et al (2021) presenting findings of detailed review of the LHW curriculum to examine its alignment with the 28 suggested interventions, reported significant gaps with adequate coverage of only 13 interventions (46.4%) in the current LHW curriculum. Oral health was identified as one of the topics that need immediate attention along with others such as care of preterm babies, and education on emerging health issues (Sohail, Wajid et al., 2021).

Thus, it is evident that despite the high burden of dental caries in children in Pakistan and availability of a national health care delivery programme which focuses on child and maternal health, oral health promotion still remains a neglected component of overall health promotion.

1.8 Development of health interventions

1.8.1 Role of theory

Development of health promotion intervention is critical to behaviour change (Walker, Kim et al., 2010). Over the recent years, there has been much emphasis laid on use of theory to underpin the development of health interventions. There is now a growing body of evidence to suggest that health interventions that have been developed with a theoretical base are much more likely to be effective than those lacking one (Glanz and Bishop, 2010). Michie and colleagues (2008) explain that an intervention has high chances of being effective if there is an understanding of the causal determinants of

behaviour change (also known as the mechanism of action) and these are targeted through the intervention. Furthermore, they state that theoretically informed interventions can be evaluated to develop an understanding of what works and areas that need improvements for development of better future interventions (Michie, Johnston et al., 2008).

Along with the due consideration given to the theory, it is also important to consider the evidence base. The Medical Research Council put forward a helpful guide to allow intervention developers to work in a systematic manner (Craig, Dieppe et al., 2008).

Although the MRC guidance for developing and evaluating complex interventions allows for systematic development, testing and evaluation of interventions, it lacks sufficient details regarding the intervention development phase which could be challenge for a novice researcher. To provide further guidance in this regard and assimilate work done in this area, O' Cathain et al (2019) conducted a consensus study and produced a guidance detailing the steps to be carried during development of an intervention (O'Cathain, Croot et al., 2019a). The key elements of their guidance is the advocacy for the use of a systematic approach and relying on both theory and evidence for intervention development. Furthermore, they also highlight the importance of involving stakeholders in the intervention development process to make it more contextually relevant (O'Cathain, Croot et al., 2019a).

Context refers to anything that is external to the intervention and may facilitate or hinder its implementation or effects (Moore, Audrey et al., 2015). Context may refer to the physical or the geographical setting where the intervention is intended to be implemented (for example: hospital, health care centres, participants' homes etc), or the cultural, social, economic, political or implementation related factors (funding, organisation, policy etc) (Craig, Di Ruggiero et al., 2018). In order to understand the context, O'Cathain and colleagues suggest different approaches that may be undertaken such as: stakeholder consultations, primary data collection or reviews of evidence (O'Cathain, Croot et al., 2019a).

Thus, it can be said that, health interventions developed systematically on a sound evidence base, with links to theory and with due consideration of the context, have the potential to be better implemented and evaluated, and also be sustainable over a period of time.

1.8.2 Behaviour change techniques

There has been much work done in the recent years to develop a common language that behaviour change intervention developers could speak and understand. This would minimise waste of resources and provide a better understanding of what works to allow for replication to other settings. One of the notable contribution to this work under progress is the development of behaviour change technique taxonomy version 1 (BCTTv1). This provides a standardised way of reporting intervention components. The behaviour change techniques (BCTs) are defined as the 'active ingredients' and are "observable, replicable and irreducible component of an intervention designed to alter or redirect causal processes that regulate behavior." (Michie, Richardson et al., 2013).

The work presented in this thesis uses the BCTTv1 to report on the BCTs identified and selected as part of the intervention development process.

1.8.3 Behaviour change models, theories and frameworks

As explained previously, this is now well established that children's oral health is influenced at multiple levels. With the emphasis on having theoretical underpinnings for health interventions, it is crucial to select, for the development of a behavioural intervention, a health behaviour change model that not only considers individual factors but also the contextual elements.

A critique of the existing models

There have been many different behaviour change theories/models used in oral health research. Some of the commonly used behaviour change models/ theories in oral health promotion research are: theory of planned behaviour (TPB), health belief model (HBM) and the stages of change (SoC) which is also referred to as transtheoretical model. However, a critique of these models/theories is that they lay the responsibility of behaviour change on the individual without considering the influence of wider social and environmental factors (Morris, Marzano et al., 2012).

Theoretical Domains Framework

A plethora of behaviour change models and theories exist, however their varying degrees of complexity, overlapping constructs (conceptual elements) and lack of comprehensiveness make them challenging for use by researchers and practitioners (Dyson and Cowdell, 2021). To address these challenges and the need to make theory more accessible to researchers and practitioners, the theoretical domains framework (TDF) was created by Michie and colleagues (Michie, Johnston et al., 2005). The TDF

was developed through expert consensus and validation to advance the science of implementation research for identification of influences on health professional's behaviour as a result of implementation of evidence-based practice. Since then it has also been extensively used for understanding wide range of barriers and facilitators for health behaviour change related to patients and general population such physical activity, dietary, smoking cessation and oral health behaviours (Campbell, Fergie et al., 2018, Flannery, McHugh et al., 2018, Grady, Seward et al., 2018, Marshman, Ahern et al., 2016, Nathan, Elton et al., 2018), and to facilitate development of health interventions. The TDF allows consideration of multiple levels of influences (individual, social, environmental) and is a comprehensive synthesis of 33 theories of behaviour and behaviour change including 128 separate constructs clustered into 14 domains (theoretical constructs). The initial developed version contained 12 domains (Michie, Johnston et al., 2005) and was later updated and validated to contain 14 domains (Cane, O'Connor et al., 2012). The TDF domains are: knowledge; skills; social/professional role and identity; beliefs about capabilities; optimism; beliefs about consequences; reinforcement; intentions; goals; memory, attention and decision processes; environmental context and resources; social influences; emotion; behavioural regulation (Atkins, Francis et al., 2017, Cane, O'Connor et al., 2012, Cowdell and Dyson, 2019).

The TDF is a method that can help explain behaviours theoretically in order to understand which behaviour processes need to be targeted for behaviour to change (Alexander, Brijnath et al., 2014, Michie, Johnston et al., 2005). It basically provides a 'theoretical lens' to analyse the cognitive, affective, social and environmental influences on behaviour, and itself does not propose any testable relationship between different elements (Atkins, Francis et al., 2017).

COM-B Model

The COM-B model or framework was developed by Michie and colleagues (2011), as a means for characterising interventions into three key domains: *capability (C), opportunity (O) and motivation (M),* that interact to predict behaviour (B). According to the developers, the model "represents the observation that at any given moment, a particular behaviour will occur only when the person concerned has the capability and opportunity to engage in the behaviour and is more motivated to enact that behaviour than any other behaviours" (West and Michie, 2020). This process along with definition of different components is presented below (Figure 1.2) as illustrated by the developers.

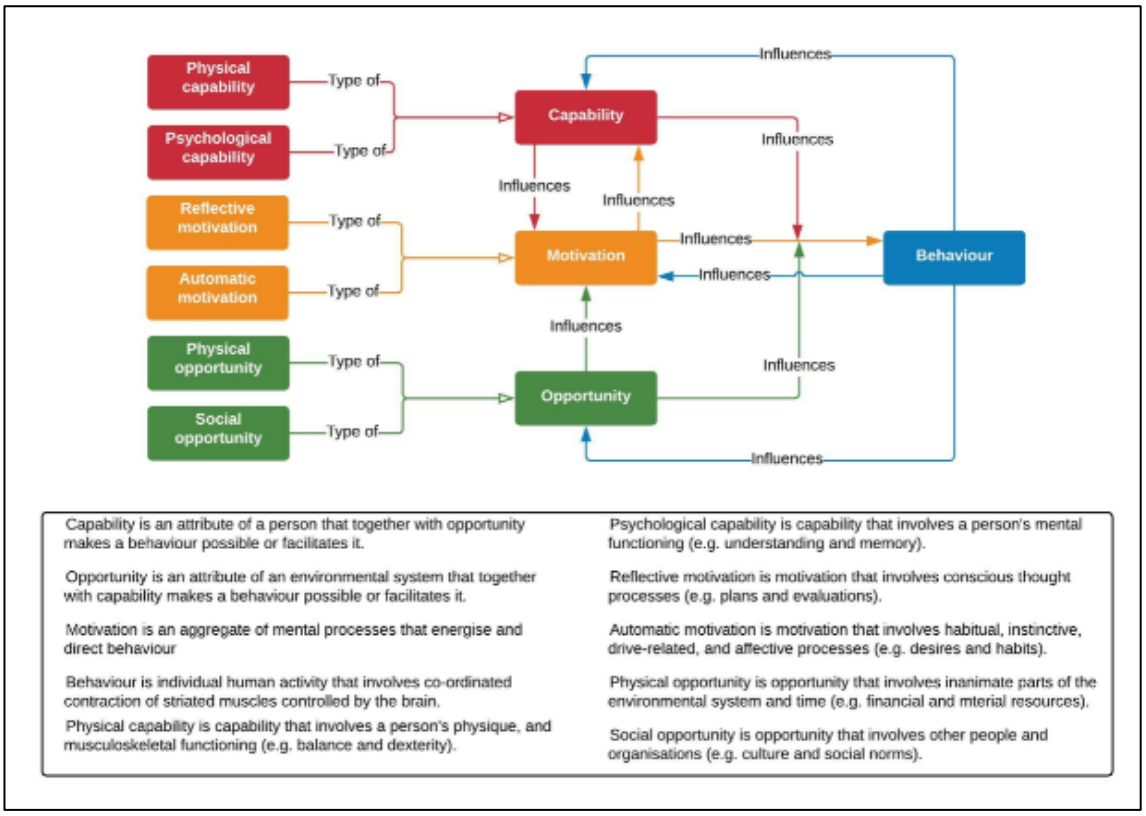


Figure 1.2 Workings of COM-B model (taken from West and Michie 2020)

The process as depicted in the figure has been explained as follows (West and Michie, 2020):

- Capability and opportunity influence the relationship between motivation and behaviour instead of directly acting on the behaviour. In other words, the more capable we feel of performing a behaviour and more conducive the environment is for enacting the behaviour, the more likely we are going to indulge in it and vice versa.
- Behaviour feeds back through both positive and negative cycles, to all three components: capability, opportunity and motivation. For example, learning to drive leads to increase in capability through skill acquirement which in turn influences motivation to engage in the behaviour. Negative feedback can be explained through homeostatic drives such as eating behaviour- eating more leads to decrease in drive to eat.
- In a given situation, capability and opportunity permitting, motivation can be thought of in quantitative terms. In other words, it can be considered that motivation involves competition against alternative behaviours- such that getting someone to enact a behaviour might mean decreasing the motivation to engage

in competing behaviour as much as increasing the motivation for that behaviour (West and Michie, 2020).

Another advantage of using both TDF and COM-B model is that they have been linked to each other (Figure 1.3), such that all of the 14 domains of TDF map to the 3 domains of COM-B model, thus offering a simpler approach to determining the influencers of behaviour. Hence, TDF provides a more granular approach to establishing the behavioural determinants- spread out as 14 domains, whilst COM-B model categorises them under 3 key influencers (Dyson and Cowdell, 2021, Richardson, Khouja et al., 2019).

Figure 1.3 The TDF linked to COM-B model (as presented by Michie et al., 2011)

The COM-B forms the hub of the behaviour change wheel which is an elaborate system devised to make the intervention development process systematic and easily understandable for researchers and health practitioners. Based on the salient features of the TDF and the COM-B, intervention components (BCTs), intervention functions and policy categories can be selected, thus providing guidance on identifying elements of an

intervention that will help achieve change in behaviour (Michie, Van Stralen et al., 2011, Richardson, Khouja et al., 2019).

The focus of this research will be based primarily on TDF and COM-B model to both develop, and test feasibility and acceptability of a behaviour change intervention for promoting children's oral health in Pakistan.

Chapter summary

This review chapter highlights that tooth decay in children is a public health problem both in Pakistan and elsewhere in the world, which can have significant impacts on physical health and wellbeing of the child and the family with economic repercussions extending beyond the family. The review presented the evidence for toothbrushing, dietary and dental visiting behaviours for prevention of dental caries and as children are dependent on their parents or caregivers, it is important to consider parental/family related factors while developing strategies for children's oral health promotion. The following problems statements and potential solution have been identified from the review:

- **Problem statement and analysis**:
  Despite dental caries being preventable, it poses a public health problem in Pakistan. There is a need for high quality intervention studies (randomised controlled trials) with robust methodologies (evidence based along with involvement of stakeholders) *and* a theoretical base to provide evidence for addressing this problem.
- **Potential solution and barriers/facilitators to the potential solution**:
  There is clear evidence for effectiveness of toothbrushing and fluorides in preventing caries, however, in order to build effective preventive strategies, wider factors (such as social and environmental factors) need to be considered to provide adequate support to parents/families to enable them to adopt healthy oral health behaviours for their children.
- **Context for the solution**:
  Specifically, in Pakistan, despite the high prevalence of dental caries and availability of a successful national primary health care network, the LHWP, oral health has not been a part of the health promotion efforts. Due to the nature of their work, LHWs are in a strategic position to deliver support to mothers/families for adopting healthy oral health behaviours from early in child's life. Thus, an opportunity to focus on early prevention of the disease.
- **Frameworks to further develop the solution:**
  Many health behaviour change theories/models place responsibility on the individual for changing behaviour. In order to consider wider factors which may influence the behaviour change, it is important to use theoretical frameworks that take into account these wider influences.

In the next chapter, I present how this PhD research aims to address the problems identified through the potential solution stated.

Chapter 2: Aims and overview of methods

2.1 Rationale

The literature presented in the past chapter highlights the high prevalence of dental caries in children in Pakistan and lack of preventive programmes to address this public health problem. Given the early initiation of disease in a child's life, it is important that children's parents or caregivers be supported for early adoption of positive oral health behaviours for their children. As presented in the previous chapter, there is clear evidence of role of toothbrushing and fluorides in prevention of dental caries. Moreover, studies have reported that people already engage in some sort of toothbrushing behaviours, and the view is to enhance those behaviours to reach the recommended level. On the other hand, evidence suggests dietary behaviours are harder to change which may be because they are socio-culturally embedded in a society and/or supporting to change them may require significant environmental (decreasing availability of low-priced, high sugar foods such as sweets, confectionary items, sugar sweetened beverages in/near schools), and policy level changes (e.g. subsidised costs of healthier food options such as fruits and vegetables, increased taxation on foods high in sugar), in addition to those at the individual level. Therefore, the focus of this PhD research will be on promoting positive oral health practices for young children, through delivery of a behavioural intervention to provide the opportunity, and increase the capability and motivation of mothers/families to engage in their children's toothbrushing behaviours.

Along with the aim to promote health and prevent diseases in their community, the Lady Health Worker programme in Pakistan primarily focuses on improving maternal and child health through provision of basic curative and preventive health services. Due to the nature of their work, they are in a strategic position to promote children's oral health and support families in improving children's oral health outcomes. Although, given the high dental caries prevalence in children, including oral health promotion as part of LHWs duties may seem a natural extension of health promotion strategies implemented in the country, however, this has not been the case so far. Hence, in order to address these gaps in research, it is important, to develop and test a behavioural intervention that would promote children's oral health in the community through provision of support to parents for adoption of healthy oral health behaviours for their children.

2.2 Aims

The overall aim of this research was:

To develop and test the feasibility of a behavioural intervention aimed at parents and delivered by Lady Health Workers for oral health promotion of children in Pakistan

This aim was divided into following secondary aims that relate to the 4 individual studies conducted as part of this thesis:

- To assess the effectiveness of interventions delivered by non-dental health professionals and health workers and (BCTs) used in effective interventions for promoting children's oral health.
- To explore the barriers and facilitators for children's toothbrushing practice and promotion.
- To map the BCTs based on previous evidence of effectiveness to the TDF alongside the barriers and facilitators, in order to identify the modifiable behaviour determinants, and to finalise the intervention components through stakeholder consultation.
- To assess the feasibility of the intervention and its evaluation design.

Further details about the objectives in relation to each study are presented as part of the individual studies. Next in this chapter, I present details about the mixed methods approach that has been used to address the research aims.

2.3 Mixed methods design

Using a mixed methods research (MMR) design entails 'mixing' quantitative and qualitative methods to answer research questions which might not be possible if a single method alone was used (Shorten and Smith, 2017). It can be defined as:

"*Mixed methods research is the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e. g., use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the broad purposes of breadth and depth of understanding and corroboration."* (Johnson, Onwuegbuzie et al., 2007).

The quantitative and qualitive research differ on their ontological (nature of reality) and epistemological (how knowledge is created) philosophical assumptions which are "basic

set of beliefs or assumptions that guide inquiries" (Creswell and Clark, 2017) . The quantitative research approach is typically associated with a post-positivist worldview in which claims for knowledge are made based on cause-and-effect thinking, study of select variables through detailed observation and measures and testing theories for refinement. On the other hand, qualitative approaches are often associated with constructivism which proposes that a researcher develops subjective meanings of a phenomena by relying on participants' views (Creswell and Clark, 2017).

Mixed methods research has often been associated with the pragmatist paradigm and embraces the plurality of methods with orientation towards what works best to answer the research question (Creswell and Clark, 2017, Kaushik and Walsh, 2019, Tashakkori, Teddlie et al., 1998). Thus, mixed methods research draws on the strengths of individual quantitative and qualitative approaches to address the research problem (Fetters, Curry et al., 2013).

Three core designs have been outlined by Creswell & Clark (2017) for conducting mixed methods research. These include: 1. convergent design in which a quantitative and qualitative data is collected and analysed concurrently and then their results are combined together; 2. explanatory sequential design in which initial quantitative phase is followed by qualitative enquiry to explain the quantitative results; 3. exploratory sequential design in which qualitative data is collected and analysed first in order to develop a tool or an approach to be tested quantitatively. The use of upper or lowercase letters depicts the priority or importance of quantitative or qualitative elements in the research design (Creswell and Clark, 2017).

This PhD research is based on the typology (classification of different designs) of multi-phase design which is a type of mixed methods research design in which different concurrent and/or sequential strands collected over a period of time as part of different phases, are used within an overall programme of study (Creswell and Clark, 2011, Guest and Fleming, 2014, Schoonenboom and Johnson, 2017). Figure 2.1 depicts the multi-phase mixed methods design used.

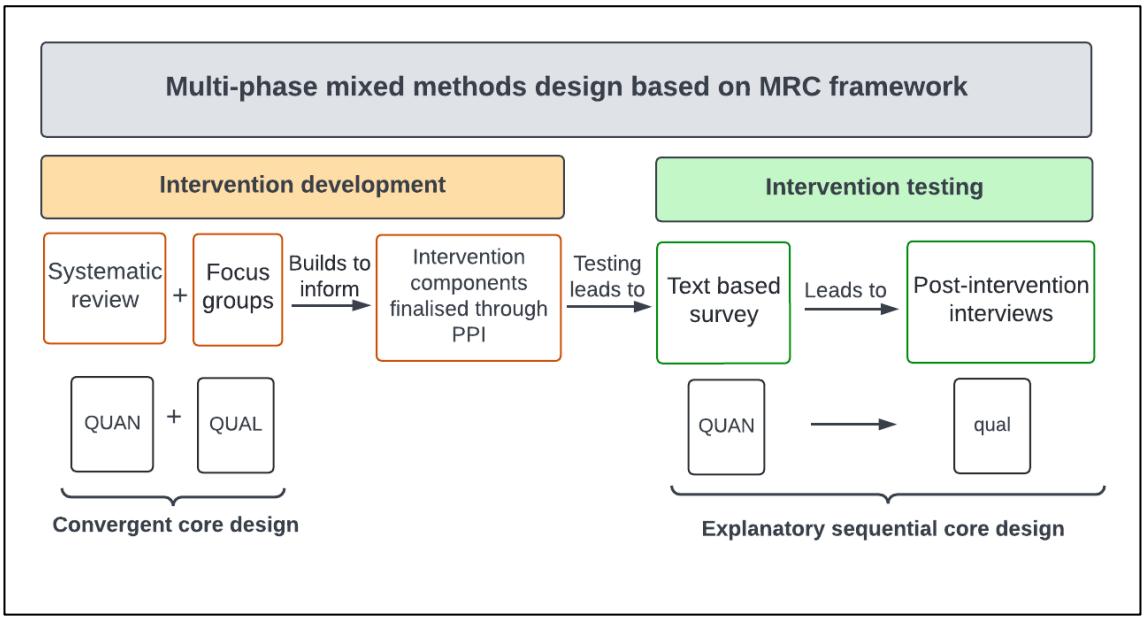


Figure 2.1 Multi-phase mixed methods design used as part of the PhD research

The order of quantitative and qualitative strands was predetermined from the start of the research, thus following the fixed methods design as opposed to emergent designs in which the need to use mixed methods emerges during the process of research. Table 2.1 provides a summary of the different studies conducted, their aims, development framework used, and methods employed as part of this PhD research. In the next section each of the studies are presented in detail.

Table 2.1 Summary of the overall programme of research

<table>
<tr><td rowspan="2">Study Aims</td><td colspan="2">Stage A</td><td>Stage B</td><td>Stage C</td></tr>
<tr><td colspan="2">1: Identifying BCTs from effective interventions delivered by non-dental health workers

2: Exploring barriers and facilitators for children's toothbrushing (parents and LHWs perspectives)</td><td>3: Identifying modifiable behaviour determinants through mapping of BCTs, barriers & facilitators, and to finalise the intervention components through PPI</td><td>4: Assessing feasibility of the intervention and its evaluation design</td></tr>
<tr><td rowspan="2">MRC Framework</td><td colspan="3">Development phase</td><td>Feasibility/piloting phase</td></tr>
<tr><td>Identify evidence base</td><td>Identify Theory</td><td>Modelling process and outcomes</td><td>Testing procedure</td></tr>
<tr><td rowspan="2">Mixed Method Approach</td><td colspan="4">Multi-phase design</td></tr>
<tr><td colspan="4">Convergent → Intervention development → Explanatory sequential</td></tr>
<tr><td rowspan="2">Research Method</td><td colspan="4">Design</td></tr>
<tr><td>Systematic Review</td><td>Focus groups</td><td>Intervention development through PPI</td><td>Feasibility study with post-intervention interviews</td></tr>
</table>

Section 2: Methods and results

Chapter 3: Systematic review and meta-analysis

3.1 Chapter overview

This chapter provides a systematic review of studies that have quantified children's oral health promotion interventions, and examines their effects in decreasing dental caries prevalence (through meta-analyses) and/or improving oral health related behaviours. The key purpose of this chapter is to identify promising interventions that can provide a basis for developing an oral health intervention to be delivered by LHWs in Pakistan.

The introduction section (3.2) provides a brief overview of the literature that is available on the topic and presents the rationale for conducting this review and what this study adds to the current literature. The sections 3.4 present details of the methods used and how the result have been synthesised. This is followed by the results section (3.5) including the findings of the result syntheses. The discussion section (3.6) considers the findings in relation to the existing literature, and presents the strengths and the limitations of the current study and the research recommendations. The chapter ends with conclusion (3.7).

3.2 Introduction

As highlighted in the previous chapter (chapter 1), oral health inequalities still exist both in high- and low-income countries, posing a serious public health concern despite numerous strategies and programmes undertaken to overcome them. This is very disconcerting in view of the fact that dental diseases in children are largely preventable albeit significantly moderated by behaviour change. The key to bringing about behaviour change is to first understand people's social behaviour and what works and what doesn't in different contexts (Davies, Terhorst et al., 2015).

Many studies have examined the results of integrating oral health promotion of children in existing primary care networks or health care delivery systems, however very few attempts have been made at summarising this literature (Abou El Fadl, Blair et al., 2016, George, Sousa et al., 2019, Menegaz, Silva et al., 2018). The previous literature reviews conducted on the topic have limited their focus on either type of intervention (educational interventions in dental or non-dental setting (Menegaz, Silva et al., 2018)), type of intervention delivery personnel (nurses or midwives only) (Abou El Fadl, Blair et al., 2016), or have assessed outcomes of interventions targeting mothers of very young children, up to 24 months of age (George, Sousa et al., 2019).

A more recently published systematic review presenting evidence synthesis of home-based toothbrushing interventions to reduce dental caries in children presented their findings based on the barriers that the individual studies attempted to cover through the delivery of the intervention (Aliakbari, Gray-Burrows et al., 2021b). In each of these reviews, due to the various methodological considerations, only a narrative synthesis has been presented. In order to evaluate the effectiveness of the interventions, there needs to be a quantification of results. Furthermore, to facilitate development of future interventions that can draw upon the results of previous effective interventions, it is important to identify the individual intervention components or the BCTs used in them. These BCTs are the 'active ingredient' of an intervention that can regulate the process of behaviour change.

In order to fill these knowledge gaps, two previously validated tools have been used in this systematic review (1) to aid reporting of interventions, the template for intervention description and replication (TIDieR) checklist (Hoffmann, Glasziou et al., 2014), and (2) the BCTTv1 for identification of the BCTs as part of individual interventions (Michie, Richardson et al., 2013). The TIDieR checklist was developed to improve reporting of interventions in studies for reliable implementation of effective interventions in other settings, or to build on previous research findings. It is a 12- item checklist (brief name,

why, what (materials), what (procedure), who provided, how, where, when and how much, tailoring, modifications, how well (planned), how well (actual)) and is an extension of the CONSORT 2010 statement (item 5) and the SPIRIT 2013 statement (item 11), developed by international experts (Hoffmann et al., 2014). Although the emphasis of checklist is on trials, it can be effectively applied to other evaluative study designs as well. The BCTTv1 which was developed to aid in consistency of intervention reporting, for the purpose of evaluation and replication, was used for BCT coding (Michie, Richardson et al., 2013). Both these tools have been widely used in systematic reviews of health interventions but their use in systematic reviews of oral health interventions has been limited.

3.3 Aim & objectives

This systematic review is an attempt to use a systematic, rigorous and transparent approach to synthesise evidence on effectiveness of oral health promotion of children through non-dental health professionals and health workers to provide evidence base for development of a behavioural intervention, to be delivered by LHWs in Pakistan for promoting children's oral health.

The specific objectives were:

1. To provide detailed description of previously tested interventions using the TIDieR checklist.
2. To determine the effectiveness of interventions delivered through non-dental health care professionals and health workers for children’s oral health promotion.
3. To identify the BCTs used in effective interventions by using the BCTTv1.

The review protocol was developed following the guidance provided in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis for Protocols 2015 (PRISMA-P) to ensure systematic and transparent reporting.

The PROSPERO (Centre for Reviews and Dissemination, 2013) was searched in February 2019 for any ongoing reviews on this topic and as none were identified, the review protocol was submitted for registration on 6th July 2019 and was accepted for registration on 6th August 2019 (CRD42019139401).

3.4 Methods

3.4.1 Eligibility criteria

The study eligibility for the review, based on its characteristics was determined using the mnemonic PICOS (Participants, Intervention, Comparison, Outcome, Study design).

Participants

Pregnant women, mothers or parents of children aged 0 to 7 years. The age range of children for studies' inclusion was set 0 to 7 years. This was done to provide assessment for caries in the primary dentition. The lower age limit was ascertained to include pregnant women and mothers' of newborn children. The upper age limit was decided based on recommendation of Public Health England (2017) for parental supervised toothbrushing of children up to at least 7 years of age (Public Health England, 2017), in order not to inadvertently exclude studies with interventions to promote parental supervised toothbrushing.

Studies involving children with special healthcare needs or any systemic illness were excluded. As the focus of the review was on those non-dental health professionals and health workers who had the opportunity to come into regular contact with children's caregivers, hence studies in which the delivery team consisted solely of non-dental health professionals such as physicians, paediatricians, obstetricians, any active member of the dental professional team such as dental nurse, dental hygienists, dental therapists or dentists were also excluded.

Intervention

Studies with following interventions were eligible for inclusion in the review.

1. Nature of intervention

   Oral health interventions including preventive or behaviour change interventions with either an educational component, and/or for improving skills and/or eliciting behaviour change.

2. Delivery method

   Delivered by non-dental nurses or midwives or community health workers or lay health workers including health volunteers or peer support groups.

3. Target population

   Pregnant women, mothers or parents of children aged 0-7 years.

4. Designed to achieve

   Improved oral health outcomes in their children measured either as clinical and/or behavioural outcomes.

Studies were excluded if they:

- Consisted of interventions focusing on primary outcome of the parent(s)/primary caregiver rather than that of their children.
- Were delivered and/or supervised by teachers at schools.
- Evaluated only the effect of preventive or restorative treatment (e.g. Atraumatic Restorative Technique (ART), fluoride varnish application etc.).

Comparison

Control group with usual care or other interventions.

Outcome

Studies were included if they measured at least one of the following outcomes for study and comparison group.

Main outcomes:

- Change in clinical oral health status of children indicated by caries index and/or plaque or gingival/periodontal index.
- Change in oral health behaviours such as tooth brushing, dietary behaviours, use of dental services.

Additional outcomes:

- Change in oral health related knowledge of parent(s)/caregiver(s) of children
- Oral Health related Quality of Life (OHRQoL) of parent(s) and/or children.

Study design

As the purpose of this systematic review was to evaluate the intervention components that are effective in improving oral health behaviours, trials such as randomised controlled trials (RCT), cluster-RCT, feasibility and pilot studies of trials were included. As the focus was on studies of interventions, quasi-experimental designs and controlled before and after studies (CBA) study designs were also included. A systematic review design was chosen over 'traditional' narrative reviews because it is a transparent, replicable approach and is less likely to produce biased findings compared with the traditional literature review. As a systematic review consists of including all of eligible studies it avoids the reviewer from 'cherry picking' or selecting only studies that confirm the reviewer's pre-existing view of the world (Rudnicka and Owen, 2012).

3.4.2 Study selection

Search strategy

The search strategy was developed by reviewing the previous systematic reviews published on similar topics and refined through consultation with the University of York Health Sciences Liaison Librarian. The search strategy was developed in Medline (OVID) using keywords derived from: *children, parents, oral health promotion, oral health education, dental caries, toothbrushing, primary care, nurses, mid-wives, community health workers* (Appendix 3.1: Systematic review search strategy (Medline). A combination of key terms and subject headings was used and to ensure all relevant subject headings were included, the data function 'map to subject heading' was used. The subject headings were exploded and sub-headings relevant to the topic were included. The same search strategy was modified according to the database searched.

Study design filter

Study design filter previously developed and tested were applied to only include randomised trials (Cochrane highly sensitive search strategy for identifying randomised trials in Medline) (Higgins and Green, 2011), and non-randomised studies of interventions including quasi-experimental studies and pretest-posttest study designs (Glanville, Eyers et al., 2017) (Appendix 3.1).

This was appended to the search strategy using the Boolean operator 'AND' and applied only in Medline database. No search filter was applied in other databases searched as use in them has not been verified.

Country & Language

No restrictions were placed on the type of country the studies were conducted in, however, studies published only in English language were included.

Publication type

Only published studies where full text was available through University of York Library subscription or interlibrary loan, or could be accessed through Open Access Publishing, were included. Conference abstracts were excluded due to the possibility of insufficient details provided for assessment of relevance based on inclusion/exclusion criteria and time constraints limited the possibility of writing to authors to seek further information.

Sample size

No limits on sample size were specified.

Publication date

There were no date restrictions placed and studies were included if published from database inception till March 2019.

3.4.3 Information sources

Databases

Following databases were searched:

- Medline via OvidSP
- PubMed
- Cochrane Library including CENTRAL (Cochrane Controlled Register of Trials)
- CINAHL (Cumulative Index of Nursing and Allied Health Literature)
- Web of Science
- TRoPHI (Trials Register of Promoting Health Interventions)

Grey Literature

Grey literature refers to material that has not been through a formal publication process. Theses as grey literature source were searched via ProQuest.

Reference list searching

Hand searching of reference lists of previous systematic reviews on similar topic and reference lists of articles included in the final stage of the search were checked for any additional relevant articles.

3.4.4 Study screening

The study screening and selection process was performed between April and July 2019. Search results were imported into EndNote (X9 desktop) and after removing duplicates, titles and abstracts of all retrieved searches were reviewed independently by two reviewers (MRF and FJ), against the inclusion and exclusion criteria.

3.4.5 Data Collection Process

Using guidance from the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0, section 7.5 (Higgins, 2011) a data extraction form was developed which was reviewed by the supervisors and pilot tested for data extraction of five studies to ensure it provided sufficient information based on the objectives of the review. Two reviewers (MRF and MPM) independently reviewed the full text of articles for data extraction purpose and quality appraisal. Regular meetings were held to review the findings and to resolve any disagreements.

Study characteristics

For each study, data was extracted for: the study title, design, setting, eligibility criteria of participants, sample size, and baseline characteristics of participants. For details about the intervention delivery or programme implementation, the template for intervention description and replication (TIDieR) checklist was used.

3.4.6 Quality Assessment

In order for reviewers to make judgement about the interventions effects, it is necessary to assess whether the results of the studies included are valid. The risk of bias assessment of studies provides information about their internal validity (section 8.1) (Higgins, 2011). Thus, the quality assessment of included studies included risk of bias assessment.

Risk of bias

The RCTs and quasi-experimental studies have different risk of bias related to their study design, hence they require assessment accordingly. For risk of bias assessment in RCTs, the Cochrane risk of bias (RoB) assessment tool was used (Higgins, Altman et al., 2011), and for quasi-experimental designs or non-randomised studies of intervention (NRSI), the Cochrane group recommended tool, ROBINS-I (Risk of Bias in Non-randomised Studies-of Intervention) was used (Higgins, Thomas et al., 2019, Sterne, Hernán et al., 2016)

The Cochrane RoB tool was used to assess studies for bias in six domains: selection bias, performance bias, detection bias, attrition bias, reporting bias and other bias. For each domain the studies were rated as low risk, high risk or unclear risk and an overall judgement of risk of bias across all domains within a study provided (Higgins, Altman et al., 2011).

The ROBINS-I tool facilitated the risk of bias assessment in quasi-experimental and NRSI by evaluating each study on four domains: confounding bias, selection bias, information bias and reporting bias. Each study was rated as: low risk, moderate risk, serious risk or critical risk for each domain and an overall judgement provided based on risk across all the domains within the study (Higgins, Thomas et al., 2019, Sterne, Hernán et al., 2016).

Publication bias

It is common practice to use funnel plots to detect reporting bias. The funnel plot is a scatter plot of intervention effect size of individual studies against measure of study's precision, which is the standard error of the effect size. In case of low possibility of publication bias, the funnel plot appears symmetrical resembling an inverted funnel. However, it is not advisable to use funnel plots as a standalone measure of publication bias due to high level of subjectivity involved in visual inspection and high possibility of spurious results. Use of funnel plot asymmetry test allows determination of association between intervention effect and measure of study size (standard error of the intervention effect) to be greater than what might be expected to occur by chance. For continuous outcome data such as standardised mean difference, the Egger test proposed by Egger et al (1997) assesses the linear relationship between intervention effect and its standard error by assessing how far the intercept for the line of best fit for the studies deviates from zero. A p-value of <0.05 is an indication of significant publication bias (section 10.4.3) (Higgins, 2011).

3.4.7 Synthesis of Results

The studies are first described for their general characteristics, and synthesis of their results presented as summary statistic- or the effect size.

Summary Statistic

In this review, both clinical and behavioural outcome measures were included and summary statistic, also called the effect size, was calculated (if not already listed in the study), according to the information provided. In case of any ambiguity, further information regarding outcome measures was requested by contacting the study authors.

Presentation of effect size allows making a judgement about the magnitude of difference between intervention and control group based on effectiveness of an intervention in achieving the outcomes that it purported to do. Effect sizes reported in studies included in this review have been presented in various forms such as mean difference (MD) for outcome measurements using continuous data, and odds ratio (OR), relative isk (RR) and hazard ratio (HR) for dichotomous outcome measurements.

For studies reporting continuous data as an outcome measurement, standardised mean difference (SMD) was calculated (Cohen's d) which is the size of the intervention effect relative to the variability observed in the study. This allows conversion of results measured in different ways, onto a same scale with same units so they could be compared (section 9.2.3.2) (Higgins, 2011), for example to account for difference in unit of measure for e.g. use of decayed, extracted, filled surfaces (defs) index and not dmfs.

Cohen suggested benchmarks to facilitate interpretation of effect sizes as small (d= 0.2), medium (0.5) and large (d= 0.8) (Cohen, 1988). Hedges' g is the bias corrected Cohen's d and this is also presented where they are different.

For studies reporting proportions, OR/RR were calculated. For proportions presented in single arm pretest-posttest study designs, relative risk reduction (RRR) was calculated. The RRR is defined as relative lowering of risk of adverse health outcome compared to the control group (Mirzazadeh, Malekinejad et al., 2015). For ease in comparison between studies, all reported OR, RR and HR, or those calculated were converted to RRR.

Meta-analyses

The Cochrane Handbook (section 9.1.4) advises undertaking of a meta-analysis if studies are similar enough to allow justification of pooling the data. In case of a review including diverse studies, the handbook suggests keeping the scope of a meta-analysis to answer the broad question of whether there is evidence of interventions producing an effect instead of focusing on the effect size as the diversity of implementation means that the effect estimate could be interpreted in a specific context (Higgins, 2011).

Following the guidance, the aim of the meta-analysis contained as part of current research is to determine whether there is evidence of effectiveness for interventions delivered by non-dental health professionals and health workers for prevention of dental caries in children. For this reason, studies included in the review that reported clinical outcomes as measure of caries experience in the form of decayed, filled, missing surfaces (dmfs) and/or decayed, filled, missing teeth (dmft) indices along with variance estimates, were included in the meta-analysis.

Heterogeneity is defined as variability in studies included in a systematic review. It can be because of variability in participants, interventions and outcomes studied, and is known as clinical heterogeneity. Methodological heterogeneity can be because of variability in study design and risk of bias. Both or either the clinical or methodological heterogeneity can result in statistical heterogeneity, which manifests itself as intervention effects being very different from each other than can be expected due to random error (section 9.5). There was expectation of considerable heterogeneity due to varying sample sizes and diversity of outcomes and measures, and different study designs used. In order to examine and limit the impact of heterogeneity, techniques such as test of heterogeneity, use of random-effects model, sub-group analysis and presentation of predictive intervals (PI), were used (Higgins, 2011).

Use of a random-effects model has been suggested as the model of choice for a meta-analysis when there is expectation of heterogeneity. The random-effects model as opposed to the fixed-effects model, assumes that the study effects observed for individual studies are not identical but follow some distribution (section 9.5.4). This is in contrast to a fixed-effect model which assumes the result to be 'typical intervention effect' of the included studies (Higgins, 2011).

In order to determine the generalisability of the findings of a meta-analysis, it is important to consider the consistency of the findings (Higgins and Thompson, 2002). The Cochrane's Q test is presented along with forest plots as standard test for heterogeneity

with a low p-level (<0.05) indicating presence of significant between-study variability or heterogeneity. However, the test is considered to have low power to detect true heterogeneity in meta-analyses with small number of studies. To mitigate this effect, researchers usually set the p-value threshold at 0.1 rather than the traditional value of 0.05, however this increases the risk of a false positive or a type 1 error. As presence of heterogeneity in meta-analyses is inevitable, it would be much more informative, instead of just determining its presence, to know how much is present and how it influences the conclusions of the meta-analyses. The I^2 statistic is a measure of variance across studies that is present due to heterogeneity rather than chance, and is presented as a percentage (Higgins and Thompson, 2002). Following thresholds have been suggested by the Cochrane Handbook (section 9.5.2) to help with the interpretation of I^2 results, with 0% to 40% indicating insignificant heterogeneity, 30%-60% which may represent moderate heterogeneity and 50%-90% considered as substantial and 75%-100% as presence of considerable heterogeneity (Higgins, 2011).

However, it is advised to be cautious while interpreting the results as they could be potentially misleading especially when the importance of inconsistency is dependent on several other factors such as the magnitude and the direction of the effect, and strength for evidence of heterogeneity (Higgins, 2011). In the meta-analyses conducted, the I^2 statistic is presented along with the forest plots as a measure of heterogeneity.

One way to explore heterogeneity present in the results of meta-analysis is to conduct sub-group analyses, however, it is advisable to limit their number in order to decrease the likelihood of false positive or false negative significance test results (section 9.6.2). As sub-group analysis entails arranging studies in a homogenous group based on certain characteristics, the heterogeneity due to clinical or methodological diversity is expected to decrease (Higgins, 2011). As the current meta-analyses included studies of interventions that used either randomised or quasi-experimental study designs, a sub-group analysis based on study design was performed to investigate methodological heterogeneity manifesting as statistical heterogeneity. If there is a high level of heterogeneity observed in the overall analyses which is not explained by the sub-group analysis, then it can be concluded that heterogeneity is unexplained and there is need to exercise caution when generalising the findings.

The confidence intervals (CI) for pooled effect does not consider the within-study variations. This can be misleading in the sense that it does not provide a realistic indication of true range of effect, especially when there is statistically significant pooled estimate in the presence of high heterogeneity. This can lead to over generalisation of

the findings. The prediction interval presents heterogeneity in the same metric as the effect size and provides a range within which the effect size would be expected in future studies with 95% certainty (IntHout, Ioannidis et al., 2016). In the absence of between study variation, the PI coincides with the CI but in presence of heterogeneity can provide a range wider than the CI with an indication of what can be expected in future studies.

Therefore, a random effects model was used, sub-group analyses conducted and tests for heterogeneity presented along with forest plots for meta-analyses of caries outcome reported in dmfs and dmft indices. The estimated 95% PI were also presented to provide a range in which the point estimate of 95% of future studies will fall, in order to allow for informative inferences to be made from the meta-analyses

Software

The SMD calculations were carried out through calculator provided by Centre for Evaluation and Monitoring (Centre for Evaluation & Monitoring). The OR/RR calculations were undertaken using excel based calculator developed by Mirzazadeh et al (2015) for calculation of RR and Relative Risk Reduction (RRR) based on desirable or undesirable outcome(s) (Mirzazadeh, Malekinejad et al., 2015). Meta-analyses and assessment of publication bias was undertaken using Stata version 17 with metan package to generate the forest plots (Harris, Deeks et al., 2008).

3.4.8 Behaviour change technique coding

Based on the effect size estimate, intervention descriptions of effective interventions were coded for BCTs using the BCTTv1 (Michie, Richardson et al., 2013). Additional materials were sought when intervention descriptions were not detailed enough to facilitate the BCT extraction process. Coding was performed by two coders (MRF and SY) independently and any disagreement was resolved through discussions. Both the coders undertook training prior to BCT coding (www.bct-taxonomy.com). Cohen's Kappa was calculated to indicate level of agreement. A BCT was labelled as 'promising' if it had been used in two or more effective interventions (Brown, Hardeman et al., 2019, Campbell, Fergie et al., 2018).

In the case of failure to obtain further intervention details, following coding assumptions were undertaken whilst following the BCTTv1 guidelines (De Vasconcelos, Toskin et al., 2018). When no further details of intervention contents were provided other than 'health education' or 'counselling', following BCTs were coded: *3.1 "social support (unspecified)"* and *5.1 "information about health consequences"*. For printed materials (leaflets, pamphlets etc) mentioning provision of 'information' or 'education' without any further

details, they were coded, at the minimum for *5.1 "information about health consequences"* and *4.1 "instructions on how to perform the behaviour".*

3.5 Results

3.5.1 Description of the studies

In this section, the reviewed studies are initially described generally under sub-heading 'study characteristics' and then more specifically following the PICO format.

Study selection

The search retrieved 7657 records initially from database searching (Figure 3.1). After removal of duplicates, 7174 title and abstracts were screened against the eligibility criteria. Thirty-eight studies met the inclusion criteria. The full texts of 38 studies were then assessed for inclusion. Seven studies were excluded due to: detailed results not presented (n=1), ineligible intervention and/or delivery personnel (n= 5) and secondary data analysis without description of the intervention (n=1). A total of 31 studies were found to meet the inclusion criteria and were included in this review.

Study characteristics

The publication dates of included studies ranged from October 1993 to January 2019. Out of the included studies 15 were randomised controlled trials (48.3%) including eight cluster randomised control trials; 16 studies were based on quasi-experimental designs (51.6%) including five pretest-post test studies, 11 studies with a comparison or control group.

Studies were conducted in 12 different countries: three in Australia (9.6%), one in Belgium (3.2%), two in Brazil (6.4%), two in Canada (6.4%), one in Hong Kong (3.2%), and two in India (6.4%), one in Iran (3.4%), two in Ireland (6.4%), one in Israel (3.4%), two in Thailand (6.4%), four in UK (12.9%), and ten in USA (32.5%).

3.5.2 Participants

All the studies reviewed were conducted with parents and very young children of up to 6 years of age with two studies commencing during pregnancy (Chaffee, Feldens et al., 2013, Maupomé, Karanja et al., 2010) and one in the postpartum period (Hallas, Fernandez et al., 2015). The participants were reported to be recruited from various settings such as: health centres (n=8), hospital setting (n=3), well baby clinics (n=2), private clinics (n=1), Women Infant and Children Centres (WIC) (n=1), vaccination clinics

(n=1), community centres (n=1), through the community (n=3), through maternal & child health Nurses (MCHN) (n=1), through health visitors (n=1), preschools (n=1) and Head Start classrooms (n=1) and Early Head Start programmes (n=1). Two studies did not elaborate on the recruitment setting (Chaffee, Feldens et al., 2013, Yuan, Kerr et al., 2007) and one study consulted the Office of Population Statistics (OPCS) to obtain participants with required demographics (Kowash, Pinfield et al., 2000).

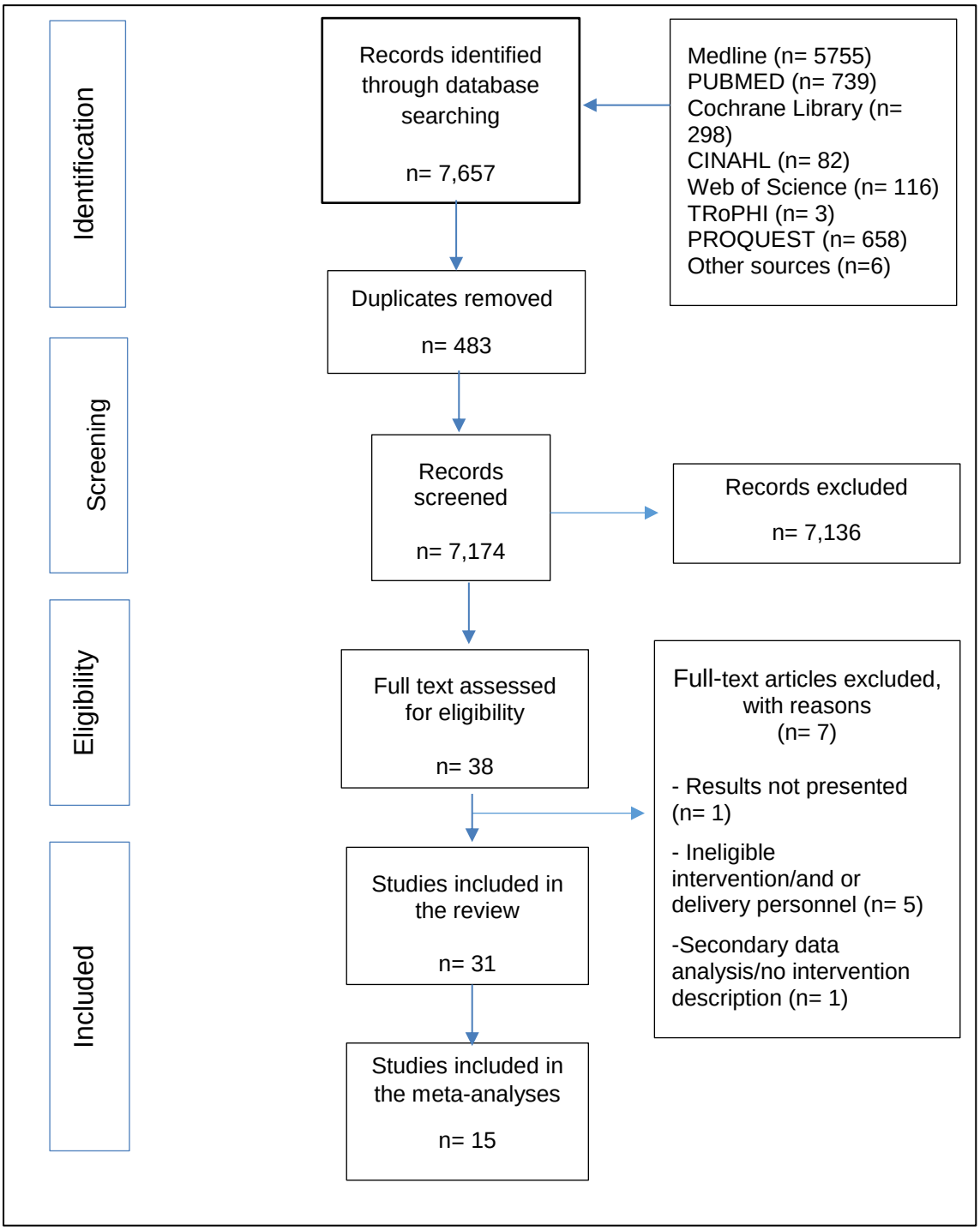


Figure 3.1 PRISMA Flow diagram illustrating study selection process

3.5.3 Intervention

The interventions reported in all the studies were appraised using the Template for Intervention Description and Replication (TIDieR) checklist and have been reported here as intervention content, intervention delivery method and intervention fidelity.

Intervention content

Eight studies (25.8%) reported basing their intervention on a theoretical model, seven studies (22.5%) described principles, guidelines or national authority advice as the theory behind their intervention and one study reported involvement of the key stakeholders in development of the intervention. The materials and procedures used as part of intervention implementation were overall described well in individual studies.

Oral health education was a basic component of the interventions used in combination with other assessments such as caries risk assessment or oral health assessment/screening (n=3) and/or oral examination (n=2), and other preventive techniques such as fluoride varnish application (n=4). Intervention materials pertaining to oral health education consisted of verbal or written material, videos or a combination of these. Some studies disseminated oral health education through the use of minilectures, flipcharts, role-play, storytelling, group activities, group discussions (n=7), anticipatory guidance, counselling, advice, instructions, structured oral health education, social support; written advice in the form of leaflets (n=7) pamphlets (n=3), brochures (n=3), posters (n=2), article in local magazine, child health booklets and educational information. Educational videos (n=4), phone call (n=3) and/or mail reminder formed part of some interventions. Oral health kits were also distributed as part of some interventions and consisted items such as toothbrushes only (n=1) or both toothbrushes and toothpaste (n=8) for the child and/or the parents, feedings cups (n=3), baby trainer cups (n=2), teething rings, finger cot, placemats and fridge magnets, dental colouring book and crayons for children and height chart. Those interventions aiming to increase dental service utilisation (n=4) by the participants also provided a list of paediatric dentists, registration vouchers or referral letters.

Intervention delivery

The focus of this review was on studies that included non-dental professionals or community and lay health workers as the staff who delivered the intervention and included physicians (n=3), nurses (n=8), dietician (n=1), health centre staff (n=3), administration staff (n=1), vaccination staff (n=1), health visitors (n=6), community health workers (n=4), Anganwadi workers (n=2), peers (n=1) and community members (n=2),

They were given different titles in various studies such as: ‘Dental Health Educators’, ‘MI Counsellors’, ‘Parent Ambassadors’, ‘Community Oral Heath Specialists’ and ‘Community Dental Health Worker’. The mode of delivery of interventions was mostly face-to face through home visits (n=15) in hospital setting (n=1), at a health centre (n=7), well baby clinic (n=3) or vaccination clinic (n=2), Head Start centre (n=1), and in a community gathering (n=2).

There was considerable variation in timing and duration of the interventions. The timing of intervention delivery in most of the studies was synchronised with routine visits at the health centre or during child’s vaccination visits (n=12). Three studies reported once only session for intervention delivery while no details were provided in another study regarding the number of contact sessions. Tailoring of interventions were reported in a number of studies in which the oral health advice or counselling was based on parents’ or child’s needs (n=10). There were no reports of any major modifications made to the intervention during the course of the study. Bentley et al (1993) reported editing the format of the dental registration referral letters provided to the parents by the health visitors based on health visitors’ recommendation (Bentley and Holloway, 1993).

Intervention fidelity

Formal process evaluation including assessment of intervention fidelity was reported in some studies (n=3), while other studies employed both quantitative and qualitative measures to assess intervention fidelity such as direct observations or monitoring (n=7), discussions or meetings with intervention deliverers (n=3) to understand their barriers for intervention implementation, and/or use of audio recording of counselling contact sessions (n=3), maintenance of work log/checklists (n=5), provision of refresher training, and patient exit interviews or satisfaction level surveys (n=3).

3.5.4 Comparison

The comparison group used mostly in studies received standard or usual care. Maupomé et al (2010), Smith et al (2018) and Kowash et al (2000) used a 'pre-cohort' or historic control group in their studies (Kowash, Pinfield et al., 2000, Maupomé, Karanja et al., 2010, Smith, Blinkhorn et al., 2018).

3.5.5 Outcomes

For ease in reporting, the oral health outcomes measured by studies included in this review were classified as clinical outcomes and behavioural outcomes. Studies reported measuring clinical outcomes using proxy measures such presence of caries or indication

of caries activity, decay (cavitated and/or non-cavitated or white spots), fillings and missing teeth or extractions through the use of various indices such as decayed, missing/extracted, filled teeth (dmft) or surfaces (dmfs or defs) (n=20). Debris index, plaque index and gingival bleeding were also used as indicators to clinically assess oral hygiene practices (n=3).

The follow up time varied between studies with the shortest from 2 weeks post intervention to the longest of about 4 years. For the purpose of this review, preventive behaviours such as oral hygiene and dietary behaviours including assessment of sugar consumption, and dental service utilisation were evaluated. A range of methods to assess oral health related behaviours were reported being used in individual studies including tooth brushing behaviours (n=11), dietary behaviours (n=13) dental service uptake (n=6). Four studies reported mean scores of oral health related behaviours. Changes in oral health knowledge of parents' or caregivers' was also assessed as a secondary outcome in this review and ten studies reported measuring oral health related knowledge or perceptions. None of the studies reported measuring Oral Health Related Quality of Life (OHRQoL).

Clinical outcomes

Twenty studies evaluated clinical outcomes as mean scores of caries increment to measure the effectiveness of intervention in improving oral health outcomes (64.5%). Out of these, nine studies reported no significant difference in caries prevalence between intervention and control or comparison group. A study in Belgium reported predominantly more caries free children in the control region and difference in proportion of caries free children between intervention and control group in favour of the intervention, at one follow up period only out of two (Van den Branden, Van den Broucke et al., 2013). For the studies that reported significant difference in caries prevalence between intervention and control group (n=11) or a difference in caries activity in single arm pretest-post test study designs (n=1), their standardised mean difference as effect sizes (if not already reported) were calculated as a measure of effectiveness of the intervention.

Behavioural outcomes

Twenty-one studies (67.7%) reported behavioural outcomes either along with clinical outcomes or as solo outcome measurement. A range of methods to assess oral health related behaviours were reported being used in individual studies including tooth brushing behaviours (n= 11), dietary behaviours (n=13) dental service uptake (n=6) and as mean scores of oral health behaviours (n=4). Studies mostly reported a positive

impact of intervention in improving oral health related behaviours assessed as part of this review. An improvement in oral hygiene and toothbrushing behaviours was reported by all the studies assessing behavioural outcomes (n=10) except in a study by Van den Branden (2013) in Belgium where better oral health behaviours were reported for children in the control region (Van den Branden, Van den Broucke et al., 2013). There was a huge variation in how dietary practices were measured in different studies and ranged from questions about bottle use, such as: ceased using bottle, night time bottle use or use of sweetened drinks/milk in a bottle; snacking between meals, frequency of sugar consumption, and daily intake of fruits and vegetables. Nevertheless, studies reported improvement in all or at least some of them (n= 7). Positive contribution of the intervention in increasing dental service uptake was also reported (n= 2) except for four studies which reported no difference between groups for average number of visits for fluoride varnish application and/or dental visits (Chaffee, Feldens et al., 2013, Gibbs, Waters et al., 2015, Kowash, Pinfield et al., 2000, Van den Branden, Van den Broucke et al., 2014).

Oral health related knowledge and perceptions were also reported to have improved post intervention in the studies assessing these outcomes (n=8) except Braun et al (2016) who reported no difference for oral health related knowledge between intervention and control group participants (Braun, Quissell et al., 2016).

3.5.6 Effect size

In this sub-section, I present a narrative synthesis of results reported in the reviewed studies according to the outcome measures that they have used. For this, I have structured and presented the findings according to clinical and behavioural outcomes. The results of meta-analyses for caries outcome reported as dmfs or dmft indices are also presented.

Out of the 31 included studies, effect size could be calculated or was provided for 28 studies. For the remaining 3 studies, one study reported very high attrition rate which precluded any calculations, and the remaining 2 studies did not provide sufficient details and no response was received from the study authors upon request for further information for effect size calculation. The description of effect sizes for 28 studies are presented in the following sub-sections and summary table is presented in the appendix (Appendix 3.2).

Clinical outcomes

Most of the studies presented clinical outcomes in the form of mean scores. The Cohen's d calculated as measure of effect size was not found to be significant for one study that reported significant difference between intervention and control group mean scores for dmfs index (Kowash, Pinfield et al., 2000). For seven studies that the effect size for clinical outcomes was found to be significant, interventions in two studies produced a very small effect size of below 0.2 to 0.31 (Davies, Duxbury et al., 2005, Kowash, Pinfield et al., 2000); two had small to medium effect size of 0.44 and 0.38 (Gibbs, Waters et al., 2014, Harrison, Benton et al., 2007); two had medium to large effect size of 0.78 (Mohebbi, Virtanen et al., 2009) and 0.75 (Smith, Blinkhorn et al., 2018); and one had a large to very large effect size of 1.18 and 0.83 in their 2nd and 3rd follow up respectively (Harrison and Wong, 2003).

Feldens et al (2007) reported effect size for the clinical outcome of caries increment as odds ratio in the primary study and relative risk in the follow up study. Hence, they were converted to Relative Risk Reduction metric for ease in comparison, and was found to be 0.48 in the main study and 0.33 (and 0.32 for severe caries) in the follow up study (Feldens, Giugliani et al., 2010). Raj et al (2013) presented proportion of children for caries activity for pre and post-test, as measure of caries and also for debris index as measure of tooth brushing behaviour and the RRR calculated was found to be 0.31 for both measures (Raj, Goel et al., 2013).

Behavioural outcomes

The behavioural outcomes in studies were presented as proportions in intervention and control group except in studies by Wilson et al (2013), Leung et al (2015) and Yuan (2019) in which they presented mean scores for behaviours and when their effect sizes were calculated as Cohen's d, all were found to be significant. There was a small effect for oral health related behaviours and attitudes (0.31) and medium effect for oral health related knowledge (0.52) in the study by Wilson et al (2013), and medium effect size for toothbrushing (0.52) and feeding practice (0.56) in the study by Leung et al (2015) (Leung, Tsang et al., 2015, Wilson, Debaryshe et al., 2013). Very large effect size owing to very small sample size was found for toothbrushing (g= 1.68) and dietary behaviour (g= 1.32) in the study by Yuan (2019) (Yuan, 2019).

In addition, effect size was found to be significant for one out of three studies evaluating mean oral health behaviours (33.3%), eight studies out of 12 studies analysing oral hygiene behaviours (66.6%) six out of 13 studies measuring dietary behaviours (46.1%);

five out of nine studies reporting changes in oral health knowledge post intervention (55.5%), and two studies out of six aiming to improve dental registration/visiting (33.3%). The reduction in risk as calculated by RRR varied from 21% to 98% for various behaviours analysed in the included studies. Details are presented in the summary table (Appendix 3.2).

3.5.7 Meta-analyses

Studies that reported outcome of caries experience at the tooth surface level (by using the dmfs index) and those reporting at the tooth level (by using the dmft index) were pooled together. Meta-analyses included 12 studies that reported mean dmfs scores, and 5 studies with mean dmft scores (including 2 studies that reported both dmfs and dmft scores for their study population). Using SMD for meta-analysis resulted in pooled estimate for dmfs -0.15 (95% CI -0.25, -0.04), and for dmft -0.24 (95% CI -0.42, -0.07) both of which were statistically significant, as indicated by the CI range.

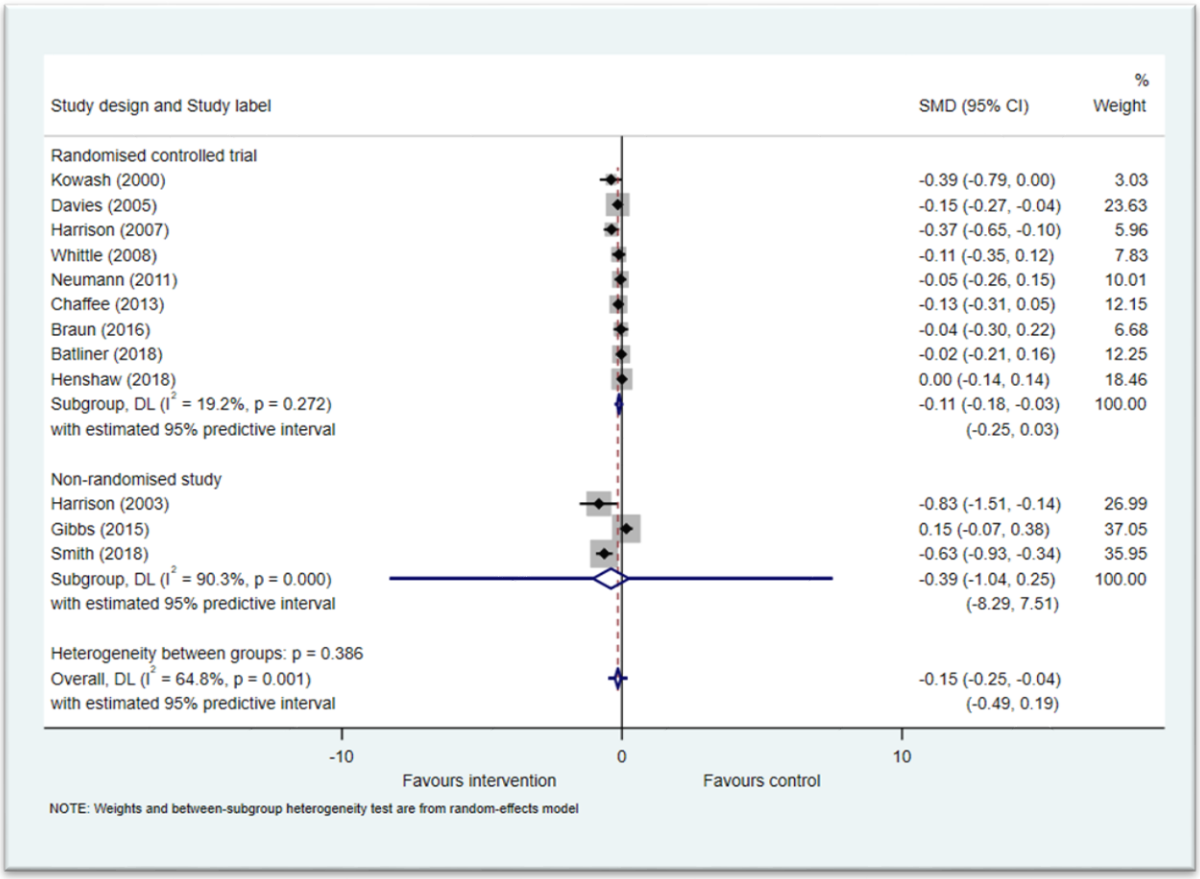


Figure 3.2 Forest plot for SMD of caries experience presented as dmfs index

The 95% PI was not statistically significant for both dmfs (-0.49, 0.19) and dmft (-0.83, 0.35). This can be interpreted to mean that based on the available data, in future studies the SMD could be as low as -0.49 for dmfs and -0.83 for dmft and as high as 0.19 for dmfs and 0.35 for dmft.

There was high level of heterogeneity encountered for both the meta-analyses, indicated by the I^2 estimate of 64.8% (p=0.001) for dmfs and 76.3% for dmft (p=0.002).

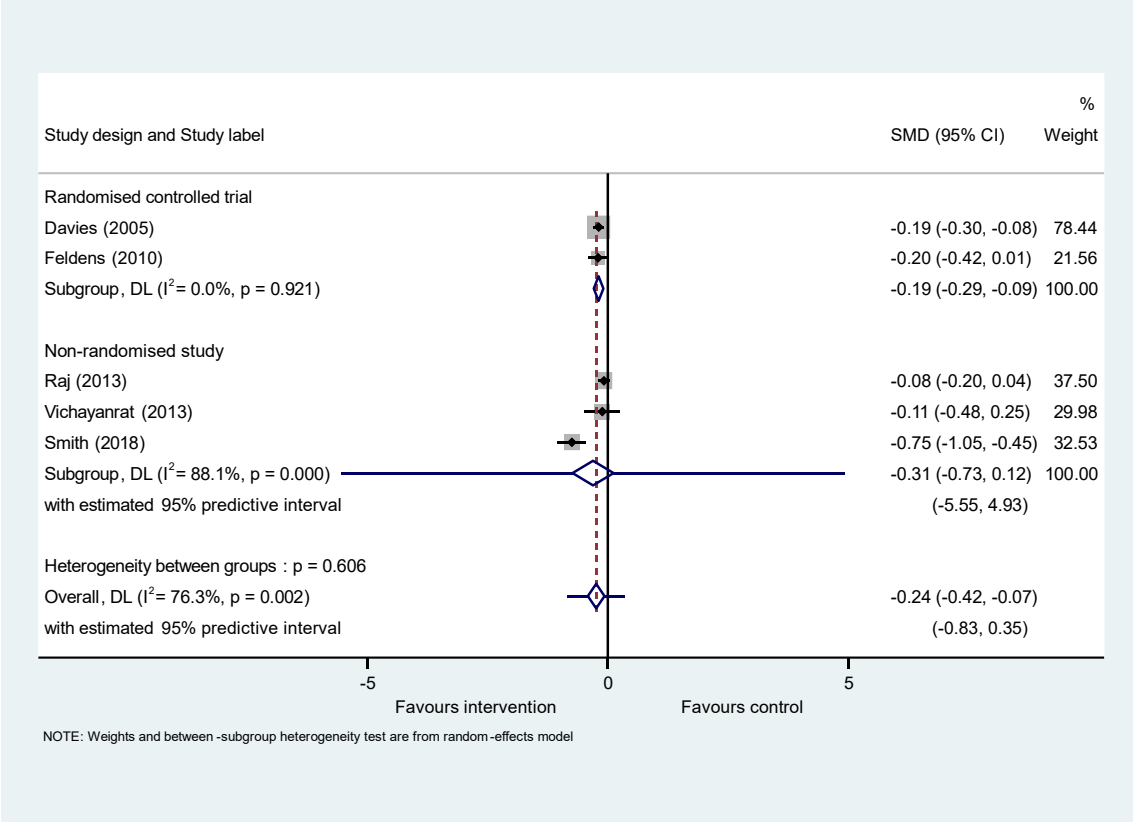


Figure 3.3 Forest plot for SMD of caries experience presented as dmft index

The pooled effect for randomised controlled studies produced a statistically significant result for dmfs: -0.11 (95% CI -0.18, -0.03) and for the dmft score -0.19 (95% CI -0.29, -0.09). On the other hand, the pooled effect estimate for non-randomised studies such as quasi-experimental and pre and post study designs were not statistically significant for either dmfs -0.39 (95% CI -1.04, 0.25) or dmft -0.31 (95% CI -0.73, 0.12).

It was also evident from the subgroup analysis that the non-randomised study designs majorly attributed to the heterogeneity observed in the overall estimate:

- For caries experience presented as dmfs score, the estimates for randomised controlled study designs were: I^2 19.2% (p= 0.272), 95% PI -0.25, 0.03; and for non-randomised study designs I^2 90.3% (p<0.001), 95% PI -8.29, 7.51
- For caries experience presented as dmft score, the estimates for randomised study designs were: I^2 0.00% (p=0.921), 95% PI (not generated due to <3 studies in the sub-group); and for non-randomised study designs I^2 88.1% (p=<0.001), 95% PI -5.55, 4.93

Although sub-group analysis explained the heterogeneity encountered, the results should be interpreted with caution due to very small number of studies in the sub groups for dmft index (2:3).

3.5.8 Behaviour change techniques

The kappa values, before the consensus phase, indicated substantial agreement between the two coders (0.761). Twenty-seven distinct BCTs were identified by coding descriptions of effective interventions as indicated by the effect size estimate (Table 3.1).

All interventions used a combination of BCTs and 2 BCTs most frequently used and present in all 23 effective interventions were – *4.1 "Instructions on how to perform the behaviour"* and *5.1 "Information about health consequences".*

Other prevalent BCTs present as components of effective interventions (coded in ≥25% interventions) were: *12.5 "adding objects to the environment"* (n =14), *3.1 "social support (unspecified)"* (n= 13), *6.1 "demonstration of behaviour"* (n= 11), *3.2 "social support (practical)"* (n= 8), *7.1 "prompts and cues"* (n= 8), 1.2 "problem solving" (n= 7). Most number of BCTs utilised in an intervention was 13 and least was 3 (Table 3.1).

Based on their being part of two or more effective interventions, 18 BCTs were labelled as 'promising' or highly likely to be instrumental in enhancing the effectiveness of intervention (Brown, Hardeman et al., 2019, Campbell, Fergie et al., 2018)

Table 3.1 Frequency of BCT in effective interventions (n=23)

Behaviour Change Techniques (n= 27)	Frequency in effective interventions	BCT Group based on BCTTv1
1.1 Goal setting (behaviour)	4	1. Goals and Planning
1.2 Problem solving	7	
1.4 Action planning	3	
1.5 Review behaviour goals	2	
1.9 Commitment	1	
2.2 Feedback on behaviour	2	2. Feedback and Monitoring
2.3 Self-monitoring of behaviour	1	
3.1 Social support (unspecified)	13	3. Social support
3.2 Social support (practical)	8	
4.1 Inst on how to perform the behaviour	23	4. Shaping knowledge
5.1 Info about health consequences	23	5. Natural consequences
5.2 Salience of consequences	1	
5.3 Info about social & environmental consequences	4	
6.1 Demonstration of behaviour	11	6. Comparison of behaviour
6.3 Info about other's approval	1	
7.1 Prompts & cues	8	7. Associations

7.8 Associative learning	1	
8.1 Behavioural practice **8.2 Behaviour substitution** 8.3 Habit formation	4 3 1	8. Repetition and substitution
9.1 Credible source 9.2 Pros & Cons	2 1	9. Comparison of outcomes
10.3 Non-specific reward 10.4 Social reward	2 1	10. Reward and threat
12.1 Restructuring physical environment **12.5 Adding objects to the environment**	1 14	12. Antecedents
13.1 Identification of self as role model	2	13. Identity

BCTs appearing ≥ 2 times labelled as 'promising' (emboldened)

3.5.9 Quality assessment

Risk of bias

The RoB assessment for RCTs yielded following results: out of the 15 trials, 10 were rated as having as low risk (66.6%), three were rated as having unclear risk of bias (20%), and two as being at high risk of bias (13.3%).

For the RoB assessment in non-randomised studies, one study was rated at low risk of bias (6.25%), seven studies were at moderate risk (43.7%) and rest were classified as having serious risk of bias (50%). The serious risk of bias mostly pertained to measurement bias based on failure to 'blind' the outcome assessors and results based on self-reporting of oral health behaviours.

Publication bias

The funnel plot for dmfs showed asymmetry among the studies and also had a significant Egger's test result z= 2.64, p= 0.0083, β1 -2.80 (95% CI -4.88, -0.722). There was no indication of publication bias for dmft reported outcome based on funnel plot symmetry and Egger's test z= -0.87, p= 0.382, β1 -1.99 (95% CI -6.44, 2.47).

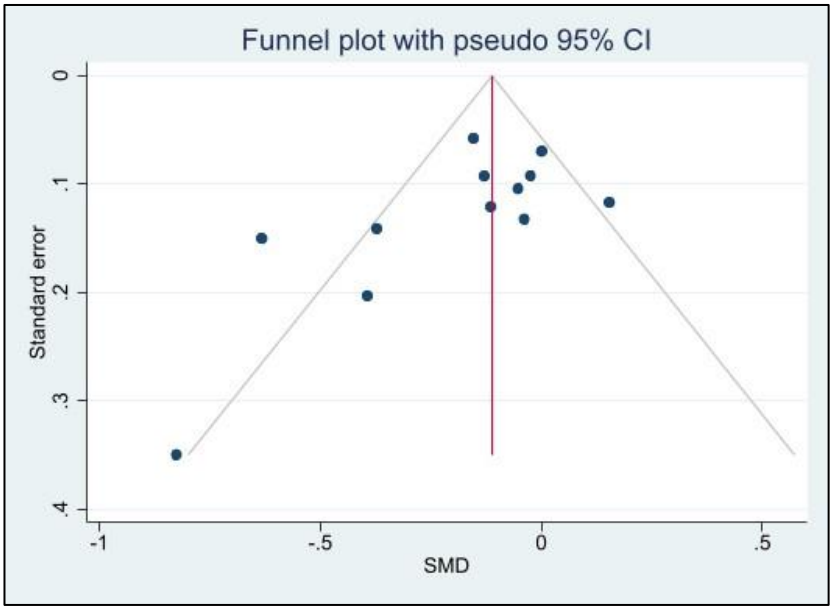


Figure 3.4 Funnel plot of studies reporting caries experience as dmfs index

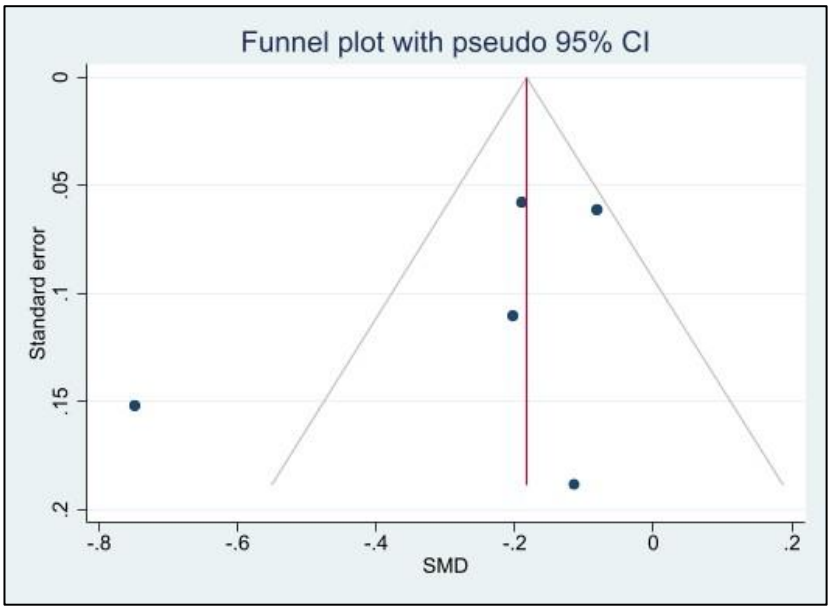


Figure 3.5 Funnel plot of studies reporting caries experience as dmft index

3.6 Discussion

Other reviews conducted on this topic have been narrative reviews describing findings reported in included studies, this review has gone a step further and synthesised evidence from results provided in the studies to enable making judgement about effectiveness of interventions delivered. In this section, findings are discussed in the context of wider literature, strength and limitations of the study outlined and research recommendations highlighted.

3.6.1 Key findings

Oral health promotion of children

Although the review identified 23 studies (out of 28 with effect size calculations), to have produced a significant effect in either clinical and/or behavioural outcomes assessed for oral health promotion of children through non-dental health professionals and health workers, there is still scarcity of evidence from high quality low bias studies. This is in line with findings of other systematic reviews which have studied effectiveness of integrating oral health promotion in nursing and midwifery practice (Abou El Fadl, Blair et al., 2016), and evaluated the effectiveness of educational interventions in oral health services (Menegaz, Silva et al., 2018), and effectiveness of preventive dental programs offered to mothers for controlling early childhood caries (George, Sousa et al., 2019). Similarly, a Cochrane review of interventions with pregnant women and new mothers/caregivers of children for preventing ECC, reported moderate-certainty of evidence suggesting that if pregnant women, mothers/caregivers of children up to 1 year of child's age were provided advice on diet and feeding, it may lead to reduced risk of ECC in children, however, there was low to very low quality of evidence to determine whether any other oral health advice (e.g. oral hygiene, child diet and feeding practice) was effective in ECC prevention (Riggs, Kilpatrick et al., 2019). Thus, highlighting the need for future high-quality intervention studies that are theory based to allow understanding of which intervention components may or may not be effective in preventing childhood caries.

Characteristics of the included studies

Setting

Most of the studies conducted were based in settings where there was a possibility of repeated contact with children's caregivers thus providing a practical opportunity for oral health promotion activities. The intervention was either integrated in the existing home

visiting models or tested as part of routine well baby/vaccination visits. Adopting this outreach method ensured that a minority and marginalised population, who usually have the poorest oral health outcomes, are not left out. This was evidenced in study by Smith et al, (2018) in Aboriginal population in Australia, in which they were provided with home visits by Aboriginal Health Workers or transport costs if they wished to travel to the Aboriginal Community Controlled Health Services (Smith, Blinkhorn et al., 2018). This produced a highly significant effect in decreasing caries prevalence in Aboriginal children. Similar significant clinical improvements were also reported for Vietnamese and South Asian population resident in Canada (Harrison, Benton et al., 2007, Harrison and Wong, 2003, Weinstein, Harrison et al., 2004). This was further highlighted by the results of study by Van Den Branden et al, (2013) in Belgium where the control group generally performed better than the intervention group because the population targeted were not a socially disadvantaged group, unlike in the previously mentioned studies (Abou El Fadl, Blair et al., 2016, Van den Branden, Van den Broucke et al., 2013).

The studies solely evaluating effectiveness of promotion of dental registration were both based in the UK (Bentley and Holloway, 1993, Yuan, Kerr et al., 2007) where there is a developed healthcare system and free dental preventive/treatment procedures provided for children.

Theoretical underpinnings

Lack of theoretical models as a basis for the intervention development hinders the understanding of what works and what does not work in a given context. The Medical Research Council (MRC) guidance on developing complex interventions posits health interventions are more likely to be effective if they are based on a theory or a theoretical framework (Craig, Dieppe et al., 2008), however, out of the 31 studies reviewed, only 15 reported basing their intervention on any theory, principles or guidelines. This can be attributed to the fact that many of the studies were conducted or had commenced before these recommendations were published (36.7%) and there is need for more studies to test effectiveness of interventions grounded in theory.

Intervention content and complexity

The intervention content differed greatly between studies and although the most effective type of intervention cannot be clearly distinguished, however, it can be positively stated that interventions usually employing a variety of methods such as verbal advice, printed material, oral health kits, video sessions and call or text reminders, were most effective in producing behaviour change similar to findings reported by other systematic reviews

(Abou El Fadl, Blair et al., 2016, George, Sousa et al., 2019, Menegaz, Silva et al., 2018). Furthermore, it was observed that intervention based solely on dietary advice had limited impact on oral health outcomes in the form of caries prevalence in long term (Chaffee, Feldens et al., 2013).

Reinforcement of health messages delivered through regular contact has been established to produce positive outcomes in health behaviours (Cascaes, Bielemann et al., 2014, Menegaz, Silva et al., 2018). This is evidenced from the results of study by Neumann et al (2011) in which a once only contact session for intervention delivery failed to produce any significant difference in caries status of children in intervention group (Neumann, Lee et al., 2011).

Intervention fidelity

Testing for intervention fidelity allows for assessment of its mediating role between context and intervention effectiveness and the resultant impact on study outcomes (Keith, Hopp et al., 2010). Although just over half of the included studies (58%) employed some form of intervention fidelity checks, almost half did not either incorporate any form of intervention fidelity testing or did not report it. Failure to evaluate intervention fidelity, also known as Type III error can result in faulty conclusions about intervention effectiveness or ineffectiveness (Breitenstein, Gross et al., 2010).

Follow-up time

The time point at which study outcomes are determined is crucial in ascertaining the impact of the intervention. Caries progression in primary teeth can take up to 12-24 months to penetrate the depth of enamel (Shwartz, Gröndahl et al., 1984) and studies determining caries prevalence with a follow up time of ≤ 1 year can have limited possibility to detect a difference in caries incidence. This is evident in a study by Harrison & Wong (2003) in which there was found to be no significant effect of intervention in decreasing caries prevalence in the first follow up period, however, the intervention demonstrated a significant positive effect in the second and third follow up in the same study (Harrison and Wong, 2003). Similarly, there was no significant difference for caries reported in two studies conducted in Thailand with 1 year follow up (Vachirarojpisan, Shinada et al., 2005, Vichayanrat, Steckler et al., 2012), and the reason for this cannot be attributed solely to failure of intervention to produce an effect but could possibly be because of relatively short follow-up time.

TIDieR checklist

Use of previously validated tools allowed systematic appraisal of interventions which was a step towards achieving a better understanding of why and how interventions produce a positive effect, by closely examining their individual components. The intervention description including content and setting was generally found to be well reported in the studies, however details of any tailoring or modifications to intervention during the study period, were the items that were mostly under reported.

Meta-analyses

The review identified statistically significant effect of the intervention delivered by non-dental health professionals and health workers in preventing caries at the surface level (SMD 0.15 (95% CI -0.24, -0.04,)) and at the tooth level (SMD -0.24 (95% CI -0.42, -0.07)). The result of sub-group analysis suggests the source of heterogeneity to be the different study designs. To account for the high level of heterogeneity observed (I^2 of 64.8% and 76.3% respectively), predictive intervals were presented to allow estimation of effect size in future studies.

Behaviour Change Techniques

The number of BCTs (n=27) identified in effective interventions indicates that a range of different BCTs can be used for prevention of dental caries in children. A range of 3 to 13 BCTs per effective intervention is an indication of how technically variable the interventions are and only few techniques can be effective in achieving the desired behaviour change for improved oral health outcomes of children (De Vasconcelos, Toskin et al., 2018).

Furthermore, although studies reported providing adequate training to the intervention deliverers, it is quite possible that delivery might have been adjusted according to participants' needs and concerns. For this reason, assessing intervention fidelity should be an essential part of intervention studies.

Traditionally, the focus of oral health promotion has been on transfer of knowledge to change behaviour (Gray-Burrows, Owen et al., 2017), as evident by the two most prevalent BCTs of effective interventions: *4.1 "Instructions on how to perform the behaviour"* and *5.1 "Information about health consequences".* As evidenced from previous literature (Aliakbari, Gray-Burrows et al., 2021b, Marshman, Ahern et al., 2016) interventions targeting a range of barriers can not only support the adoption of good oral

health behaviours but also the possibility of their being sustained for a longer time period (Gray-Burrows, Owen et al., 2017).

Quality of studies

RCTs are considered the gold standard for generation of highest level of evidence, however, it is not always feasible or practical to conduct one. Whichever study design is chosen, there should be no compromise on methodological quality of the study. Rigorous methods with adequate steps taken to prevent incorporation of bias and transparent reporting of studies allows for true assessment of the impact of the intervention and its potential to be applied to other study settings. Although the methodological quality of RCTs included was generally of good quality, the non-randomised studies mostly scored poorly in this regard.

3.6.2 Methodological considerations

Strengths

This is the only review to systematically appraise oral health promotion interventions delivered through non-dental health professionals and health workers, at granular level using validated tools, and to quantify their effects. The meta-analyses allowed assessment and reporting of the effectiveness of interventions for preventing dental caries in children. Two reviewers independently reviewing the included studies ensured systematic and proper methodological approach for conducting the review.

The use of standardised tools for quality assessment and detailed description of the intervention not only provided an in-depth assessment but also helped identify gaps in the reporting of individual studies which forms a part of the future research recommendations.

Limitations

Inclusion of only English language studies, non-inclusion of other databases, and limited inclusion of grey literature (dissertations and theses), may have caused relevant studies or other sources of grey literature particularly from global bodies e.g. WHO, NGOs or other organisations delivering dental health interventions in LMICs, to be missed during the search process. Trying to reach study authors for requesting further information to enable effect size calculation was a challenge. Despite numerous efforts to contact two study authors, there was no response received from them and for this reason these two studies had to be excluded from effect size calculation.

3.6.3 Research recommendations

Some important gaps identified through this review regarding oral health promotion of children through non-dental health professionals and health workers that need to be considered are:

- Development and use of theory-based intervention
- Use of robust study design and/or analysis to reduce risk of bias
- Assessment of intervention fidelity

3.7 Conclusion

Non-dental health professionals such as nurses and midwives, and health workers are the first point of contact for parents of very young children in most healthcare systems. With adequate training, they can play a key role in oral health promotion of children through their parents. Capitalising on this opportunity can prove to be a cost-effective solution to a public health problem, especially in resource constrained settings. The results of this systematic review suggest that there is low quality of evidence for effectiveness of oral health promotion provided by non-dental health professionals and health workers, in improving oral health outcomes in young children below 7 years of age by targeting their parents/caregivers.

The plan at this point of current research was to address the gaps identified through development of a theory and evidence-based intervention, and its feasibility testing, for oral health promotion of children through LHWs in Pakistan. These steps are detailed in the next chapters (4-6) of this thesis.

Chapter 4: Focus group study

4.1 Chapter overview

This chapter describes the second part of the first stage (Stage A) of this PhD project. This involved conducting four focus group discussions with two sets of participants-mothers as the primary caregivers of young children in Pakistan, and LHWs as the health workers working for health promotion in their communities, specifically focussing on maternal and child health.

The introduction section (4.2) provides a brief reflection on the findings of the literature review in relation to the barriers and facilitators for child's oral health behaviours, and explains how the knowledge gaps identified led to the development of this study. The methods section (4.4) presents details about the study design, settings and population, and describes the data collection and data analysis procedures. The results section (4.5) presents the findings of the data analysis along with exemplar quotes, and the discussion section (4.6) considers the key findings in relation to the existing literature, reflects on the strengths & limitations of the study and presents study implications. The chapter ends with the conclusion (4.7).

4.2 Introduction

Oral health promotion is a wide term and can be defined as *'any combination of oral health education and legal, fiscal, economic, environmental, organizational and technical interventions designed to facilitate the achievement of oral health and the prevention of disease'* (Strippel, 2008). In the background chapter (chapter 1), it was identified how children's oral health behaviours are by and large affected by parental related factors. The aim of this PhD research was to develop and test the feasibility of a behavioural intervention to promote children's oral health in Pakistan. However, first it was important to identify which oral health behaviour(s) to focus on, and secondly to explore the barriers and facilitators that the parents face for engaging in those oral health behaviour(s) for their children.

Guided by the literature, and the intervention development process, I decided to focus on one vital oral health behaviour - children's toothbrushing as the key behaviour for oral health promotion and disease prevention.

As presented in the background chapter, there is considerable existing quantitative literature documenting factors affecting oral health behaviours of children, and more recently there has been a rise in qualitative research to explore and understand how parental factors affect their children's toothbrushing and oral hygiene practices. Furthermore, the wide availability of different or often contradictory messages from dental organisations, health professionals, industry sources, and adverts regarding care of children's primary teeth further complicates the situation (Dos Santos, Nadanovsky et al., 2011, Wainwright and Sheiham, 2014).

Although previous studies have reported a range of parental barriers for good oral health practices of their children (Amin and Harrison, 2009, de Jong-Lenters, Duijster et al., 2014, Elison, Norgate et al., 2014, Finlayson, Beltran et al., 2019, Marshman, Ahern et al., 2016, Naidu, Nunn et al., 2015, Prowse, Schroth et al., 2014, Trubey, Moore et al., 2014, Virgo-Milton, Boak et al., 2016, Wong, Perez-Spiess et al., 2005) only few have focused on barriers faced by parents for child's toothbrushing behaviours (Finlayson, Beltran et al., 2019, Suprabha, D'Souza et al., 2021, Trubey, Moore et al., 2014), and specifically to supervised toothbrushing (Elison, Norgate et al., 2014, Marshman, Ahern et al., 2016). Furthermore, there has been no study conducted in Pakistan to explore the parental barriers and facilitators that may be present in the local context.

In a recent systematic review looking at the barriers and facilitators of home-based toothbrushing practices by parents of young children to prevent tooth decay, the study

authors mapped the barriers and facilitators identified in the individual studies to the TDF in order to identify the key behavioural determinants (identified as TDF domains) that need to be targeted for future interventions (Aliakbari, Gray-Burrows et al., 2021b). The review used a comprehensive framework (TDF) to highlight that parents face a variety of barriers that encompassed not only individual level factors but also those that were present at the family level, and also included wider environmental level influences. Thus, simple provision of knowledge may not translate into practice. For this reason, development of future interventions should consider exploring the parental barriers and facilitators through application of a comprehensive framework, in order to understand how parents can be supported to address the barriers and enhance the facilitators according to their needs.

Furthermore, Aliakbari and colleagues (Aliakbari, Gray-Burrows et al., 2021a) defined parental supervised toothbrushing as a process involving the parent-child dyad or a dyadic process that is a complex set of behaviours pertaining to parents actively engaging in their children's toothbrushing and children co-operating with their toothbrushing. This dyadic process is influenced at multiple levels- individually at both the child and parent level (such as knowledge and skills related to children's toothbrushing), interpersonal level (parent-child level such as child behaviour and management problems) and the environmental level including the wider family and society level influences such as social norms and availability of resources (Aliakbari, Gray-Burrows et al., 2021a).

Similarly, Elison et al (2014), conducted an interview-based study with mothers of children residing in area of Manchester, UK, with some of the worst indicators for caries experience in 5-year-old children. They described how dyadic toothbrushing is influenced at multiple levels and they framed their analysis of maternally perceived barriers and facilitators to their infants' or pre-schoolers' toothbrushing using the ecological model, suggesting that there are influences at both the proximal level such as those involving the child and the parent (such as parental factors including maternal stress, perceived self-efficacy and locus of control; parenting practices and child behaviour), at the distal level which includes external environment (such support and advice from health professionals), and a combination of both level of influences (such as advice from friends and relatives) (Elison, Norgate et al., 2014). Another qualitative study conducted by Finlayson and colleagues (2019) with mothers of 4-year-old children enrolled in home visitor component of the Early Head Start program in US, explored how children's oral hygiene practices are influenced at multiple levels. They used the Fisher-Owen's conceptual model to describe child, family and community level factors that can

significantly affect children's oral hygiene practices (Finlayson, Cabudol et al., 2019). Regardless of the type of framework used to study the level of influences on children's oral hygiene and toothbrushing practices, it is quite evident that there are multiple factors that need to be considered at the individual, family and the society or environmental level during development and implementation of an intervention.

The existing evidence suggests there are a range of factors at different levels that influence children's tooth brushing behaviours, with some of them being contextual. For example, in the study conducted in the UK by Elison and colleagues, the majority of the participants reported having received some form of oral health advice for their infant through dental professionals or health visitors (Elison, Norgate et al., 2014). This is because in this study setting children are in receipt of free dental services under the NHS. Similarly, in the study by Finlayson et al (2019) which was conducted with participants that were enrolled in the Early Head Start (EHS) program, participants reported EHS- home visitor organised parent meetings and play groups provided an opportunity to connect with other EHS parents and the playgroups incorporated an element of brushing children's teeth, which was perceived as a positive influence (Finlayson, Beltran et al., 2019).

It is evident from the previous studies that there are a range of barriers that parents face for their children's oral hygiene, however, the sample of parents in the previous studies (Elison, Norgate et al., 2014, Finlayson, Beltran et al., 2019, Marshman, Ahern et al., 2016), although belonging from a deprived area, were generally knowledgeable regarding children's toothbrushing practices. Furthermore, they also had access to free dental services for their children and/or the opportunity to have had children's oral health related conversations with dental professionals and trained non-dental health workers such as health visitors.

In Pakistan, studies examining oral health behaviours of children have reported poor toothbrushing practices. In a cross-sectional survey study of 300 parents of children aged 6 months to 10 years age, the authors reported that despite two-thirds of parents responses being indicative of positive oral health attitudes for their children, 52% stated that their children did not brush twice daily (Manzoor, Iqbal et al., 2021). Similarly, in a study which examined feeding and oral hygiene habits of 435 preschool children (12-15 months old) and their caregivers' attitude, reported only 40% mothers brushed their children's teeth, out of which only 5.1% brushed them for twice or more times daily (Awais, Naheed et al., 2019). Another study investigating maternal factors affecting toothbrushing of children less than 5 years of age, reported that out of 281 mothers

sampled, only 18.5% were aware that twice daily toothbrushing is necessary, 13.9% reported awareness regarding role of fluorides contained in toothpaste and 22.1% mothers were aware about the correct method of toothbrushing (Nisar and Mubeen, 2015).

Furthermore, there is no availability of a national dental health service including preventive services for children and although, as noted previously, there is a well-established network of LHWs working for the health of their communities, oral health promotion has never been a part of their work duties. Finally, there has been no previous study conducted in Pakistan to qualitatively explore parental barriers and facilitators for their children's toothbrushing. Thus, this study was designed to understand the context specific factors that can facilitate or hinder the performance of the target behaviour, from the perspectives of the mothers as the primary caregiver, and the context related factors that can hinder or enable oral health promotion, from the perspectives of the LHWs. This informed the development and testing of a behavioural intervention to support parents for engaging in their children's toothbrushing practices.

4.3 Aims & objectives

The aims of this study were:

1. To explore the barriers and facilitators for parental engagement with their children's toothbrushing
2. To explore the barriers and facilitators for children's oral health promotion by the LHWs

The specific objectives were:

- To understand parental oral health knowledge, beliefs and practices regarding their children's oral health.
- To establish barriers and facilitators that parents face for engaging in tooth brushing practice of their children
- To understand LHWs knowledge regarding children's oral health
- To establish barriers and facilitators for children's oral health promotion by LHWs as part of their routine work.

The findings of this study would inform the development of a behavioural intervention by mapping previously identified BCTs and the barriers and facilitators to behavioural determinants in order to provide support to families for adoption of recommended toothbrushing behaviours for their children.

4.4 Methods

4.4.1 Study design

This exploratory qualitative study involved face-to-face focus group discussions (FGDs) with parents of children in Pakistan (n=2) and LHWs involved in community health promotion provision in Pakistan (n=2). Focus groups are a useful method to explore people's knowledge and experience and to provide answers to questions about what, how and why they think the way they do (Kitzinger, 1995). By bringing people to 'focus collectively on an issue', they allow researchers to gather many perspectives at the same time from a 'group of people who have experienced the same problem' (Wilkinson, 1998). Focus groups were selected as the choice of data collection method for the current study as they allow for group interaction and opportunity for participants to take cues from other's ideas to express their own views. Although it is considered a possibility that some participants' may feel embarrassed or uncomfortable sharing their experiences in front of the other participants, there is evidence to suggest the contrary may be true. In a randomised study comparing focus groups and interviews, it was found that personal and/or sensitive information disclosures were more likely in a focus group setting (Guest, Namey et al., 2017b). This could be because as compared to an interview, it is possible to establish a more relaxed environment in a focus group where a participant does not have to answer every question and having a feeling of that convenience and a space to speak whenever they felt they wanted can facilitate self-disclosure (Coenen, Stamm et al., 2012). Furthermore, conducting focus groups was also a logistically appropriate choice as it allowed to gather many views in a short span of time.

4.4.2 Study setting

The socio-cultural makeup of Pakistan, for the urban and the rural areas is largely similar across the country. A formative qualitative report which used a representative sample from both the urban and rural areas of all four provinces of Pakistan reported distinct gender roles at the household levels without urban and rural differentials. Caring for the children and the family, and everyday household related chores such as washing, cleaning, cooking etc are considered a women's responsibility, whereas men's responsibility is to earn and provide for the family (UNICEF, 2018). Furthermore, studies that analysed the dietary consumption pattern using data of a nationally representative sample from Pakistan Household Integrated Economic Survey (HIES) reported limited dietary diversity with consumption of more calorie dense foods (Datta and Husain, 2020, Haider and Zaidi, 2017). A 40% food expenditure related to wheat and dairy products was reported with households in lowest income quintile spending more on buying wheat,

while those belonging to top income quintile spent most on dairy and meat products (Haider and Zaidi, 2017). The carbonated beverage consumption was found to be on the rise for all household groups, however, wealthier households were reported to have a higher prevalence of consumption (Datta and Husain, 2020). In terms of consumption of processed foods, a comparison of consumption of low-income Pakistani adults with that of developed nations such as the United Kingdom, has reported high dietary processed food pattern (burgers, fried food, chips, pizza) and increased confectionary food pattern (sweets, bakery items, chocolates) for Western countries (Safdar, Bertone-Johnson et al., 2013).

This study was based in District Mansehra, Khyber Pakhtunkhwa province, Pakistan (Figure 4.1). The district has a population of 1,556,460 with 90.7% classed as rural population. The literacy rate of 62.8 % and an average household size of 6.66 persons. The demographic indicators are comparable to the national average, such as, the national literacy ratio of 60% and national average household size of 6.24 persons (Pakistan Bureau of Statistics, 2018). The district is subdivided into 3 distinct units called tehsils (townships) which are further divided into smaller administrative units known as the Union Councils (UC).

The index of multiple deprivation (IMD), presents an updated national database which reflects findings from the Pakistan Social and Living Standards Measurement survey (PSLM 2019-2020). The IMD provides a composite measure for deprivations that are experienced at more than one level such as education, health, housing quality, housing services and asset deprivation (Jamal, 2022). Mansehra district scores in the low category out of low, middle and high deprivation category for the KPK province, based on the percentage of population deprived in terms of selected indicators mentioned (Jamal, 2022). Thus, making it a good testing bed, as given the high prevalence of caries in children throughout the country, findings from a highly deprived area may not be more generalisable to areas of low deprivation, and may even result in narrowly focussing on the problem. Using the researchers contacts and professional and personal networks, Mansehra tehsil was selected as the study setting for this research. According to the census 2017, majority of the area is classed as rural (85.8%) with an almost equal gender distribution (50.1% males and 49.8% females) (Pakistan Bureau of Statistics, 2018).

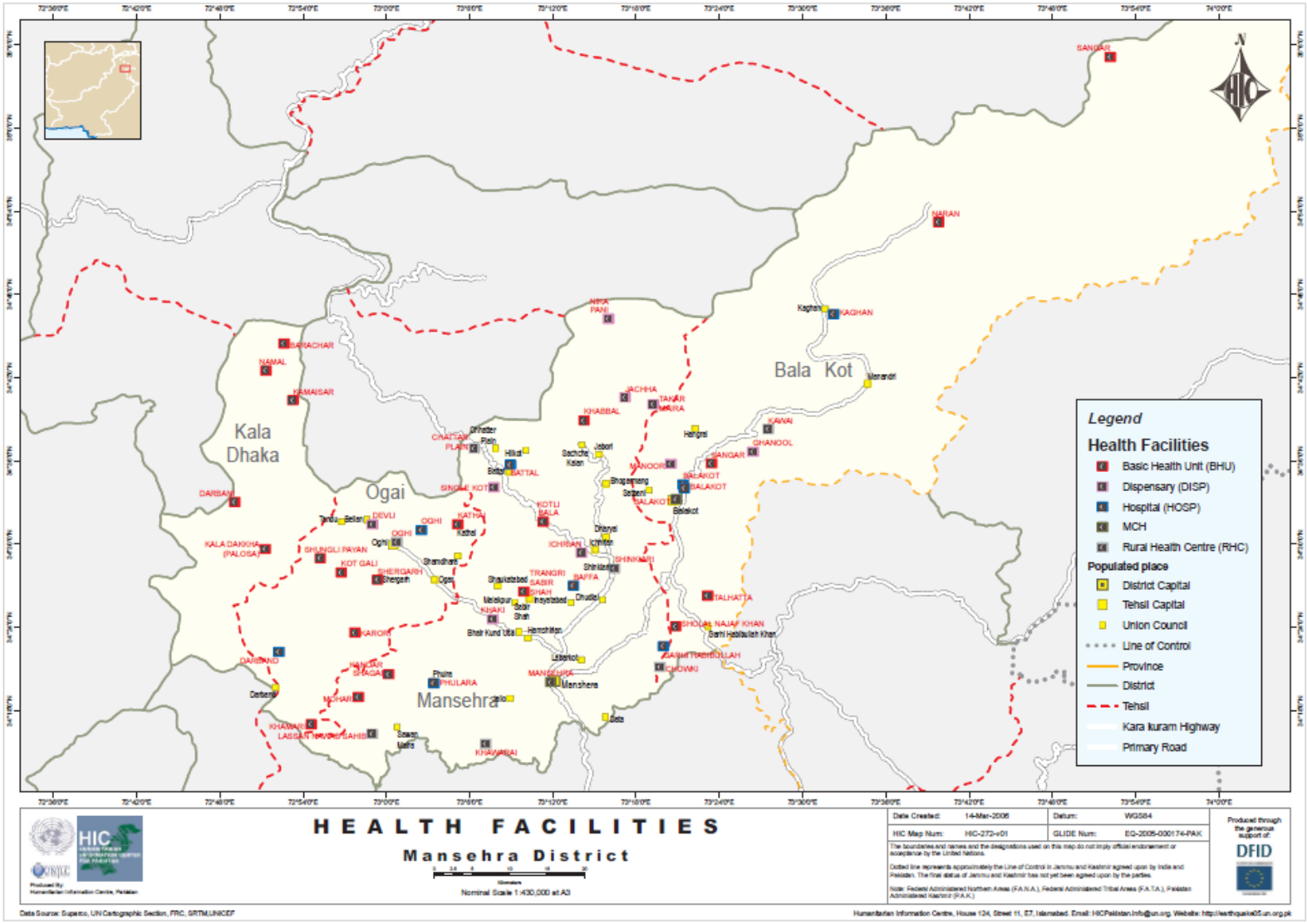


Figure 4.1 Map of Mansehra district, KP, Pakistan

4.4.3. Sampling

Eligible participants were mothers, as the primary caregivers of children with at least one child up to 7 years of age and LHWs working in the study setting.

The literature on sizes for focus groups report at least two focus groups to broadly identify themes in a relatively homogenous sample (Guest, Namey et al., 2017a). It is recommended to recruit between 6-10 participants per focus group to avoid problems with sustaining a discussion if there are very few participants or difficulty in controlling one in case of a large group (Morgan, 1997). Given that the potential participants to be recruited for the focus groups belonged to the same neighbourhood and the sample was expected to be relatively homogenous in terms of socioeconomic status and ethno-linguistics, this along with the logistical issues such as a setting a convenient location and time, two focus groups were conducted with mothers and two focus groups with LHWs with total of 34 participants.

The focus groups with mothers consisted of a total of 16 mother participants with 10 participants in the first focus group and six in the second one. The total number of LHWs was 18 with eight participants in the first focus group and 10 in the second session.

Participants

A purposive sampling strategy was adopted to recruit participants to both sets of focus groups. Within these sets of focus groups, efforts were made to include as much variation as possible based on mother and child characteristics such as by recruiting first time mothers, single child mothers and those having multiple children, mothers of very young children and also those with children belonging to different age groups. This was done to allow a meaningful discussion to be generated amongst the participants, sharing their different experiences, which would allow capturing of a range of barriers and facilitators according to mother/child's characteristics. Similarly, for the focus groups with LHWs, recruitment consisted of those with considerable experience as well as those who had relatively less experience of being in the job. This was, again, done to allow capturing of different views and to generate a meaningful discussion and sharing of different experiences.

Recruitment

Recruitment of the study participants was facilitated by the gatekeepers who are "essential mediators for accessing study settings and participants" (Andoh-Arthur, 2020). Gatekeepers are commonly used in qualitative research to allow access to participants who are otherwise hard to reach. Contact was made with a Lady Health Supervisor (LHS) whose details were provided by a mutual contact in the current study setting.

Each LHS oversees the work of 25-30 LHWs (Aftab, Piryani et al., 2021). The LHWs were informed about the research by the LHS during one of their briefing sessions. As the idea of obtaining a purposive sample based on variability of experience working in the field was shared with the LHS, she helped with recruiting a varied sample of LHWs by passing the details of those expressing interest for taking part in the research. Contact was then established with each of the potential participant to provide details of the study and allowed them the opportunity to ask questions.

The recruited LHWs helped with recruitment of the eligible mother participants as due to the nature of their work, they have detailed information on demographics of the residents in their area, and a good rapport with mothers, making them ideal gatekeepers.

Eligible mothers were contacted by LHWs to inform them about the study and direct them to the researcher. At this point mothers were provided information regarding the study verbally by me and provided time to consider and discuss with their families. They were contacted again after two days and those expressing interest to participate were then informed about the focus group timing and location details.

4.4.4 Data Collection

On the day of the FGDs, participants were provided with an Urdu translated information sheet (English version provided in appendix 4.1). It was once again stated and made clear to the participants that participation was voluntary and they did not have to participate if they did not wish to without their level of care being affected in any way. It was also reiterated that all data would be handled securely ensuring participant confidentiality. Participants were given the opportunity to ask questions regarding the study if they wished to, and informed written consent was obtained at the start of each FGD.

Two FGDs were conducted with each set of participants- the mothers and the LHWs. Participants were asked to set aside 90-120 minutes for the session to allow sufficient time for discussion and refreshments which were provided at the end of the session. Venue for each of the FGDs with mother participants was arranged at one of the LHW's health house which is a dedicated room in LHWs house where they provide health consultations and services to their community members. This was done to ensure that participants felt at ease being in familiar surroundings. The respective LHW was not present during the FGDs with mothers. Travelling cost reimbursement was offered to mothers for any travelling expense that they may have incurred whilst travelling to the venue. Focus group discussions with LHWs were arranged so that they could be conducted at the end of a LHW team meeting at the team meeting venue.

A semi-structured focus group topic guide was used to guide the discussions. This was based on the TDF and adapted by consulting previous literature on similar topics (Duijster, de Jong-Lenters et al., 2015, Marshman, Ahern et al., 2016, Virgo-Milton, Boak et al., 2016) (Appendix 4.2).

Although the topic guide was informed by the TDF, care was taken to not to apply it too rigidly to avoid restricting participants to generate new ideas. Each focus group topic guide was pilot tested with two mothers and two LHWs. There were some minor adjustments made to the topic guide after the pilot testing (such as including examples to allow better understanding of the question by the participants, for example in a question related to staying away from home, it was suggested to include examples related to the context such as a mother with her children visiting her parents' home for a few days, being away attending weddings in the family etc). These test run sessions were not included in the analysis.

The FGDs with mothers covered their perceptions regarding children's oral health beliefs, practices by exploring their toothbrushing knowledge and current toothbrushing practices (related to their skills and confidence), barriers and facilitators for engaging in children's oral hygiene practices with questions on managing child's toothbrushing, and specific questions related to development of behavioural support intervention. The FGDs with LHWs explored their work-related motivation and challenges, knowledge and beliefs regarding children's oral health, their oral health related training needs (existing skills and confidence), and specific questions related to intervention development.

The focus groups were conducted in Urdu and were moderated by the researcher who is fluent in the language. The FGDs were audio recorded using two digital recorders to avoid any technical difficulties such as equipment failure etc. This allowed accurate transcription for data analysis purposes and also precluded the need for excessive note-taking, freeing the researcher to focus on what was being said by the participants.

A pre-compiled script was used to open the focus groups in order to set a standardised introduction. This included details about the research, researcher's role as a moderator, and information and encouragement to the participants on how to keep the discussion going. In order to allow participants equal opportunity to share their views, it was highlighted that everyone's opinion mattered and to be respectful of others and allow everyone a chance to speak. Participants were assured about confidentiality and it was reiterated to them about there being no right or wrong answers.

On completion of the focus groups, both sets of participants were provided with a small token of appreciation for their time, in the form of Pakistani Rupee (PKR) 100 which is approximately GBP 0.52 (current currency rate), prepaid calling card for local talk time.

4.4.5 Data Analysis

For the purpose of data analysis, all recordings were transcribed verbatim in Urdu and transcripts pseudonymised. They were translated to English for the purpose of data analysis. A framework analysis approach guided by the TDF and COM-B model of behaviour change was employed to analyse the data. The COM-B model refers to capability, opportunity and motivation and was developed as a behaviour system to allow for intervention development by linking behavioural determinants (identified as TDF domains) to behaviour change techniques (BCTs) (Michie, Van Stralen et al., 2011). The choice of TDF and COM-B model to underpin the identification of barriers and facilitators for targeted behaviour and subsequent intervention development, was based on their comprehensive and coherent way of identifying links between behaviour and theory.

Framework analysis introduced by Ritchie and Spencer, is a valid and rigorous approach, designed to produce easily interpreted results (Ritchie and Spencer, 1994). It is a pragmatic approach that draws on both inductive and deductive processes and can be applied to generate themes with various qualitative approaches (Gale, Heath

et al., 2013). Framework analysis broadly sits within the thematic analysis method and is a systematic approach to analysing the data in order to classify and summarise it according to the structure of a preselected framework, such as the TDF and COM-B in this case.

Data analysis was carried out in following stages which incorporates the five steps of framework analysis as developed by Ritchie and Spencer (1994) and outlined by Marshman et al (2016) and Scott et al (2019) (Ritchie and Spencer, 1994, Scott, Twigg et al., 2019) Data analysis was facilitated by the use of NVivo version 12 (QSR International Pty Ltd. (2018)) qualitative data analysis software.

1. *Identifying initial themes*

Transcripts of the FGDs were read and re-read to allow coding at the basic level, in order to allow capturing of emergent themes independent of the TDF domains at this initial stage of data analysis. This relates to the step 1: data familiarisation and step 2: identifying thematic framework, of the traditional framework analysis.

2. *Sorting the data by theme*

Similar themes were organised into categories and notes made on the general fit to the TDF. To ensure codes and categories reflect the underlying themes, constant referral to original transcripts and concept maps was undertaken. This step in the data analysis relates to the step 3: indexing and applying the framework, of the framework analysis process.

3. *Mapping the determinants to TDF*

Following the step 4 of charting the data as outlined in the framework qualitative analysis steps (Ritchie and Spencer, 1994), in this stage, coded data was then mapped to the TDF domains and its related component constructs. It was decided to group together separately the codes or categories from the data that did not fit into any of the TDF domains.

4. *Synthesising the data*

While retaining the context and language used in the data, thematic charts were created for each TDF domain. This relates to the step 5: mapping and interpretation of data. Through comparison between accounts of mothers and LHWs, those domains were prioritised that need to be targeted for development of a behavioural intervention for promotion of toothbrushing practices in children. Referral to previous

literature was undertaken to ensure credibility of findings. Reporting of data includes verbatim quotes and summary of responses.

In order to present the data in a compact and easily comprehensible manner, the TDF domains with the data in them were then grouped according to the COM-B model of behaviour change as the overarching themes, to identify the capability, opportunity and motivation drivers to facilitate development of a behaviour change intervention.

4.4.6 Reflexivity

A reflexive journal was maintained from the beginning of this study to ensure a transparent and rigorous research process. Reflexivity can be described as a "continuous process of reflection by a researcher on their values" (Palaganas, Sanchez et al., 2017, Parahoo, 2006). It is an acknowledgement of how changes in researchers themselves have been brought about by the research process and how these changes have in turn shaped the research process (Palaganas, Sanchez et al., 2017). Although it is unrealistic to assume complete detachment by the researcher from the research process to be possible, it is essential on the part of a researcher to be mindful of the influence exerted by their positionality. Positionality refers to the position that the researcher has situated themselves in within their research which can be informed by being reflexive. This entails understanding one's part and influence on their research and seeking to acknowledge and disclose this information (Holmes, 2020). Coming from a dental background, my understanding before undertaking the focus groups was that mother's lacked knowledge regarding children's oral healthcare and this was compounded by lack of importance given to primary teeth. Furthermore, before speaking to the LHWs I had expected some level of reluctance from them to engage in oral health promotion of children in their communities due to workloads and this being not part of their duties.

There have been three areas identified as important for the process of reflexivity (1) the topic being studied (2) the research participants and (3) the context and the research process (Holmes, 2020). In the following subsections, I articulate my positionality as part of the research process in relation to each of these three areas.

The topic: researcher's background, experience and assumptions

My clinical background and professional work experience was the reason for my focus on this topic. From a clinician's point of view, I have on many instances asked myself, 'why don't parents brush their children's teeth twice daily to avoid tooth decay'. Later,

when I became a mother, I realised it may not be as simple as it seems. Thus, an important question to address here was whether the participant's having the knowledge of researcher's professional background could have influenced how they spoke of their own experiences. Keeping this in mind, I introduced myself not only as a dental professional but also as a mother who faced the same parenting challenges as any typical mother. This was done to allow for an open and frank discussion, which could have been potentially compromised if the participants viewed the researcher only as a dental professional, and feeling the need to exaggerate their oral health related behaviours and practices.

The participants: including a wide range of perspectives

Fair dealing (Dingwall, 1992) refers to incorporating a wide range of perspectives so that views of one group are not presented as the sole truth about a situation (Bricks et al 2014). Including both sets of stakeholders- the mothers and the LHWs, I attempted to explore perspectives from both the potential intervention receivers and the intervention deliverers. Furthermore, during the data analysis procedure, a method of constant comparison was undertaken to uncover differences and similarities in the accounts of both sets of participants especially in relation to the social norms around oral hygiene/toothbrushing practices. These were highlighted during the presentation of findings (for example: when only the LHWs spoke about children following their parents' actions and adults in the house need to role model the behaviour).

Although the main goal was to identify common themes across the focus groups, nonetheless, equal importance was given to an individual's account in an attempt to identify views of individuals as well as the majority when stated.

The research context

The insider-outsider debate

There is always the possibility of difference between how a researcher views themselves and the way that the participants view the researcher. The dilemma of being seen as an insider or an outsider is akin to that of a 'double-edged sword' with both possibilities having their own set of advantages and disadvantages. The insider advantages include the researcher to be considered as part of participants' own culture, for which reason the participants may trust them much more easily and speak more freely. This position also allows the researcher to ask meaningful questions and

avoids the case of ‘cultural shock’. On the other hand, the disadvantages include being overly sympathetic leading to formation of biased views or the inability to ask provocative questions. The participants may also consider the researcher to have detailed knowledge about the phenomena hence may not delve into the details of it or may even seem reluctant to disclose sensitive information which might not be the case if the researcher was considered an outsider without any possibility of future contact outside of the research (Holmes, 2020).

The fact that I had the same cultural background but was residing outside of Pakistan may have afforded me the best of the insider-outsider possibilities. Also, as the focus groups were conducted in participant’s workplace or a surrounding that was familiar to them, this may have allowed them a sense of control over the situation thus acting as an encouragement for them to express their views freely.

Wider perspectives

As this study is a part of the PhD research, I being the researcher, was the primary person involved in recruitment, conducting the focus groups and data analysis. Nevertheless, I had opportunities to discuss different stages of the study from planning to execution to data analysis with my supervisors and the thesis advisory panel (TAP).

4.4.7 Ethics

This was a low risk study and every attempt was made to ensure participant comfort and wellbeing at all times. It was unlikely that there would be any incidental medical findings during the study. However, in case there was any incidental medical finding, it was decided to refer the participants to the medical officer at the Primary health centre (PHC). Ethics approval was obtained from University of York, Health Sciences Research Governance Committee (HSRGC) and National Bio Ethics Committee (NBC) in Pakistan.

4.5 Results

In total 4 focus groups were conducted, out of which two were conducted with mother participants and two with LHWs.

As the data for all the focus groups was analysed using the TDF and included similar, cross-cutting themes for mothers and the LHWs, therefore, the findings are discussed

together (Table 4.1). There was found to be some overlap between the themes with more than one TDF domain but to ensure ease of readability, themes have been placed under one domain only but the overlap has been highlighted accordingly.

4.5.1 Capability

TDF domains of Knowledge & skills

Theme 1: Limited knowledge and skills around toothbrushing behaviours and routines

It was apparent, through the FGDs conducted with mothers, that knowledge about children's toothbrushing was an area that mothers needed support with. Although many mothers confessed to having the knowledge of twice daily toothbrushing, there was a mixed response when they were asked about the age when they initiated their children's toothbrushing and how many times their children brushed their teeth or had them brushed.

> *"By three to four years of age, my children started brushing" (FGD-2, M-03)*

> *"my older child is now 6 years old so from 5 years of age [she started toothbrushing]" (FGD-1, M-09)*

Considering the late start of toothbrushing in children, at an age when all their primary teeth would have erupted, points towards the lack of importance given to the primary dentition in children. This lack of knowledge regarding the importance of the primary dentition was further highlighted when two participants questioned whether it was even necessary to brush young children's teeth.

> *"Is it necessary for small children to have their teeth brushed?" (FGD-2, M-03).*

The LHWs acknowledged that they did not have enough information regarding dental and oral health and so when they were asked about their thoughts related to when toothbrushing in a child should be initiated, they offered varied responses with some suggesting, *"when they start eating"* (FGD-3, LHW-03), whilst others suggested even when children are very young and have mostly milk in their diet, their teeth should be brushed.

"No, even if they have milk, that too has sugar in it, when their teeth have emerged, they should immediately start brushing." (FGD-3, LHW-06).

Regarding the toothbrushing routine, brushing once only, during morning time was cited by the majority of mothers as the most common toothbrushing routine for their children.

"They brush only in the morning, my three children" (FGD-1, M-01).

Only a few mothers mentioned that their children brushed during the night. They stated that as their children only brushed once during the day, so they made sure it was before going to bed.

"Even if they don't brush twice a day, still they brush at night" (FGD-1, M-05).

Mothers were prompted to discuss the reasons behind their children's current toothbrushing routine and it was apparent that those who mostly had their children brush in the mornings did it for social reasons more than the health benefits of toothbrushing.

"It seems easier and also we think that they are going outside so that they don't feel embarrassed about bad smell or teeth looking unclean. At night, we leave it thinking that they just have to sleep now and when they get up they can do it. This is what happens." (FGD-2, M-03).

It was very noticeable that health benefits of toothbrushing did not come up as the most important reason for children's toothbrushing but instead cosmetic or social reasons for toothbrushing were prioritised such as to avoid bad breath and unclean appearance of teeth.

The LHWs were aware of children's once daily, especially morning toothbrushing practices that were commonly followed.

"One time during the morning they brush their teeth, that too after telling them again and again to clean their teeth. But at night, no matter how much one keeps telling them, they don't do it, they go to sleep." (FGD-3, LHW-01).

Table 4.1 Table mapping barriers and facilitators to TDF domains

TDF Domain (definition)	Barriers (B) and Facilitators (F) for children's toothbrushing practice/promotion	
	FGD- Mothers	**FGD-LHWs**
Knowledge (An awareness of existence of something)	- Lack of knowledge related to caring for primary teeth and level of involvement in children's toothbrushing (B) - Poor understanding of risk factors for caries and benefits of twice daily toothbrushing with fluoride toothpaste (B) - Awareness of importance of brushing at night (F) - Awareness of lack of knowledge related to dental hygiene (F)	- Understanding of importance of twice daily brushing (F) - Knowledge of toothbrushing practices of children (F) - Lack of knowledge related to toothpaste quantity and use of fluoride toothpaste (B) - Lack of knowledge regarding when to start child's toothbrushing (B)
Social role/Professional role and Identity (A coherent set of behaviours and personal qualities displayed in social settings)	Mother's duty to take care of her children (F)	- Working as a link between the health centre and the community (F) - Advising about health problems (F)
Skills (An ability or proficiency acquired through practice)	- Finding it difficult to brush their children's teeth (B) - Failure to maintain a routine (B) - Gentle brushing of their children's teeth (F)	- Building rapport and dispelling myths about health and health problems (F) - Not sure of how to advise mothers regarding their children's toothbrushing (B)
Beliefs about capability (Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use)	- Belief that they can manage it if they try (F) - Finding managing time difficult (B) - Making an effort to take care of their children's teeth (F)	- Ability to give proper health advice to the community (F) - Willingness to incorporate toothbrushing advice in their routine work (F)

Optimism (The confidence that things will happen for the best or that desired goals will be attained)	- Feeling of awareness about negligence towards children's toothbrushing (F)	- Confidence in effectiveness of their communication skills (F)
Beliefs about consequences (Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation)	- Feeling that not being able to take care of their teeth when they were young has resulted in poor oral health (F) - Taking care of their children's teeth at this early stage will have better outcomes for their children in future (F)	- New knowledge transferred to rest of the community (F) - People following their advice (F)
Reinforcement (Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus)	- Parents' giving incentives to children gets them to brush (F)	Regular home visiting provides opportunity for reinforcement of messages (F). - Needing to provide incentives for people to pay attention (B, F)
Intentions (A conscious decision to perform a behaviour or a resolve to act in a certain way)	- Past negative experiences makes them want to do more for their children's dental health (F)	- Willingness to provide children's toothbrushing advice to mothers (F)
Goals (Mental representations of outcomes or end states that an individual wants to achieve)	- Achieving state of good oral health for themselves and their children (F)	- Improving health of people in their communities (F)
Memory, attention and decision processes (The ability to retain information, focus selectively on aspects of the environment and	- Forgetting to remind children to brush (B)	- Knowing when to give advice and when to refer for care in acute stages of disease (F).

choose between two or more alternatives)		
Environmental context and resources (Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour)	- Easy availability of toothbrush and toothpaste (F) - Non-existence of oral health messages from health professionals/providers (B) - Breaks in routine during weekends/holidays (B)	- Working in their own communities, people trust them (F) - Confident about management's positive response for incorporating promotion of children's toothbrushing (F) - Use of traditional teeth cleaning aids and willingness to follow best advice (B, F)
Social influences (Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours)	- Negative influence of close ones having irregular toothbrushing routine for their children (B) - Support from other family members especially fathers (B, F) - Brushing only in the morning due to social reasons (B, F)	- Understanding of social norms and giving advice appropriately (F). - False beliefs around polio vaccine in the community creates general negativity (B).
Emotion (A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event)	- Mother's sense of guilt for not being able take care of her children's teeth (B) - Sense of satisfaction when children's teeth have been cleaned (F)	- Sense of dedication, pride and satisfaction for working in the community (F) - Feelings of resentment for not being recognised enough for the work and patient referrals, by other health professionals (B)
Behaviour regulation (anything aimed at managing or changing objectively observed or measured actions)	- Inability to manage difficult child behaviour (B) - Receiving proper toothbrushing advice with illustrations (F) - Reinforcement of messages (F)	- Training session for provision of toothbrushing advice (F) - Refresher training session at least once in a year or 6months (F)

TDF domains of Memory, attention and decision processes and Behaviour regulation

Theme 2: Toothbrushing not given a priority which causes dental problems and need for treatment

Another reason for skipping night-time toothbrushing was attributed to the fact that the mothers were so caught up in other household chores that getting children to brush their teeth was forgotten about most of the times until it was too late in the day when children had already fallen asleep. This finding also links to the domain of environmental context and resources of the TDF (and opportunity domain of COM-B model) and is also discussed under that domain.

> *"When I go to their room, they have already gone to sleep and waking them up to do it [toothbrushing] is difficult. Even if sometimes I wake them up, they become so uncooperative that they don't do it." (FGD-1, M-07).*

> *"If they are about to sleep and if you make them do it by being firm then they start whining and crying so it is left out most of the times." (FGD-2, M-06).*

This again is indicative of the low importance given to children's primary teeth which has resulted in a once daily toothbrushing routine.

It was however also evident that mothers were aware of this on-going vicious cycle in which toothbrushing at night was left out frequently. Hence, they improvised with other measures that perhaps allowed them a sense of satisfaction for having at least done something to look after their children's teeth, not realising that reduction of sugar intake and just rinsing the mouth may be beneficial but cannot replace the benefits of toothbrushing with a fluoride toothpaste.

> *"Yes, what I make sure is I try to limit their sugar intake before they are to go to bed. So even if they are not brushing then at least this would save them somewhat. They have dinner, drink water and go to sleep" (FGD-2, M-03).*

Some mothers also stated how for getting their children to brush their teeth, they have to remind them repeatedly and have to check up on them constantly. Child's uncooperative behaviour was perceived as a barrier to children's toothbrushing practice.

"For my 5-year-old daughter, I have to remind her to brush her teeth again and again and I have to check whether she is brushing or not." (FGD- 2, M-04).

Children's uncooperative behaviour related to toothbrushing can be linked to what LHWs had to say about adults' own toothbrushing behaviours and how children copied them. This points to a significant barrier especially as children consider their elders as role models and in order to support parents in their children's toothbrushing, it is important to make them realise the significance of the household keeping up with twice daily toothbrushing in order to model the behaviour for their children to follow.

"To be honest, adults don't do it so when would children do it" (FGD-3, LHW-01).

Furthermore, as part of the LHWs duties is providing basic preventive and curative care, they were asked in case of having no detailed knowledge of oral health and related ailments, how they managed cases in their communities when they were consulted for advice. To this they replied that in such a case they referred the person to consult a dentist.

"It's my sister's fifth day of toothache, she is holding her face and also has sugar [diabetes]. She says where should I go to? The wound will not heal, they are scared. So, then [in a case like this] we tell them to get their sugar under control and get it treated." (FGD-3, LHW-06).

This suggests that the LHWs had basic knowledge about the common ailments in this population and paid attention to details such as how the health status of a person may compromise the result of treatment that they may receive. From this it is apparent that the LHWs have the capability to give right advice and appropriate referrals for the people in their community and this can be further built on to incorporate children's oral health promotion through provision of appropriate training

4.5.2 Opportunity

TDF domain of Social Influences

Theme 3: Social norms

It was quite apparent from both the mothers' and LHWs' accounts that children brushing their teeth only once, during morning before going to school was a norm. Many mothers also stated that they were aware of their family and friends toothbrushing practices for

their children which was done whenever they could spare time for it otherwise it was just left out many times.

> *"My sister doesn't brush her children's teeth that often, she is always so busy." (FGD-2, M-04).*

This suggests that mothers compared their children's toothbrushing practices with that of their family and friends which perhaps afforded them a sense of doing much better than their peers in this regard, even if they had their children brush only once a day.

The LHWs were aware of their professional identity within their setting and spoke about the trust and rapport that they shared with the people in their community. With an exception of a handful of families who were averse to any kind of health initiatives delivered to them (such as polio vaccine campaign), they were confident that mothers would find it acceptable to receive children's oral health advice from them.

> *"Our knowledge about this is limited, we have some but it is limited. Whatever you tell us, we would then go and tell people properly. This will benefit us and the people too" (FGD-3, LHW-02).*

TDF domain of Environmental context & resources

Theme 4: Availability/unavailability of resources/support

Also linked to the domain of social role or identity which is a part of the previously discussed social influences, mothers spoke about how the responsibility of caring for their children lays primarily with them. This includes managing their children's toothbrushing practices according to their circumstances. For example, mothers who were tied up with their household chores explained that they were not able to implement a night time tooth brushing routine. On the other hand, those mothers who were unable to have their children brush in the morning said that was because it was left off in the midst of the morning school rush.

> *"The reason is that I am so busy in my chores and they are sleepy after being up the whole day. They are tired at night, they just do their homework and then go to sleep." (FGD-1, M-10).*

"because in the morning when sending them to school, it becomes very difficult, they are in a hurry so that is why I don't make them do it in the morning." (FGD-2, M-06).

The mothers shared their views regarding the availability of the toothbrushes and toothpaste, and additionally, a LHW who is a mother herself spoke about buying the toothbrushes and toothpaste for her family as part of her grocery shopping routine.

"when I get everything on the 1st of every month then I buy 5 brushes too with it." (FGD-4, LHW-08).

Furthermore, mothers also spoke about how they managed to continue with their children's toothbrushing during holidays or when they stayed away from home. Some stated that in such a case, they would try and bring theirs along with them, while others mentioned they just bought new ones so that they did not have to worry about always packing them for a stay away from home, such as when children visit their grandparents.

"When I go to my mother's house to stay, I take them [referring to her own and her children's toothbrushes] with me." (FGD-1, M-01).

"Nowadays you know they are easily available everywhere so we get them and do the brushing then." (FGD-2, M-03).

However, it was apparent that during the weekends, even the morning toothbrushing practice was often overlooked because of the lax in the morning routine which was otherwise much more diligently followed during the weekdays as part of getting ready for school.

"It is usually left off during the days off as children wake up late and then so don't pay much attention to it… During school days it is something that is definitely done." (FGD-2, M-05).

Another finding that linked to both the social influences (such as practices of older people in the house/family, for example: grandparents), and the domain of environmental context and resources, was the use of additional/alternative teeth cleaning aids such as *dandasa* (walnut tree bark) which is used locally in Pakistan or the *miswak stick*, the use of which has religious meaning attached to it. However, these traditional practices may not be particularly followed by the younger generation for themselves or their children. Furthermore, the LHWs views about following the best advice for health, was identified as a facilitator for promoting children's oral health.

"My mother-in-law still uses dandasa, she has never used any type of brush…"

"Nowadays nobody does it, we people don't use it. Those were people from old times, they were more into using such things. These are good things, but now like how the times are advancing, new things keep coming out and we got to follow the best advice" (FGD-4, LHW-03 and 09 speaking respectively).

Furthermore, LHWs views were also explored about how supportive they thought other members of their team or the management would be of them providing mothers support and advice regarding children's toothbrushing. They replied very positively, saying that they will be happy for this topic to be brought up as tooth decay is a household problem and any initiative to tackle this issue would be an opportunity that would be greatly appreciated.

"I think, this point about teeth, it is a part of our health, health is the most important thing, I don't think they should have objections." (FGD-4, LHW-03).

"If there is new knowledge addition for us, so people of our staff, meaning obviously if we have this information and we pass it on to people so it keeps increasing." (FGD-3, LHW-08).

Further to this, the LHWs were enquired about their views related to their oral health training provision such as its format, duration, and frequency. They were quick to respond with suggestions as they frequently received trainings and workshops from professionals and the industry sector, related to maternal and child health and health related products that can be promoted in their communities. They spoke about how they have set days for training and workshops, and coordinating with that routine will ensure seamless inclusion in their work cycle. Duration was stated as not a problem as long as it was included in their training days. However, they did discuss about how simple measures such a provision of refreshments or training packs (including stationery and memorabilia) can increase the motivation of those attending the trainings. They all agreed that periodic refresher trainings would benefit them which would again be similar to what happens in their routine work practice.

“So, the people from Jacob gave us training and with that they would also give us some refreshment….and people from Nestle came to give us some training [about Lactogen infant milk formula], in that they provided us each with a lunch box. This way we have some refreshment too and can listen to them attentively.” (FGD-3, LHW 03).

4.5.3 Motivation

TDF domains of Beliefs about consequences, Emotion

Theme 5: Preventing tooth decay

Both the mothers and the LHWs acknowledged that tooth decay was a very common problem and a very painful one too. Mothers stated that they regretted not being able to take care of their own oral health, which is something that they did not wish for their children. Furthermore, although they were aware of children's toothbrushing not being prioritised in their daily routine, they did feel a sense of satisfaction whenever they could get their children to brush their teeth.

"I tell them in my childhood maybe it was because of my laziness or because I was not made to do it regularly when in hurry, during my childhood and now I have this problem so that you don’t have it too." (FGD-1, M-05).

"When we have made them brush then we have the satisfaction that their teeth are clean, this will benefit them" (FGD-2, M-01).

Another significant point raised by mothers was the lack of information regarding consequences of tooth decay in children and how it could be prevented. This highlights the lack of availability of support from dental and non-dental health professionals such as physicians and paediatricians, and failure to consider oral health as part of the general physical health and overall wellbeing. This also links to the theme of availability/unavailability of support covered by the environmental context and resources domain of the TDF.

"They should be telling more about the advantages, to the mother, that it will save doctor’s expenses, save from toothache" (FGD-2, M-06).

The LHWs showed considerable interest for promotion of toothbrushing and oral health in their respective communities. For them this is linked to their motivation of being able

to help people and being recognised for the crucial work that they perform in the communities.

> *"If a child's teeth turn out well, so how much they would pray for us that they have been guided properly by us" (FGD-3, LHW-06).*

TDF domains of Beliefs about capabilities, Intentions

Theme 6: Making an effort

Although it was apparent during the FGDs that oral health was not given a priority, but mothers indicated their intention for wanting the best oral health outcomes for their children and demonstrated willingness to work towards it.

> *"It will be difficult as there are many chores to attend to but a person can try to do it for them, twice a day, and also for one's own self." (FGD-2, M-06).*

In the end, the LHWs views were explored regarding one of the most important question: would they like to provide children's toothbrushing advice to mothers? And the response was overwhelmingly positive. One reason for such a welcome response was that they had people regularly complain of toothache caused by tooth decay and this problem being a "*every household disease*" (FGD-3, LHW-02), the LHWs expressed keen interest in working to prevent to it.

> *"So, these things when we would tell them, they would be happy and this will also add to our knowledge. When we would also go and tell people then they would in turn tell others. This is what happens, when we tell a mother, she in turn tells that to ten other people, it keeps on spreading." (FGD-3, LHW-06).*

The LHWs were very clear about their professional role and stated that their job is to advise people on health-related matters and not to treat them as they do not have a professional medical background, but their advice carries a lot of weight with the people in terms of people following the advice.

> *"Especially those who have become mothers for the first time, they are very excited, they ask about everything, how to do this, how to do that? So, when we tell someone about breastfeeding, they think now she would tell me about other things too. If the child is not sleeping at night, they even call us that time to ask, sister what should I do, baby is not sleeping, what should I give him?" (FGD-4, LHW- 08).*

4.5.4 Additional theme related to development of intervention

The focus groups with relevant stakeholders also provided an opportunity to discuss with them the format of the intervention that would fit in with LHWs work delivery style and would also engage mothers and their children.

Both mothers and the LHWs agreed that more graphically informed materials would be suitable for a wide range of abilities.

> *"If you want to give us training regarding this, regarding dental health then my suggestion is, you can listen to others too, but my suggestion is to be given brochure cards. When we give a [health education] session to someone, we show them that.*
>
> *We have flip cards that we show to the mothers when we have sessions like this, when mothers see it, they understand.*
>
> *"Like the card about pregnancy, on one side there are pictures and on the other side there is text written about it. They would look at the pictures in the front and we would read about them from behind." (Excerpt from FGD-3 with LHW- 03, 04 and 01 speaking respectively).*

4.6 Discussion

4.6.1 Key findings

The aim of this study was to explore the barriers & facilitators that mothers face for engaging in their children's toothbrushing practice and the barriers & facilitators for oral health promotion by the LHWs. Using FGDs with both set of participants, key themes were uncovered guided by the TDF and the COM-B model of behaviour change.

Limited knowledge and skills (knowledge and skills domain) around toothbrushing practices coupled with low priority given to oral health/primary dentition and child's uncooperative behaviour (memory attention & decision processes and behaviour regulation domains), lack of information and support regarding children's oral health (environmental context & resources domain) and the social norms (social influences domain) around toothbrushing were the themes identified that linked to the barriers faced by both the mothers and LHWs. On the other hand, mothers' past dental experiences and LHWs' motivation to improve health of their community (beliefs about consequences and emotion domain), mothers' willingness to make an effort (beliefs about capabilities and intentions domain), and LHWs' interest in following and passing on the best (evidence-based) advice (environmental context and resources and social influences domain) for prevention of tooth decay in children were the facilitators that can be tapped into for development of a behaviour change intervention to support mothers in engagement with their children's toothbrushing.

Limited or even lack of knowledge related to importance of primary teeth and their hygiene, and time of initiation of toothbrushing in children was a finding that was different to another similar study conducted in the UK. In a study by Marshman et al (2016) which explored parents' experience of toothbrushing with children, carried out with parents residing in a deprived neighbourhood, reported that parents were generally knowledgeable about frequency and age of initiation of toothbrushing and use of fluoride toothpaste (Marshman, Ahern et al., 2016).

Some other results of this study were on the similar lines to those reported in the previous literature. Trubey et al (2015) in their study carried out in socioeconomically deprived area of the UK, reported cosmetic reasons for parent's toothbrushing their children's teeth were most often seen as the benefit of toothbrushing. Although with many parents being aware of twice daily toothbrushing, mostly only managed to perform the morning brushing routine (Trubey, Moore et al., 2015).

In this study context, the late initiation of toothbrushing in children (4-5 years of age) coincides with the time of their starting school. It is evident from the time of initiation of toothbrushing in children when they start going to school, and morning toothbrushing routine that cosmetic benefits are considered the most important reason for children's toothbrushing.

With the well demarcated gendered roles in Pakistan, men are expected to provide for the women and children in their household whereas the women carry the responsibility of a 'home maker' which includes taking care of the household chores (cooking, washing etc.) and looking after the children and the family. Given that caring for a child is considered primarily the mother's responsibility, from both mothers' and LHWs' accounts, it was evident that women were responsible for making sure all the household items (e.g. toothbrushes/toothpaste) needed are timely supplied. They did this either by shopping for groceries themselves (with their own source of income or a set budget allocated and provided to them by the male bread earner of the family), or providing a list of things needed, to the men of the household for the grocery shopping.

Furthermore, other themes around difficulty managing child's behaviour, parents' own stressful and busy lives and the belief that they were at least getting their children to brush once daily which was the average for most parents, and even better in some cases where parents did not even have a proper routine for children's once daily toothbrushing, were some of the other influencing factors that influenced children's toothbrushing. These themes were similar to those reported by studies conducted with sample of parents from UK, Australia and India (Marshman, Ahern et al., 2016, Suprabha, D'Souza et al., 2021, Trubey, Moore et al., 2015, Virgo-Milton, Boak et al., 2016), and these findings suggest that provision of information or increasing parental knowledge regarding children's toothbrushing alone is not enough to have these behaviours translated into practice. Although it is considered majorly a mother's responsibility to care for her children's health, especially so in the study context, it would be vital to highlight the whole family approach towards children's toothbrushing, also considering the traditional oral hygiene practices that might be followed by the older people in the family/house.

Therefore, there is a need for more wider support to parents around child rearing practices and a community effort involving health workers and health professionals who can support mothers by initiating conversations about good oral health practices from early in a child's life.

The main barrier reported by LHWs for incorporating children's oral health promotion as part of their routine home visits was limited knowledge regarding oral health. This is in

line with the results reported by Eskyte et al (2021) as part of organisational barriers for oral health conversations between health visitors and parents of very young children in the UK (Eskyte, Gray-Burrows et al., 2021). Although the LHWs expressed confidence regarding management team's positive response to LHWs including oral health promotion as part of their work duties, which is contrast to the findings reported by Eskyte el al (2021) related to issues with funding cuts and limited resources posing a barrier, this topic would need to be further explored with those in the supervisory and managerial position.

Another important theme reported by Virgo-Milton and colleagues in their study exploring views of mothers on promoting their child's oral health was the influence of mother's own negative or positive oral health experiences (Virgo-Milton, Boak et al., 2016). As reported in this study too, a mother's own experience of oral health can be an important facilitator that can motivate them to engage in their children's toothbrushing to establish healthy oral health habits for long term health benefits.

4.6.2 Methodological considerations

Strengths

This study is first of its kind in the study context- Pakistan to explore parental barriers and facilitators for engaging in their children's toothbrushing. Although an initial qualitative exploratory study, it allowed to bring in the voices of the stakeholders which enriched the previously available, albeit limited data regarding children's oral health in Pakistan. Furthermore, the use of focus groups allowed to gather many views in a short span of time. Taking advantage of LHW training days to conduct the focus groups saved the participants the trouble of travelling back and forth to the venue and also allowed the opportunity to catch them at a time when they all were gathered together at the same place. Similarly, the focus groups with mothers were conducted on the day when the LHWs usually invite them for delivery of a health session or any other health related services in their communities.

Although there was the possibility that my- the researcher's dental background could influence participants' responses, they were informed whilst providing the study information and again during the start of the session that there were no right or wrong answers and it was their honest views that were needed for this research. Moreover, I introduced myself as a mother first and then a professional, to help develop a sense of shared identity in order to allow participants to express their thoughts and views candidly.

The use of TDF and COM-B model of behaviour change to guide the focus groups and to frame the data analysis provided a robust theoretical framework to identify the barriers and facilitators for parental engagement with their children's toothbrushing that could be targeted through development of a theory and evidence based, culturally relevant intervention.

Limitations

Although recruiting participants for this study was relatively easy, logistical considerations such as setting up the focus groups at the LHW team meeting venue or the health house, only allowed for two focus group sessions with each set of participants-mothers and the LHWs. Nevertheless, these focus groups were able to provide a good breadth of data which was also in line with other published literature on this topic.

Views of those in the supervisory (LHS) and management roles (project/operation manager) could not be undertaken to allow exploration of views of the senior management with regards to LHWs incorporating oral health promotion as part of their work duties. This needs to be considered in the future study. Nevertheless, as the aim of my research, within the scope of this PhD was to develop and test a behavioural intervention, I was able to gather the views of the main stakeholders who would be involved in receiving and delivering the intervention. Once (or if) there is enough evidence to establish the feasibility of the intervention, views regarding its sustainability can be gathered from the senior management at a later stage.

4.6.3 Implications

The findings of this study suggests that there is a need to promote children's oral health through provision of support that would enable families to adopt healthy oral health behaviours for their children which includes routinising twice daily, supervised toothbrushing. The results will be used to develop a behavioural intervention to help deliver advice and support related to children's toothbrushing to mothers. The LHWs shall be trained to deliver the intervention. Following chapters provide details on this process and the subsequent testing of the intervention.

Wider implications include incorporation of oral health curriculum in health professional's training to enable them to initiate conversations around toothbrushing with parents. Unavailability of free dental health care for children largely precludes the possibility to incorporate early preventive visits for children. Nevertheless, involving other health professionals such as nurses and paediatricians, may provide an opportunity, such as during neonatal visits to impart basic oral health care advice to parents.

4.7 Conclusion

The current study identified key barriers and facilitators faced by the mothers for engaging in their children's toothbrushing. It was evident that there are wider factors that need to be considered for development of an intervention, such as parenting and child behaviour management, and home and social environment, in order to provide support to mothers other than knowledge transfer alone.

The willingness of LHWs to incorporate oral health promotion as part of their health promotion activities provides an ideal opportunity to utilise an existing established framework of support available in the community to further children's healthy oral health behaviours.

Chapter 5: Intervention development

5.1 Chapter overview

In this chapter, I describe the steps involved in developing a behavioural intervention to be delivered by Lady Health Workers (LHWs) for oral health promotion of children in Pakistan. Starting with the introduction (5.2), details are presented on why it is important to develop theory-based interventions followed by aims and objectives (5.3) of this study. The methods section (5.4) describes the intervention development process by mapping the BCTs identified in the systematic review (chapter 3) and the barriers and facilitators for children's toothbrushing identified from the focus group study (chapter 4), to the TDF. The stakeholder consultation process to finalise the intervention is also presented. The results section (5.5) presents the finalised intervention components and the chapter ends with the discussion (5.6) about the intervention development process, strengths & limitations, and implications of the work, followed by the conclusion (5.7).

5.2 Introduction

Individual behaviour dictates to a very large extent the prevention of oral diseases and maintenance of good oral health, and out of the three most critically important behaviours, regular daily toothbrushing with fluoride toothpaste ranks the foremost (Asimakopoulou and Newton, 2015). Health behaviour change is a complex process and for development of health interventions, it is vital that these complexities are considered (Cowdell and Dyson, 2019).

The intervention development process is a crucial part which can maximise the possibility of intervention to be effective and sustainable. This is necessary to avoid research waste and production of an intervention that is both feasible and acceptable (O'Cathain, Croot et al., 2019b). Over the years there has been much information published regarding intervention development to guide new developers and O'Cathain et al (2019) have attempted to synthesise the evidence to produce a helpful taxonomy based on different approaches to intervention development. One of the approaches mentioned is the use of theory to develop health behaviour change interventions. This approach has been widely advocated as the use of theory helps explain the pathways or the mechanism of action through which behaviour change occurs and also allows for replication of the intervention to other similar settings (Cowdell and Dyson, 2019).

The Medical Research Council's (MRC) guidance on developing and evaluating complex interventions (Craig, Dieppe et al., 2008) , has been extensively used for developing complex health interventions, and it emphasises the importance of developing interventions based on theory in order to understand how the intervention works to cause change, thus enabling identification and strengthening of weak causal links in the chain (Craig, Dieppe et al., 2008). There has been much work done to translate theoretical constructs into practical techniques for facilitating behaviour change. The BCTs are directed at individual behaviour change and can be delivered in various ways.

However, the BCTTv1 which is an extensive taxonomy of 93 BCTs clustered into 16 groups, is a methodological tool for specification of intervention content and in itself does not indicate any links to theory (Michie, Richardson et al., 2013). Furthermore, although the MRC guidance broadly identifies the steps involved in development of a theory-based intervention, it lacks sufficient detail. Moreover, due to the existence of multiple models of behaviour change, intervention development may appear to be a

daunting task especially for the less experienced. In this situation, use of a comprehensive theoretical framework such as the TDF would not only ensure the intervention developed is based on theory but also help provide structure to the whole process.

However, there is sparse literature available which clearly specifies linkage of intervention components to proposed theoretical constructs. In such a case, 'reverse coding' can help map specific BCTs to theoretical constructs or domains (Bourne, Ivanova et al., 2019). This way, even when there is no specification of underlying theoretical constructs of an intervention, BCTs extracted from intervention description can be linked to theoretical domains to identify the behavioural determinants or causal determinants that have been targeted through intervention components. This can help in understanding the pathways of behaviour change.

Finally, it is equally important for developers of theory-based intervention to specify how BCTs work to bring about behaviour change (their mechanism of action) in order to improve reporting of interventions and enhance understanding of pathways of behaviour change, to facilitate evaluation. Unfortunately, until recently, there has not been much information available in this regard. This can be attributed to lack of consensus on a method to link active ingredients of interventions (BCTs) to theoretical mechanisms of action (MoA) (Bourne, Ivanova et al., 2019). The MoA are the processes through which BCTs have their effects and are hypothesised to be theoretical constructs through which BCTs affect the behaviour. In other words, MoAs are theoretical constructs from theories of behaviour and behaviour change, that mediate the intervention effects (Carey, Connell et al., 2019).

Conversely, there have been evidence syntheses in the form of systematic reviews and meta-analyses reporting theoretical basis of interventions produced no significant difference in intervention effectiveness or that adoption of certain BCTs did not produce desired results in terms of intervention effectiveness (Hagger and Weed, 2019, Prestwich, Sniehotta et al., 2014). The reason for this has been explained by failure to adequately map theory to intervention components by intervention developers. Prestwich et al., 2014 in their systematic review to investigate the extent and type of theory used in physical exercise and dietary interventions (n=190), identified just over half of the studies (56%) reporting any theoretical basis of their intervention. Out of these 90% did not report any links between all the BCTs employed in the intervention to theoretical constructs and 91% did not report links between all specified theoretical constructs to BCTs (Prestwich, Sniehotta et al., 2014). Thus,

these ‘theory-inspired’ interventions although state using a behavioural theory to develop interventions, in reality, fail to adequately link intervention components with theoretical constructs. Furthermore, inadequate reporting of intervention development process hinders the evaluation of intervention effectiveness based on its theoretical basis (Hagger and Weed, 2019).

As presented previously (chapter 1), oral health promotion of children is an umbrella term and at the broadest level comprises of three key elements (1) oral hygiene practices, e.g. twice daily toothbrushing with a fluoride toothpaste; (2) dietary behaviours, e.g. reduction in amount and frequency of consumption of sugary foods and drinks between meal times; (3) regular dental visiting (Levine and Stillman-Lowe, 2009, Public Health England, Department of Health and Social Care et al., 2021). The focus of my research was to develop an intervention which would help in improving oral health outcomes in children through routinisation of parental supervised, twice daily toothbrushing with fluoride toothpaste. Selection of toothbrushing behaviour as the target behaviour, outlined in step 1 of methods presented in this chapter, was carried out before the focus groups study (chapter 4) was conducted. This was done to ensure the barriers and facilitators for that specific target behaviour (toothbrushing) were explored in the focus groups. However, for ease in readability and coherence, the target behaviour selection as part of intervention development process is detailed in this chapter.

5.3 Aim & objectives

To develop a behavioural intervention that would be delivered through LHWs for oral health promotion of children in Pakistan.

The specific objectives were:

1. To determine which oral health behaviour and whose behaviour needs to be targeted.

2. To identify important and modifiable behavioural determinants linked to the barriers and facilitators for parents to engage with their children’s toothbrushing.

3. To select BCTs based on previous evidence of effectiveness, to address the modifiable behavioural determinants.

4. To finalise the intervention in consultation with stakeholders, with a view to test its feasibility.

5.4 Methods

In this section, I outline the steps for development of a behavioural intervention for oral health promotion of children through Lady Health Workers (LHWs) in Pakistan. The steps are broadly aligned according to the MRC guidance for developing and evaluating complex interventions in healthcare (Figure 5.1), while the actual development process follows the method detailed by French et al (2012), using the TDF, broken down into 4 steps which fit well with the development phase of the MRC guidance.

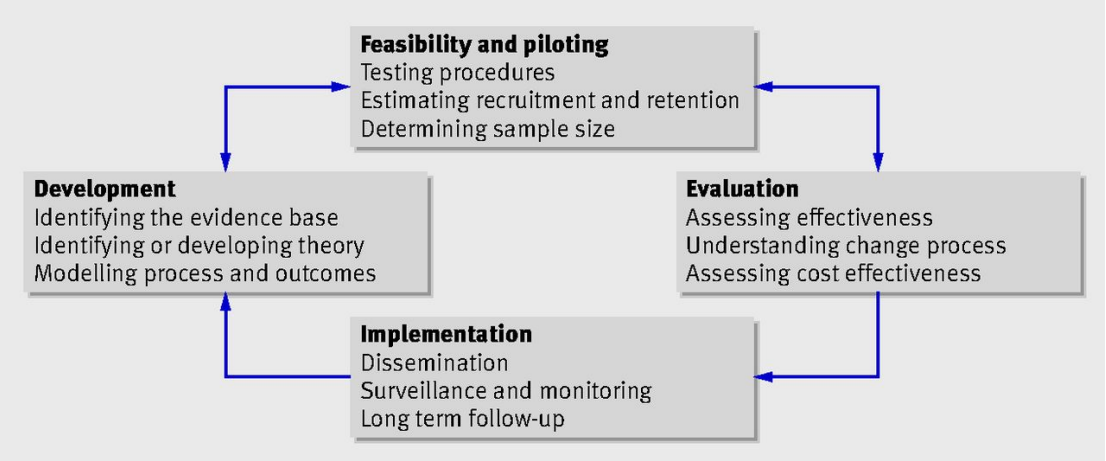


Figure 5.1 Key elements of intervention development and evaluation process (from MRC guidance on developing and evaluation complex interventions)

The method described by French et al (2012) is for development of a theory-informed implementation intervention which utilises the TDF as its core element. The TDF has also been previously used successfully in studies other than implementation research such as understanding behavioural determinants of general population, and for this reason, extension of this method to develop an intervention for general population seems not only appropriate but also pragmatic and feasible. Table 5.1 illustrates the 4 steps for theory-informed intervention development process described by French et al (2012).

Table 5.1 Steps for developing a theory-informed intervention (adapted from French et al, 2012)

Steps/objectives	Tasks	Activities
STEP 1: Who needs to do what, differently?	· Identify the research gaps	Literature review to identify problem statements regarding children's oral health in Pakistan (Chapter 1)
	· Specify the behaviour that needs to change · Specify the group whose behaviour needs changing	Use of BCW for selection of toothbrushing behaviour to target, and the parents whose behaviour needs to change
STEP 2: Using a theoretical framework, which barriers and enablers need to be addressed?	· Use qualitative and/or quantitative methods to identify barriers and enablers to behaviour change	FGDs with mothers in Pakistan to identify barriers and facilitators for engaging in toothbrushing practices of their children (Chapter 4)
STEP 3: Which intervention components (behaviour change techniques and mode(s) of delivery) could overcome the modifiable barriers and enhance the enablers?	· Use the chosen theory, or framework, to identify potential behaviour change techniques to overcome the barriers and enhance the enablers	Mapping the barriers & facilitators to TDF in order to identify key behavioural determinants that would need to be targeted through relevant BCTs identified as part of effective interventions through the systematic review (chapter 3).
	· Identify evidence to inform the selection of potential behaviour change techniques and modes of delivery	Mapping of BCTs from previous effective interventions onto TDF using the TaT to generate a list of potential BCTs for consideration as intervention components
	· Identify what is likely to be feasible, locally relevant, and acceptable and combine identified components into an acceptable intervention that can be delivered	Conducting PPI to involve stakeholders in finalising the intervention components by considering BCTs identified from systematic review to address the barriers and facilitators identified from FGDs.
STEP 4: Can the developed intervention be successfully implemented?	· Determine feasibility of testing the intervention -Exploring the acceptability of the intervention	Testing the feasibility of the intervention and exploring its acceptability through interviews with the participants

As the current research was part of a PhD, the final step of the 4-step process was modified to fit the scope of this research. This meant that the originally outlined step 4 pertaining to 'how can behaviour change be measured and understood? Which linked tasks such as identification of mediators of change, selection of outcomes measures and determining the feasibility of the outcomes to be measured, was changed to fit within remit of this PhD research.

Hence, step 4 changed to 'can the developed intervention be successfully implemented' with related tasks of determining the feasibility of testing the intervention and exploring its acceptability.

In the following section, each of the step is described in detail.

Step 1: Who needs to do what differently?

In order to devise an intervention for children's oral health promotion, the first step was to identify who needs to do what differently. For this purpose, it was important to first identify the research gaps. To this end, a literature review was conducted to examine the oral health related behaviours for children's oral health and to identify behaviours that need to be targeted by the intervention in order to improve children's oral health outcomes.

Michie and colleagues in their book 'Behaviour Change Wheel: A Guide to Designing Interventions', advise intervention developers to select only one or few behaviours to target in the first instance and then to build up on the success by incrementally introducing change. Doing it this way can be more effective rather than doing it all at once (Michie, Atkins et al., 2014). The authors provide a prioritisation criterion to help reach a decision for selection of the target behaviour(s). They encourage intervention developers to assess the potential of a behaviour to be a promising target behaviour based on the 4 criteria of: impact, ease of changing behaviour, centrality of behaviour and measurability. Hence, it was decided to target one oral health behaviour that can have significant impact in improving children's oral health and would also fit well with the selected mode of delivery – through the LHWs.

Step 2. Using a theoretical framework, which barriers and enablers need to be addressed?

This step pertains to developing a 'theoretical understanding of likely process of change' highlighted by the MRC guidance on developing and evaluating complex interventions (Craig, Dieppe et al., 2008). Based on previous literature, and comprehensiveness of the framework, I chose the TDF, which has been previously validated both theoretically and empirically (Cane, O'Connor et al., 2012). The framework provides a theoretical basis for linking barriers and facilitators to behavioural determinants (14 key domains based on theoretical constructs) by indicating which behavioural determinants need to be targeted to address the barriers and facilitators for the desired behaviour. Qualitative methods based on this theoretical framework- focus group discussions (FGDs) with mothers, were used to elicit barriers and facilitators for the target behaviour (chapter 4).

The focus of FGD was on capturing views and perceptions of mothers as they are considered to carry the responsibility of family health particularly those of their children (Al-Ayed, 2010, Goodwin, Garrett et al., 2005). This was also appropriate considering LHWs majorly provide basic preventive and curative health services for improving maternal and child health.

Step 3. Which intervention components (behaviour change techniques and mode(s) of delivery) could overcome the modifiable barriers and enhance the enablers?

The choice of BCTs was based on the behavioural determinants that they are proposed to target. Selection of BCTs for intervention development was informed by the evidence of effectiveness of interventions for children's oral health promotion through non-dental health workers (Faisal, Mishu et al., 2022), the theoretical framework, and a mapping matrix. The tasks in this step are divided in two parts: (A) Mapping of BCTs to the theoretical framework; (B) Selection of BCTs to include as intervention components.

A. Mapping of BCTs to the theoretical framework

A systematic review was conducted previously to assess effectiveness of interventions delivered through non-dental professionals and health workers (chapter 3). Descriptions of effective interventions were subjected to reverse coding by

extracting BCTs used as part of the intervention components. The BCTs thus identified were then mapped to the theoretical framework- the TDF. This was facilitated by the theory and techniques tool (TaT). The TaT has been produced by triangulating evidence of links between BCTs and theoretical MoAs through literature review of published studies and expert consensus (Behaviour Change Project). This tool is presented as an interactive heat map which links 74 BCTs to their 26 theoretical MoAs (theoryandtechniquetool.humanbehaviourchange.org). The MoAs presented in the tool are those contained within the 14 theoretical domains and 12 other frequently occurring MoAs that are not a part of the TDF (Connell, Carey et al., 2019). In cases where mapping was not available for a particular BCT, a previous mapping tool compiled together through expert consensus and validation (Cane, Richardson et al., 2015), was used. Furthermore, where no previous mapping was available at all, decision was made based on the context (Richardson, Khouja et al., 2019).

B. Selection of BCTs to include as intervention components

The final selection of BCTs to include as intervention components was done through involvement of stakeholders such as LHWs and mothers, in the decision-making process. Patient and Public Involvement (PPI) in research is now increasingly being considered an essential part which helps bring broader perspective and ensures research conducted is relevant, appropriate and acceptable to potential participants (NIHR Involve).

Because of the unprecedented times when research had to be carried out during the Coronavirus pandemic, certain modifications were necessary to put in place. Due to the ensuing lockdown it was decided to use an online software or an app to conduct a group meeting with each of the participants joining in individually from their homes. Furthermore, due to the virtual medium of group meetings, purposive sampling was employed to recruit mothers and LHWs who had access to mobile/internet technology and would be able to easily navigate the online medium of the session. To this end, one LHW was approached through previous contact and after explaining the purpose and rationale for the meeting, she was asked to help recruit LHWs and mothers for the purpose of an online PPI meeting. Following guidance provided in the BCW book, elements from the APEASE criteria (affordability, practicability, effectiveness, acceptability, side-effects and equity) were used to assess utility of BCTs as part of the intervention. As effectiveness, equity and side-effects can only be evaluated after intervention implementation or testing (West and Michie, 2019), it was decided to

focus on 3 elements only: affordability; practicability and acceptability, for the purpose of BCT assessment.

The possible mode(s) of delivery (how the chosen BCTs would be delivered) were identified beforehand through qualitative exploration of LHWs' views on children's oral health promotion (chapter 4). The content of the intervention (what will actually be delivered) including the BCTs and the mode of delivery was based on consideration of local relevance and context, feasibility and deliverability as one cohesive intervention (French, Green et al., 2012).

For the PPI meeting, *WhatsApp* mobile app was used to create a working group. WhatsApp is the most popular means of communication in Pakistan and decision to use it was based on participants' accessibility and familiarity with the app and availability of the group call feature in it. Another useful feature of the app is the ability to send and receive voice messages in the group, which are accessible to all the group members even if they are not online or connected to the internet at the particular time when the message(s) were sent. The group consisted of 3 LHWs and 2 mothers and prior to creating the group, I spoke to all the members individually, explained about the research and its rationale and also what would be required of them for the purpose of the PPI meeting. In the event that they did not wish to participate, they could indicate so by exiting the group.

A document was prepared listing all the potential BCTs with their explanation and an example to illustrate the concept. The language was kept very basic and Urdu translation was provided alongside the English version. Once the group was created, a time and date was set for the first group call during which the purpose of the research was explained once again followed by the purpose of the PPI working group. They were then given the opportunity to ask any questions and were sent the document file containing the 18 BCTs with instructions on how to assess each of the BCT on 'acceptability' by mothers; and 'affordability', 'practicability' and 'acceptability' by the LHWs. It was explained to them they could send a voice/text message in the group if they encountered any problems during the process. Participants were given two days' time to read the document and assess the BCTs on the criteria mentioned after which the group was to reconvene to discuss the findings.

Due to the technical difficulties and connectivity problems during the group call session, it was later decided to individually call each of the participants to discuss their findings and a summary to be presented in the group.

At the end of the session, all the group members were thanked for their participation and time. They were also asked whether they could be contacted in future for their input on intervention materials, to which they all agreed. As a token of appreciation for their time, they were given Rs.300 each (approximately £1.40) top-up of local talk time of the network of their choice.

Step 4. Can the developed intervention be successfully implemented?

In order to determine whether the developed intervention can be successfully implemented, it was important, first of all, to test its feasibility and acceptability to identify operational challenges and any refinement to the intervention that may be required before a larger trial can be planned.

5.5 Results

The resultant PROSPECT intervention (**PRO**viding **S**upport to **P**arents for **E**ngaging in **C**hildren's **T**oothbrushing) developed consists of behavioural support for twice daily toothbrushing of children with fluoride toothpaste, to be delivered by LHWs to mothers of young children as part of their health advice and support provided during routine home visits. The main message conveyed through PROSPECT is that 'strong teeth make healthy kids', and how brushing children's teeth twice daily with a fluoride toothpaste, from the time the first tooth appears can prevent tooth decay and result in strong teeth.

The intervention materials include a flipbook to aid in delivery of messages; a leaflet summarising the main messages and containing a cut-out portion to be pasted in a place at home where it can act as a prompt/reminder; and a pack containing toothbrush and fluoride toothpaste for the family. In addition, a handbook with scientific details related to children's oral health, an advice guide detailing how to deliver the behavioural support via flipbook and a training video was also produced to improve LHW's knowledge and skills regarding children's oral health and toothbrushing, and to provide training for intervention delivery (English version of training and intervention materials provided in appendix 5.1 and 6.3).

Following are the results presented detailing the four steps undertaken for development of the PROSPECT intervention (Figure 5.3).

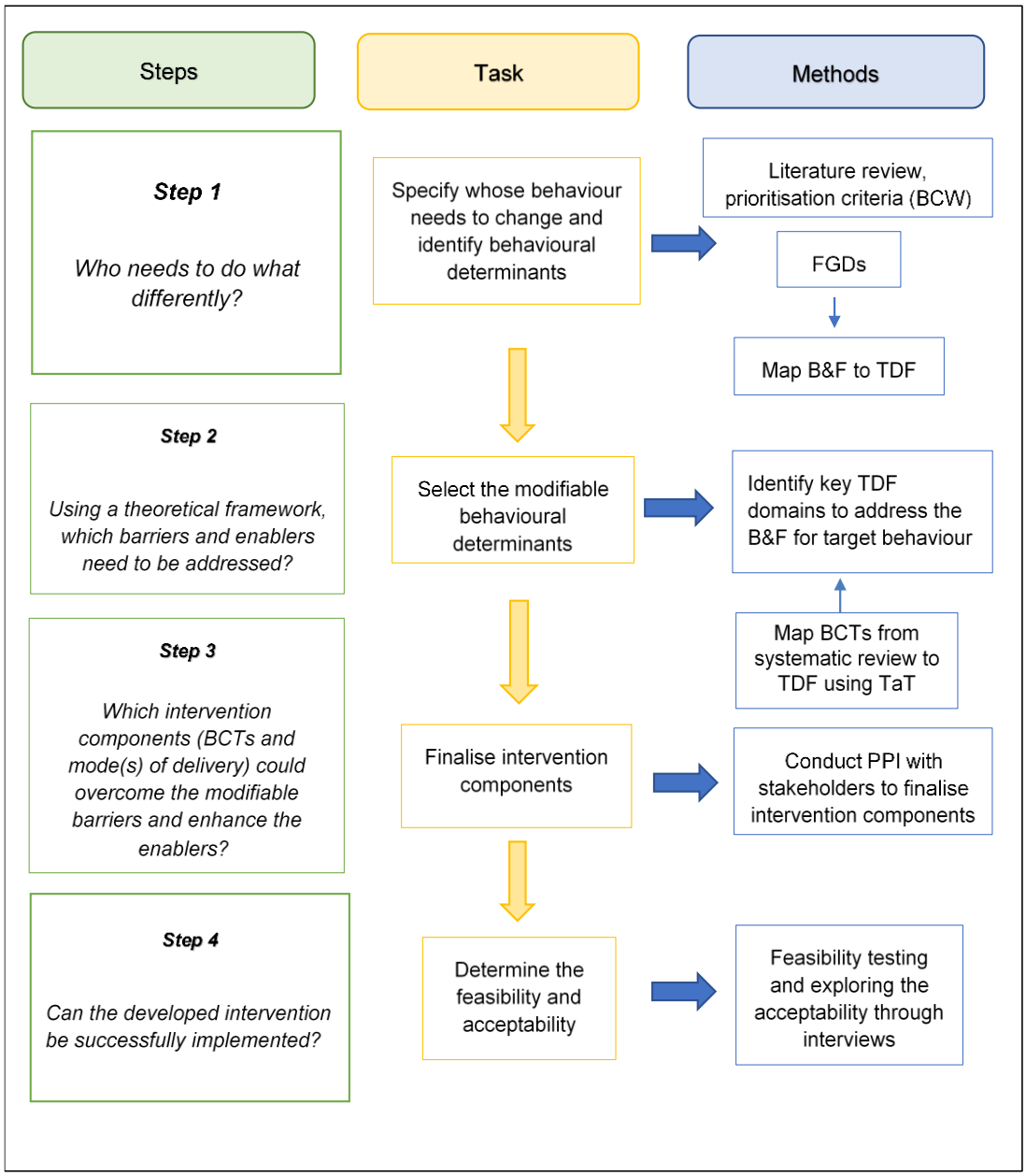


Figure 5.2 Flow diagram depicting stages of intervention development

Step 1: Who needs to do what differently?

For the development of an intervention, the foremost step is to understand how to address the problem of high prevalence of tooth decay in children, and to identify who needs to do what differently. Toothbrushing behaviour was selected as the targeted behaviour for the intervention based on problems identified through the literature review. Following the evidence-based recommendations of parental supervised toothbrushing of children up to the age of 7 years, and also in line with the LHWs duties of provision of maternal and child health services, whilst also considering the cultural context identifying mothers as children's primary caregiver, it was decided that mothers would be targeted by PROSPECT intervention as the primary caregiver.

The focus on toothbrushing behaviours was based on the prioritisation criteria mentioned previously and detailed in Table 5.2 for the prioritisation of a target behaviour. This decision was also based on evidence presented for the effectiveness of three key oral health behaviours in chapter 1.

While choosing the target behaviour, another important consideration was its suitability to seamlessly fit into LHWs home visiting routine and provision of health advice. As the LHWs duties include advising about personal and hand hygiene, it was decided that toothbrushing behaviours such as twice daily toothbrushing with fluoride toothpaste, as the target behaviour would be very promising, as it clearly fit well according to all the selection criteria.

Table 5.2 Prioritising behaviours to select the target behaviour (adapted from Michie et al 2014)

Elements of prioritisation criteria	Oral health behaviours		
	Toothbrushing	Dietary behaviour	Dental visiting
Impact of changing behaviour on desired outcome (reduction in prevalence of tooth decay)	Very promising as evident by vast literature on effectiveness of toothbrushing	Unpromising as evident by conflicting evidence, but worth considering	Unacceptable as there is no free dental service or programmes for children
Likelihood of changing behaviour based on Capability, Opportunity and Motivation	Very promising as families already perform oral hygiene practices which can be built upon	Unacceptable because this may require families to introduce significant changes in their dietary practices which may not be feasible for all	Unacceptable because of out-of-pocket payment model and lack of free preventive services
Centrality of behaviour or 'spill-over' effect	Promising as observing/hearing from relatives/friends can prompt others to do the same	Unpromising but worth considering as this may have positive spill-over effect for other behaviours	Promising as regular checkup may motivate them to adopt good oral health behaviours
Measurability of behaviour	Very promising. Validated objective measures available to measure for tooth decay/cleanliness	Unpromising but worth considering. Mostly subjective measures available	Unacceptable as no central record keeping system available to record dental attendance

Based on suggested ratings of: unacceptable, unpromising but worth considering, promising, and very promising

Step 2. Using a theoretical framework, which barriers and enablers need to be addressed?

The barriers and facilitators elicited through the FGDs were mapped to TDF to highlight the domains that were modifiable thus guiding the choice of intervention components (Table 5.3). Except for the two domains: social role and optimism, all other 12 domains were considered to be significant for intervention development.

Step 3. Which intervention components (behaviour change techniques and mode(s) of delivery) could overcome the modifiable barriers and enhance the enablers?

A. Mapping of BCTs to the theoretical framework

The results of the systematic review revealed that theoretical underpinnings of interventions were rarely specified. From a list of 23 effective interventions, BCT coding of 20 intervention descriptions was undertaken. Three studies were excluded because they were not relevant to our context as they did not include promotion of toothbrushing behaviours as part of the intervention (one study was excluded because it was based on promotion of dietary behaviours only and two others were excluded as they were solely based on dental service utilisation behaviours (chapter 3)).

In the second step, 27 distinct BCTs identified were mapped on to the TDF, alongside the parental barriers and facilitators for engaging in children's toothbrushing behaviour, using the TaT, to determine which previously effective BCTs can be used to address the modifiable behavioural determinants, identified as TDF domains (Table 5.3). BCTs for which no mapping was available was '9.1 credible source'. This was mapped according to the context in which it was used.

Table 5.3 Mapping of barriers and facilitators and BCTs to TDF domains

TDF Domain (definition)	Barriers (B) and facilitators (F) for children's toothbrushing practice FGD- Mothers	BCTs appearing ≥ 2 times (n=18) in effective interventions (identified from systematic review) coded using BCTTv1 and mapped to TDF using TaT tool	Potential BCTs to be considered during PPI based on Acceptability, Practicability and Affordability (n= 18)
Knowledge (An awareness of existence of something)	- Lack of knowledge related to cleaning primary teeth and level of involvement (B) - Poor understanding of risk factors for caries and benefit of fluoride (B) - Awareness of importance of brushing at night (F) - Awareness of lack of knowledge related to dental hygiene (F)	- Information about health consequences - Information about social and environmental consequences - Instructions on how to perform the behaviour - Feedback on behaviour*	- Information about health consequences - Information about social and environmental consequences - Instructions on how to perform the behaviour - Feedback on behaviour - Behavioural practice/rehearsal - Demonstration of behaviour - Problem solving - Non-specific reward - Goal setting (behaviour)
Skills (An ability or proficiency acquired through practice)	- Finding it difficult to brush their children's teeth (B) - Failure to maintain a routine (B) - Gentle brushing of their children's teeth (F)	- Instruction on how to perform the behaviour - Behavioural practice/rehearsal	

Social role/Professional role and Identity (A coherent set of behaviours and personal qualities displayed in social settings)	Mother's duty to take care of her children (F)	None and domain not identified as significant	- Review behaviour goals - Action planning - Prompts and cues - Adding objects to environment - Social support (practical) - Social support (unspecified) - Identification of self as role model - Behaviour substitution - *Reduce negative emotions* †
Beliefs about capability (Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use)	- Belief that they can manage it if they try (F) - Finding managing time difficult (B) - Making an effort to take care of their children's teeth (F)	- Instruction on how to perform the behaviour - Demonstration of behaviour - Behavioural practice/rehearsal - Problem solving	
Optimism (The confidence that things will happen for the best or that desired goals will be attained)	- Awareness about negligence towards children's toothbrushing (F)	None and domain not identified as significant	
Beliefs about consequences (Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation)	- Feeling that not being able to take care of their teeth when they were young has resulted in poor oral health (F) - Taking care of their children's teeth at this early stage will have better outcomes for their children in future (F)	- Information about health consequences - Information about social and environmental consequences	
Reinforcement (Increasing the probability of a response by arranging a dependent relationship,	- Parents' giving incentives to children gets them to brush (F)	- Non-specific reward	

or contingency, between the response and a given stimulus)			
Intentions (A conscious decision to perform a behaviour or a resolve to act in a certain way)	- Past negative experiences makes them want to do more for their children's dental health (F)	- Goal setting (behaviour)	
Goals (Mental representations of outcomes or end states that an individual wants to achieve)	- Achieving state of good oral health for themselves and their children (F)	- Goal setting (behaviour) - Review behaviour goals - Action planning*	
Memory, attention and decision processes (The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives)	- Forgetting to remind children to brush (B)	- Prompts and cues	
Environmental context and resources (Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour)	- Easy availability of toothbrush and toothpaste (F) - Non-existence of oral health messages from health professionals/providers (B) - Breaks in routine during weekends/holidays (B)	- Prompts and cues - Adding objects to environment - Social support (practical)	

Social influences (Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours)	- Negative influence of close ones having irregular toothbrushing routine for their children (B) - Support from other family members especially fathers (B, F) - Brushing only in the morning due to social reasons (B, F)	- Social support (unspecified) - Social support (practical) - Social reward - Identification of self as role model* - Credible source §	
Emotion (A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event)	- Mother's sense of guilt for not being able take care of her children's teeth (B) - Sense of satisfaction when children's teeth have been cleaned (F)	None identified from systematic review	
Behaviour regulation (anything aimed at managing or changing objectively observed or measured actions)	- Inability to manage difficult child behaviour (B) - Receiving proper toothbrushing advice with illustrations (F) - Reinforcement of messages (F)	- Problem solving - Behaviour substitution	

* *indicates mapping based on Cane et al 2015*
§ *indicates mapping according to context (when no other mapping available)*
† *indicates BCT applied based on TaT for a domain considered significant for mapping when there was none identified from previous effective interventions*

B. Selection of BCTs to include as intervention components

The Table 5.3 also lists potential BCTs that were to be considered as intervention components of PROSPECT intervention. Based on their being part of two or more effective interventions, 18 BCTs were labelled as 'promising' or highly likely to be instrumental in enhancing the effectiveness of intervention (Brown, Hardeman et al., 2019, Campbell, Fergie et al., 2018). As it was not practically possible to apply the BCT '*9.1 credible source'* which entails presenting verbal or visual communication from a credible source (such as dental professional) in favour of or against the behaviour, it was not taken forward for consideration. However, as none of the BCTs identified from effective interventions linked to the 'emotions' domain of the TDF which was considered a significant modifiable behavioural determinant, so a BCT- '*11.2 reduce negative emotions'* which links to this particular domain was identified using TaT tool. Hence 18 BCTs were brought forward for final selection through PPI, to be a part of the PROSPECT intervention.

During the PPI sessions, both mothers and LHWs agreed that all the 18 BCTs listed were very significant in supporting mothers to engage in toothbrushing practices for their children, and it would be very useful to include them all. However, one concern regarding the BCT 'adding objects to the environment' which entailed provision of toothbrush and fluoride toothpaste, was its sustainability in long term. Nevertheless, it was decided by the group to keep the BCT as part of the intervention in order to assess their acceptability by the intended users. Logic model of the intervention is presented as Figure 5.3.

Step 4. Can the intervention be successfully implemented?

For this final step, a feasibility study (chapter 6) was conducted to test the intervention in order to identify operational challenges related to participant recruitment and data collection methods. Also, exploring the acceptability of the intervention following the intervention delivery provided important information which would allow to refine the intervention before a larger study such a randomised controlled trial can be planned.

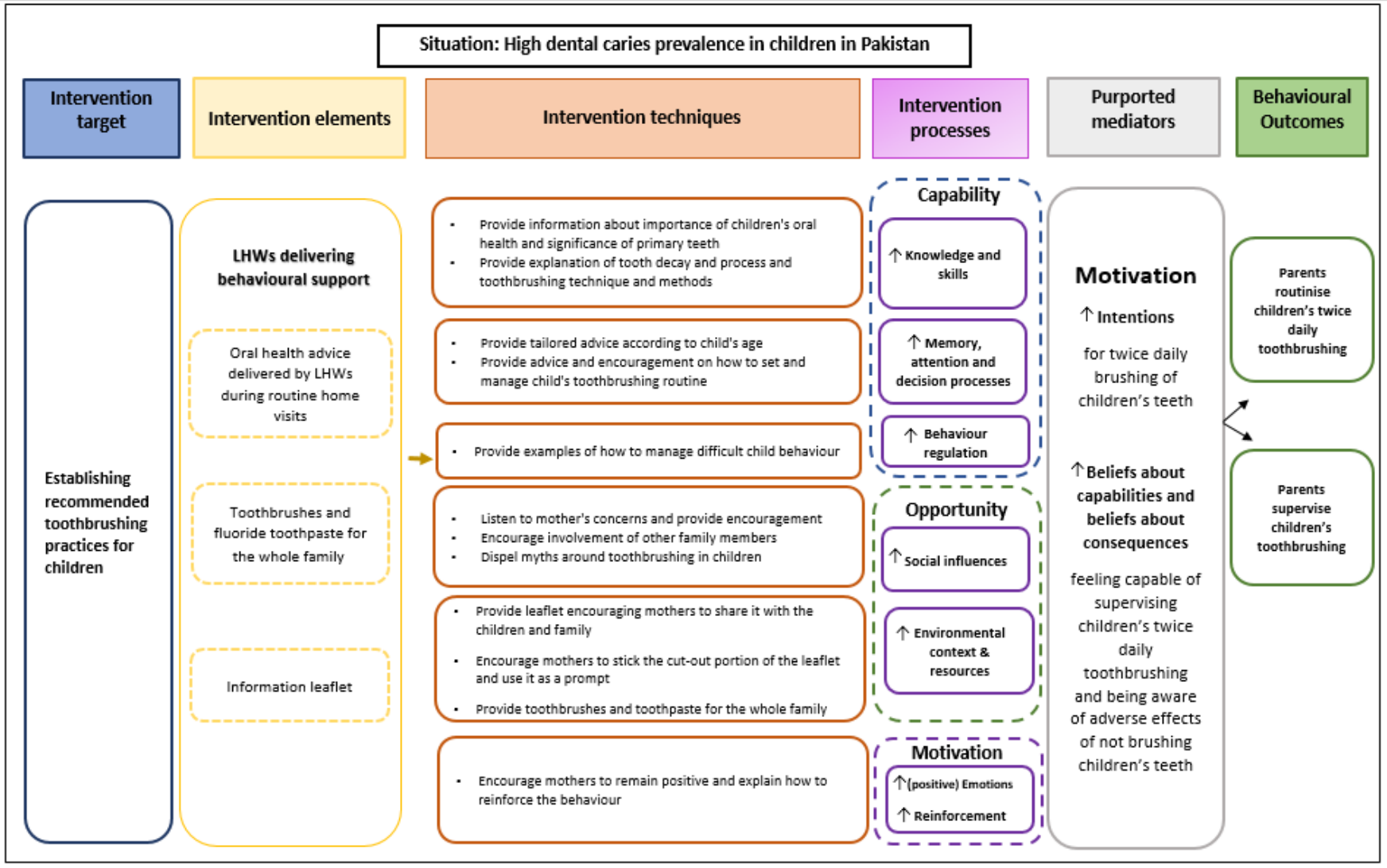


Figure 5.3 Logic model of PROSPECT intervention

5.6 Discussion

5.6.1 Key findings

The aim of this chapter was to report the development of PROSPECT intervention. Following the MRC framework for intervention development and evaluation, along with use of TDF helped structure the whole process which would not have been possible if a solely atheoretical, pragmatic approach had been used. Thus, justifying the effort put into developing a contextually relevant, evidence and theory-based intervention. Framing the determinants according to TDF domains, allowed to develop an intervention that is not only relevant in the given context and but also includes selection of linked BCTs that can direct behaviour change. Although this does not imply that interventions developed this way are guaranteed to be effective, it does increase the likelihood of success of an intervention by building on previous evidence and also considering a wide range of determinants at the same time. Furthermore, it also helps to study intervention fidelity by identifying the mechanism of action of components of an intervention that may or may not be effective.

While drawing on previous research helped map BCTs to TDF domains, use of some flexibility based on the context was inevitable especially when there was no previous mapping available for certain BCTs (Richardson, Khouja et al., 2019).

The results of BCT mapping to behavioural determinants identified from TDF domains, were in line with previous work done to examine the quality of UK based oral health promotion materials for parents of young children (0-5 years old) (Gray-Burrows, Owen et al., 2017). The most targeted domain in previous oral health promotion interventions was found to be ‘Knowledge’. Although knowledge transfer is important, there is little evidence to show that improving knowledge alone can lead to long term behaviour change (Gray-Burrows, Owen et al., 2017, Kay, Hocking et al., 2015). Therefore, making it pertinent to address a range of barriers to facilitate adoption of good oral health behaviours.

Lack of parental skills in managing difficult child behaviour with regards to toothbrushing has been identified as a significant predictor of parental supervised toothbrushing of children both in qualitative and quantitative studies (Berzinski, Morawska et al., 2020, Duijster, de Jong-Lenters et al., 2015, Marshman, Ahern et al., 2016). This highlights the fact that interventions providing support to parents in order to increase their self-efficacy for performing and routinising twice daily

toothbrushing of their children, should also focus on supporting parents in managing resistant child behaviour.

Specifying the MoA through which BCTs produce change in behaviour is another important aspect for consideration during intervention development. However, there was no agreed method or framework available until recently, to guide the intervention developers. The theory and techniques tool developed as a result of call for specification of causal processes of an intervention, can greatly aid in its evaluation and enhance understanding of why and how interventions can be effective in changing behaviour.

5.6.2 Methodological considerations

Strengths

Use of MRC guidance and TDF as core framework provided structure to the intervention development process. It enabled to draw on theory, evidence and practical issues as highlighted by French et al (2012). By systematically moving from identification of target behaviours to highlighting key domains and choosing behaviour change techniques, to linking them to their mechanisms of action for future evaluation purpose, makes explicit the hypothesised mechanism of behaviour change.

Use of two coders to individually code the intervention descriptions ensured a rigorous method was employed. Furthermore, undertaking BCT taxonomy training prior to coding helped in developing a deeper understanding and provided valuable experience of the whole process.

Involvement of stakeholders in finalising the intervention components was an effort to bring voices of those to the table who would interact most with it (those who would be delivering and receiving the intervention). Thus, ensuring not only the context is considered but also the potential deliverability and acceptability of the intervention. Use of technology made it possible to interact with people even during the Coronavirus pandemic lockdown and travel bans, thus avoiding stalling of research and enabling it to move forward during unprecedented and difficult times.

Limitations

Although individual BCTs were selected to be promising based on previously used techniques in other studies, this was more or less arbitrary. Nevertheless, the additional steps for mapping of selected BCTs to the TDF, and stakeholder

consultation meant that there was not just reliance on what seemed promising through a previously used criteria, but also included examining how these BCTs can address the barriers and facilitators, and whether there were any gaps that required additional input (such as no BCT was previously used for the emotion domain of TDF).

Whereas the study was able to draw on stakeholder consultation through use of technology, the internet connection issues with various members precluded holding a live discussion which could have afforded an opportunity of dynamic brainstorming activity. Given the uncertainty around lifting of restrictions related to travel and social distancing, it was thought prudent to make best use of the available resources.

Furthermore, the work could have benefitted from involvement of other wider stakeholders such as LHS or LHWP project manager to bring an element of wider perspective especially related to sustainability of intervention components. However, lack of face-to-face interaction (due to a global pandemic), largely prevented this from happening as given the traditional manner in which most government systems work in Pakistan, in person presence would have greatly facilitated the process to take members on board from higher authority positions.

5.6.3 Implications

A systematic and transparent approach used for development of an intervention, which if found to be effective, may allow for easy replication or adaptation to other similar populations or settings. Furthermore, use of theory to underpin the development process can help with the assessment of the MoA of the intervention components in order to develop an understanding of how they bring about the change in behaviour. Involving stakeholders early in the development process can bring in the wider perspectives and allow consideration of the contextual factors which can affect the intervention implementation.

5.7 Conclusion

A step-wise intervention development process was followed to develop an evidence and theory based, culturally appropriate intervention. Use of TDF as theoretical basis of the intervention and linking it to BCTs, ensured the research process was made explicit and to built on the previous evidence of effectiveness. Use of PPI allowed to bring in an important component of stakeholder input. Feasibility testing of the intervention can help identify any operational challenges, thus providing an opportunity to further refine the intervention.

Chapter 6: The feasibility study

6.1 Chapter overview

This chapter describes the fourth and final study of the PhD, the feasibility testing of the PROSPECT (PROviding Support to Parents for Engaging in Children's Toothbrushing) intervention in which behavioural support sessions for children's toothbrushing were delivered by seven LHWs to 34 mothers of children between 6 months to 7 years of age, living in Pakistan. In this study, LHWs were trained regarding children's oral health and they delivered the behavioural support sessions to mothers as part of their routine home visits. Pre- and post-intervention text message-based surveys helped to establish children's toothbrushing routine before and after receiving the behavioural support session. Post-intervention qualitative exploration of the acceptability and perceived impact/sustainability of the intervention was also carried out. The introduction (6.2) provides an overview of feasibility studies and outlines the aims and objectives of this study. The methods section (6.3) describes the study population and how the study was conducted. The results section (6.4) presents the main findings from the study, addressing each of the study objectives in turn. Finally, the discussion section (6.5) reflects on the key findings of the study and how they compare to and add to the existing literature. The discussion section also presents study limitations, and reflection on methodology and an outline of the next steps. Conclusion is presented in section 6.7

6.2 Introduction

Equally important alongside intervention development is evaluation of its feasibility in order to identify any implementation problems at an early stage which could otherwise result in weak interventions resulting in poor compliance or uptake, and evaluations which may produce biased results (Campbell, Murray et al., 2007, Craig, Dieppe et al., 2008, McCrum, Watson et al., 2020).

Conducting a feasibility study helps examine whether the intervention “can work?” (Bowen, Kreuter et al., 2009) whereas pilot studies are "smaller versions of main study" which mainly look at the logistics of running a major study of showing whether an intervention does work (National Institute for Health Research, 2012). However, the distinction between feasibility and pilot study has often been blurred in the scientific literature. Orsmond and Cohn (2015) argue that this may lead to an expectation of rigorous examination of outcomes when the main purpose of the research study is to assess the feasibility of a newly developed intervention. In order to avoid this confusion, they put forth a helpful guide stating that the distinctive features of a feasibility study is the focus on processes such as those related to recruitment of participants, data collection procedures and outcome measures, intervention acceptability, resources and ability to manage the study, and preliminary evaluation of participant responses (Orsmond and Cohn, 2015).

More recently, the Medical Research Council (MRC) jointly with National Institute for Health Research (NIHR) produced an updated version of MRC’s guidance published in 2006 on developing and evaluating complex interventions (Skivington, Matthews et al., 2021). The updated version provides elaboration on the processes, labelled as core elements that need to be considered at every stage of the developing and evaluating a complex intervention (Figure 6.1).

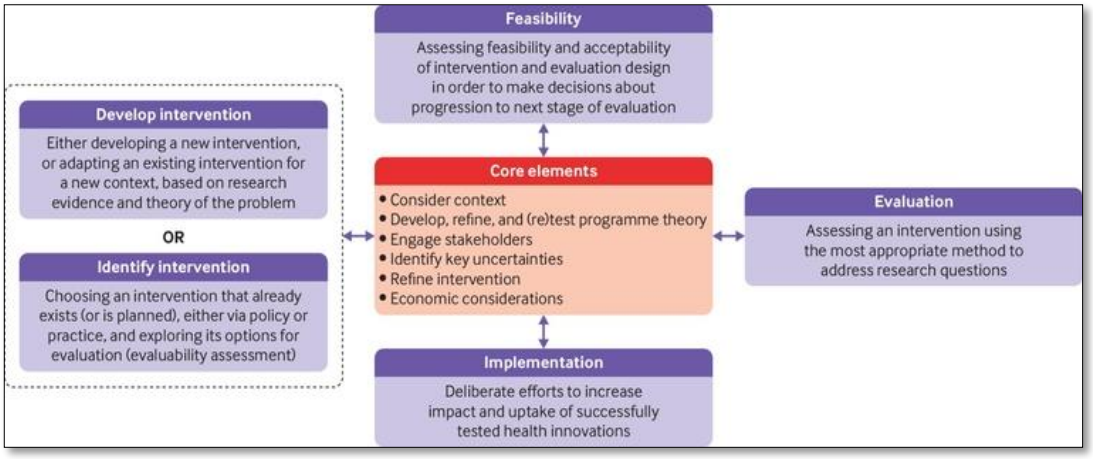


Figure 6.1 MRC and NIHR guidance on developing and evaluating complex interventions depicting the four phases with six core elements

These core elements relate to answering the following six questions which need to be considered at every stage:

“How does the intervention interact with its context?

What is the underpinning programme theory?

How can diverse stakeholder perspectives be included in the research?

What are the key uncertainties?

How can the intervention be refined?

What are the comparative resource and outcome consequences of the intervention?” (Skivington, Matthews et al., 2021).

In this chapter, I describe the feasibility study using mixed methods approach consisting of both quantitative and qualitative methods undertaken to evaluate the: i) feasibility of the intervention, i.e., processes involved in the delivery and receipt of the designed intervention (e.g. acceptability and feasibility of implementation), and ii) feasibility of the evaluation design, i.e., the processes involved in carrying out an evaluation study in terms of recruitment, suitable outcome measures, participant eligibility, data collection procedures, resources to manage the study and a preliminary evaluation of participant responses.

The feasibility testing of the PROSPECT intervention will allow for consideration of the five of the core elements listed in the MRC and NIHR guidance. This includes **(1)**

testing of the programme theory which drew upon the theoretical domains framework (TDF) and the capability opportunity motivation (COM-B) model of behaviour change, to develop the PROSPECT intervention (chapter 5). This will allow assessment of how the intervention works in the **(2) intended context** such as its feasibility, and acceptability to the **(3) relevant stakeholders** to address their barriers and facilitators (chapter 4).

In order to understand how an intervention functions, one of the factors that needs to be examined is its implementation. The implementation process refers to how delivery is achieved (such as training and resources) and what is delivered (for example its fidelity, dose, reach, adaptations) (Moore, Audrey et al., 2015). Furthermore, in order to be able to correctly interpret the outcomes of an intervention study, it is important to ascertain the consistency with which an intervention was delivered in practice, (Dogar, Boehnke et al., 2020). The Behaviour Change Consortium (BCC) recommends assessment of fidelity in five areas: study design, training, delivery, receipt, and enactment of skills (Bellg, Borrelli et al., 2004). The focus on fidelity in this feasibility study would be to assess the fidelity of delivery of the intervention, which refers to the degree to which the intervention was delivered as intended (Borrelli, Sepinwall et al., 2005).

The feasibility testing of the PROSPECT intervention will help uncover any **(4) key uncertainties** and **(5) refine the intervention** before the research can proceed to the next stage- planning for a definitive trial. An assessment of the comparative resource and outcome consequences of the intervention as part of the economic considerations (listed as one of the core elements) has not been undertaken in the current research.

Thus, in phase 1 of the research, a systematic approach was followed in developing the PROSPECT intervention to target the behavioural determinants and increase capability, opportunity, and motivation of parents' for initiating and routinising supervised twice daily toothbrushing of their young children. In this chapter, the feasibility of the PROSPECT intervention is described.

6.3 Aims and objectives

The aim of this study was to evaluate the feasibility and evaluation design of the PROSPECT intervention in providing support to parents for engaging in their young children's toothbrushing, in a non-randomised feasibility study (phase 2). The initial

plan was to conduct a randomised feasibility trial, however, due to the global Coronavirus pandemic, to allow conduct of research remotely, the design was changed to that of non-randomised study. Based on the results of this feasibility study, there may be a need to conduct a randomised pilot trial to allow for assessment of the randomisation process, recruitment and retention rates, sample size calculation and informing the design of a definitive trial later on (Torgerson, 2008).

The specific objectives are to:

- Assess the feasibility of the intervention including training of LHWs, intervention delivery and its fidelity, and exploration of acceptability and perceived impact by those receiving the intervention (mothers), and acceptability and perceived sustainability by those delivering the intervention (LHWs).
- Assess the feasibility of the evaluation design including recruitment strategy and parental self-report data collection measures and procedures.

6.4 Methods

6.4.1 Study design

This is a mixed-methods feasibility study involving two groups of participants: (1) LHWs who were trained to deliver the intervention, and (2) mothers as the primary caregiver of children aged 6 months to 7 years, who received the intervention.

A text message based pre and post survey used to assess parent's toothbrushing behaviour for their children, was administered to all the mothers who participated in the feasibility study. Based on their responses regarding their children's toothbrushing habits, a sub-sample of mothers were interviewed to explore the acceptability of the intervention and its perceived impact in overcoming the barriers to engage in their children's toothbrushing.

All LHWs who participated in the study were interviewed post intervention delivery to explore their views on oral health training that was provided to them, recruitment of mothers into the study, and acceptability of delivering the intervention and their perceptions regardings the intervention’s sustainability in the long term.

6.4.2 Study setting

The study was set in Mansehra city, part of Mansehra district in Khyber Pakhtunkhwa province of Pakistan. The setting is the same as one that has been used for the focus group study, and has been described in detail in chapter 4.

6.4.3 Participant recruitment

Lady Health workers

The LHWs who were working actively or fulltime were purposefully recruited based on their level of experience. This allowed for uncovering of any potential challenges encountered during recruitment and intervention delivery and also to capture variation of views based on how long they had been working in their field.

An exsiting contact of a Lady Health Supervisor (LHS) was used to help recruit LHW participants. The LHS informed LHWs about the study during one of their team meetings and based on their work experience, details of those expressing interest were provided with a participant information sheet and consent form and their contact details were passed on to me- the researcher. Contact with potential participants was established through telephone and details about the research study were provided. LHWs were provided time for due consideration and opportunities to ask questions and were asked to sign the consent form if they agreed to particpate which were later collected from them (Appendix 6.1). A WhatsApp messenger working group was created and participants were provided another opportunity to withdraw if they wished by simply exiting the group.

Mothers

The recuited LHWs helped in recruiting mothers for the study. The inclusion criteria was: families/mothers with atleast one child between the age of 6 months-7 years. This criteria was shared with the LHWs to identify eligible families including those mothers who had access to a mobile phone and who were due to receive a home visit by the recruited LHWs. Mothers from eligible families were contacted by the LHWs and informed about the research study. Contact details of those who expressed interest were then passed on to me. Telephonic contact was established with the potential participants and research details were discussed with opportunity provided to ask questions. The LHWs passed on to them the printed copies of the participant information sheet and the consent forms (Appendix 6.1). They were given time for due consideration and those who agreed to participate were asked to respond

to the text message inviting them to participate with options to reply if they agreed to participate or to opt out of the study. As I was not physically present in field to collect the signed consent forms and it was neither safe or practical to ask LHWs to make an additional visit to collect the forms before the time of their actual visit, this option of confirming written consent through text message was included. The mothers were asked to give their signed consent forms to their respective LHWs during the home visit, which were then later collected from the LHWs along with other study related documents.

6.4.4 Sample size

As this was a feasibility study, no formal power calculations were undertaken. A sample size of 6 LHWs and 30 mothers was deemed a feasible recruitment target for this study based on a similar study undertaken in the UK (Eskyte, Gray-Burrows et al., 2018). Given the logistical challenges especially related to remote management of the study, this was estimated to be sufficient to achieve study objectives and capture different perspectives.

For the post-intervention qualitative interviews with mothers, a sub-sample of participants was purposely selected inorder to capture variation based on toothbrushing behaviours such as those at either the lower end, those at the higher end- the recommended level, along with those in between on the spectrum of: (1) toothbrushing frequency (2) supervised toothbrushing. As the aim of the intervention was to promote oral hygiene behaviours of children based on universally accepted guidelines of twice daily toothbrushing with a fluoride toothpaste and parental supervised toothbrushing of children's teeth, this criteria was used for selection of a purposive sub-sample of mothers for qualitative interviews.

Furthermore, purposive sampling strategy also allowed for diversity in the sample so as to have adequate representation of mothers with children ranging from very young to older age groups (between 6 months- 7 years of age), and also an even representation of each of the seven LHWs who delivered the intervention to them.

All seven LHWs who took part in the study were invited for a telephone interview.

6.4.5 Intervention

Development and materials

The PROSPECT intervention was designed and developed during the phase 1 study as described in chapter 5. By drawing upon the results of a systematic review to identify effective intervention components or BCTs for oral health promotion of children through non-dental health professionals and health workers, and qualitative exploration of behavioural determinants (barriers and facilitators) encountered by children's caregivers for enagaging in children's toothbrushing in the study context, it was possible to develop an evidence and theory based intervention which is also contextually relevant.

The PROSPECT intervention consists of 18 BCTs to help parents/caregivers initiate and routinise children's supervised toothbrushing, to be delivered by LHWs targeting mothers as the child's primary caregiver. The intervention is based on the message 'Strong teeth, healthy kids' and consists of behavioural support delivered by LHWs with the help of a flipbook to provide chilren's oral health related advice, a leaflet as a reminder of key messages and toothbrush and toothpaste to aid with toothbrushing behaviour.

The intervention delivery materials such as the flipbook, the detailed guide book (for guidance on how to use the flipbook to deliver the messages), the intervention checklist and checklist filling guidance were arranged as a set for each of the LHWs taking part in the study. All documents including 1 handbook (part of written training material), 1 flipbook, 1 guidebook, 5 checklists & 1 checklist filling guidance, and 5 leaflets were arranged for each of the seven LHWs as individual folders.

Based on approximate calculation of five family members in each of the participants' family, including those of LHWs and the LHS, 200 adult toothbrushes, 50 children's toothbrushes and 40 fluoride toothpastes (family size of 40g tube with 1000ppm fluoride concentration) were arranged.

The toothbrushes, toothpastes and the document folders were then delivered to the LHS from where all the LHWs collected their individual packs. As the provision of toothbrushes and toothpaste was based on estimated numbers before the actual recruitment of mothers/families into the study, the LHWs were asked to inform the researcher if they required any more so those could be delivered to them.

6.4.6 Training

The LHWs are trained based on a universal national curriculum. This involves three month classroom based sessions and 12 months of field training including one week of training per month for a period of 12 months, followed by 15 days of refresher training each year (Hafeez, Mohamud et al., 2011, Oxford Policy Management, 2009). The behaviour counselling skills involving techniques such as rapport building and active listening are some of the core competencies that they gain as part of their job training and work experience (Policy & Strategic Planning Unit). Thus, to enable them to provide behavioural support to mothers for their children's supervised toothbrushing, it was necessary to train them regarding children's oral health and dental care. For this purpose, a handbook was prepared comprising all the important terms and definitions regarding oral health and with a focus on scientific facts and figures related to children's oral health.

Initially I planned to deliver an in-person training session to the LHWs regarding children's oral health and dental care in Pakistan. However, due to the Coronavirus pandemic and ensuing travel restrictions and social distancing measures, it was decided to provide the training session virtually. The internet connectivity issues faced by the participants during an earlier patient and public Involvement (PPI) meeting (chapter 5) meant that conducting an online training session was considered to be not a feasible option. Hence, it was decided to develop 3 short video segments, which were under 10 minutes in duration. This allowed for quick delivery of video clips to the LHW participants. Information was provided succinctly, regarding study procedures including recruitment of mothers, data collection procedures, guidance for LHWs on using of the fidelity checklist and explanation of key oral health messages. The concepts explained in the video segments were illustrated by the use of appropriate pictures and input from an oral health and dental expert (Appendix 6.1).

WhatsApp is the most widely used web based communication App in Pakistan. It was used for the purpose of creating a working group with the LHWs. The App suppports delivery of text & voice messages, and graphics and video messages. Futhermore, it also allows for placing group video or voice calls over the internet. Learning from the past experience of conducting PPI, it was clear that it would not be possible to convene a group meeting due to internet connectivity issues. Instead, training video segments were sent via the WhatsApp group, from where they were accessible to all the LHWs participants. Each video segment was sent in the WhatsApp group after an interval of two days in between, to allow participants ample time for the video to be

received whenever the participant connected to the internet and to watch it at a convenient time. Message prompts were sent the next day of sending 1st and 2nd video segments to encourage participants to view the video clips if they hadn't already, before the next one was sent the day after.

The LHWs were asked to watch each video segment and then send any questions or comments in the group via a text or a voice message so they could be discussed and other group members would also be able to benefit from the clarification. LHWs were also given the option to ask any questions by individually messaging me through WhatsApp, in which case, I would then present clarification for that point in the working group for the benefit of all the participants.

In addition, written training material including a printed copy of a handbook was also supplied to the LHWs with other intervention materials. This contained all the scientific facts regarding children's oral health and was meant as a quick reference guide for them.

6.4.7 Data Collection

Data collection consisted of both quantitative and qualitative methods. The measures recorded for each method and the procedure followed for data collection from each set of participants- mothers and LHWs, are detailed below.

6.4.7.1 Outcome measures

The first line of study outcomes were to explore the acceptability of intervention to both set of participants- LHWs who delivered the intervention and mothers of young children who were the recipient of the intervention.

Supporting feasibility outcomes included assessment of intervention fidelity, LHW training, recruitment and data collection procedure.

Other supporting outcomes were: LHWs perception of sustainability of the intervention; and the perceived impact of the intervention in addressing the barriers that mothers face for their children's toothbrushing.

6.4.7.2 Quantitative data collection

Feasibility of recruitment

Number of participants (both LHWs and the mothers) that the study was able to recruit, informed the feasibility of recruitment.

Feasibility of data collection measures and procedures

A text message-based survey was used to collect data on children's toothbrushing behaviours from the mothers at pre-intervention stage when they were recruited into the study and then at the post-intervention stage which was 15 days after the intervention was delivered to them. This allowed assessment of the feasibility of data collection measures (toothbrushing behaviours and (any) subsequent change in behaviour, and procedures (Appendix 6.3).

Feasibility of intervention fidelity

For assesment of intervention fidelity, a specially designed checklist was used (Appendix 6.4) which was based on the intervention components and their linked BCTs, that the LHWs completed during the intervention delivery sessions.

6.4.7.3 Qualitative data collection

The qualitative data collection was organised as post-intervention, semi-structured qualitative interviews.

Feasibility of training, recruitment and intervention fidelity

Feasibility of training LHWs was explored during interviews with them. Additionally, intervention fidelity and the feasibility of recruitment were further explored during post-intervention interviews with the LHWs.

Acceptability of the intervention

The acceptability of the intervention was explored for both set of participants- LHWs who delivered the intervention and mothers of young children who were the recipient of the intervention.

Perceived sustainability/impact of the intervention

Perceived sustainability of the intervention was explored with LHWs; and the percieved impact of the intervention in addressing the barriers for children's toothbrushing was explored with mothers.

Figure 6.2 presents diagrammatic representation of the data collection procedure and schedule for this study.

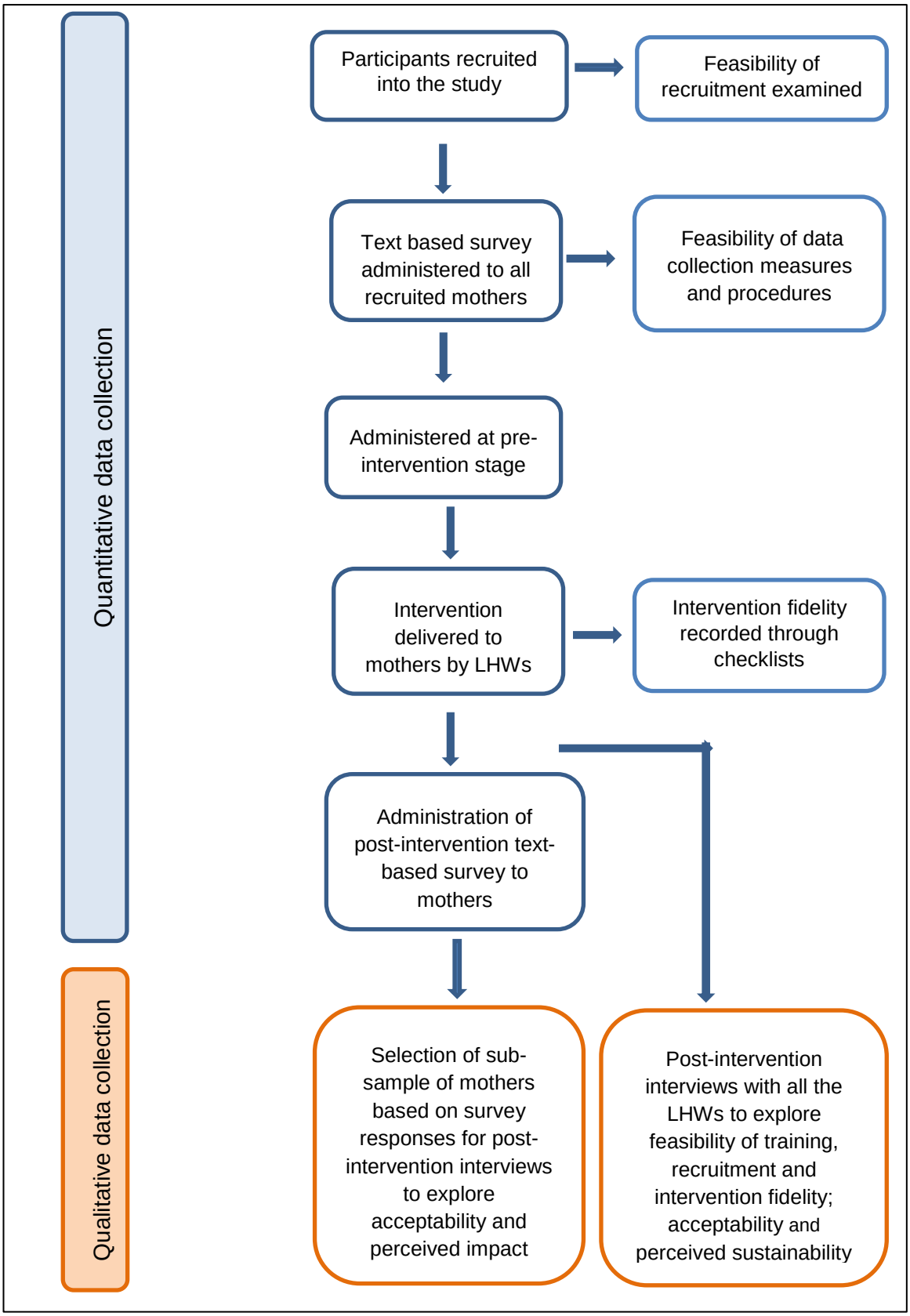


Figure 6.2 Flowchart illustrating the data collection methods and procedure for the study

6.3.7.4 Data collection procedure

Lady health Workers

For LHWs the data collection consisted of intervention fidelity, their views on training, recuitment of mother participants and the intervention acceptability and its perceived sustainability.

Intervention fidelity

The LHWs were asked to complete a checklist to record the components of the intervention that were delivered, in order to enable assessment of intervention fidelity. As there are various methods that have been reported, which can be employed to measure intervention fidelity such as direct observation, audio recordings, given the current circumstances and keeping in line with the current health & safety guidelines, the use of a checklist was the most feasible option. Furthermore, this also fitted well with the LHWs current work practice in which they are required to keep a log of their home visits and services delivered. The checklist was created in such a way to enable unpicking of different elements or parts of the intervention along with their mapped BCTs, that proved to be undeliverable or inappropriate. Thus ensuring any required modification to the intervention can be carried out.

To facilitate development of a fidelity checklist that would help capture information regarding delivery of different components of the intervention, a framework was initially created outlining the intervention content. The guidance on developing measures of fidelity and engagement detailed by Walton and colleagues (Walton, Spector et al., 2020) was followed for this purpose. The guidance outlines five steps for systematic development of fidelity checklists, starting with (1) reviewing previous measures, followed by (2) analysing intervention components and developing a framework outlining the content of the intervention, leading to (3) development of fidelity checklists and coding guidelines, followed by (4) obtaining feedback about the content and wording of checklists and guidelines, and finally (5) piloting and refining checklists and coding guidelines (incase of multiple researchers carrying out fidelity assessment which is not necessary for participant self-report). The fidelity checklist developed for this study has 8 activities in the checklist divided according to flipbook topics which map to the 18 behaviour change techniques (BCTs) that were identified as relevant to the study context during the development phase (intervention component framework and checklist presented in Appendix 6.4). The activities are then subdivided into elements that need to be covered to complete that particular

activity. Using the checklist enabled capturing of the elements of the behavioural support intervention that were delivered and the reasons if any elements could not be delivered. Detailed written instructions on how to fill the checklist were provided to each LHW and reference to this was also made in the training videos.

The LHWs were prompted to provide an update as soon as they delivered the intervention during their home visit to the mother participants. This helped in keeping an accurate record of time of the intervention delivery and allowed calculation of the time for adminstration of post-intervention survey for each of the mother participants at 15 days post-intervention.

Feasibility of training and recruitment, acceptability

Once each LHW confirmed delivery of the intervention to all study recruited mother participants, a suitable date and time was arranged for the purpose of conducting post-intervention interviews with them.

The interviews provided an opportunity to explore training & recruitment strategies, intervention fidelity and use of intervention fidelity checklist

During the interviews, LHWs views were also explored regarding the intervention acceptability and its perceived sustainability, to understand whether the intervention has potential to be taken forward for the next stage of testing and upscaling of the intervention in future.

A semi-strcutured topic guide was developed to facilitate the interviews, by reviewing the literature around exploring behaviour change intervention acceptability and feasibility for health interventions (Mann, Thomson et al., 2016, Siddiqi, Dogar et al., 2016). The interviews with LHWs were conducted over the telephone and lasted 30-40 minutes on average.

Mothers

For mothers the data collection consisted of a short text or SMS (Short Messaging Service) based survey and the qualitative exploration of the intervention acceptability and its perceived impact in overcoming barriers to children's toothbrushing.

Feasibility of data collection measures and procedures

The text based survey was used to record the self-reported toothbrushing behaviours and was administered at baseline and then 15 days post intervention. The advantages of using this type of survey greatly minimises the chances of over-reporting or social desirability bias in which a participant may feel obligated to respond with the socially acceptable response even when they do not perform the desirable behaviour (Brenner & De Lamater, 2017). Moreover, SMS based surveys have been shown to have good response rates (Dal Grande, Chittleborough et al., 2016), rule out the need for an internet connection, reduce the paperwork and most importantly provide responses in real time, as soon as the participant responds.

The baseline survey consisted of 6 questions including questions about the: age of the child, age of initiation and currrent frequency of toothbrushing, supervised toothbrushing and importance of children's teeth and confidence in their ability to brush their children's teeth (Appendix 6.2). Questions have been adapted from Children's Dental Health Survey, UK (2013) and 'Strong Teeth' study in the UK to assess the effectiveness of complex oral health intervention delivered by dental teams to parents of young children (Tull, Gray-Burrows et al., 2019). The post-intervention survey consisted of five additional questions: two enquiring about when they started to consider and work towards changing their child's toothbrushing behaviour, usefulness of the behavioural support session and two parental proxy-rated global rating questions asking how would they rate their child's dental health and how satisfied were they with their child's dental health (Abanto, Tsakos et al., 2013).

The questions were translated into Urdu using forward and back translation techniques by two native bilingual Urdu speakers inorder to retain the context of the content. The Urdu translated version was then pilot tested on 5 mothers and based on their suggestions, minor changes related to the wording were incorporated into the final version of the pre and post-intervention questionnaire.

A biometric registered number in Pakistan was used through the help of an assistant to generate SMS to participants' mobile numbers. Participants were given 24 hours to respond to a question after which a reminder SMS was sent. A maximum of two reminders were sent after which the survey proceeded to the next question. For those participants who wished to be contacted through the WhatsApp messenger, I administered the survey following the same rules for sending reminders. All the data

was imported securely to University of York Filestore and presented in a Microsoft Excel spreadsheet. Once all the data had been transferred, all participant information was deleted from the mobile numbers used for sending and receiving the participant responses.

Acceptability of the intervention and its perceived impact

Traditionally the focus of qualitative studies was to strive for a number of interviews or focus groups that would lead to the point of 'data saturation' defined as the point when no new no information, in the form of codes or themes can be developed from the data. With the current ongoing debate around the utility of the data saturation concept in thematic analysis (Braun and Clarke, 2021) and allocating a random number of interviews/focus groups as a minimum to ensure having reached the point of 'data saturation', I concur with the argument presented by Fusch & Ness (2015) that there is no 'one-size-fits-all' and other factors such as the study design and its aims, and the researcher's personal lens should also be considered when determining the number of interviews to be conducted (Fusch and Ness, 2015).

Allowing consideration for these factors, it was decided to create a categorisation matrix, based on the mother's survery responses related to children's toothbrushing frequency and supervised toothbrushing. This allowed for selection of a purposive sample for interviews and an opportunity for even representation, based on 4 broad categories: (A) mother who changed their children's toothbrushing behaviour to reach the recommended level (B) mothers who were able to improve their children's toothbrushing behaviour to some extent but were not yet at the recommended level (C) mothers of children for whom there was no change or improvement in their children's tooth brushing behaviour, and (D) mothers who were already performing their children's toothbrushing according to the recommendations.

The stopping criterion for number of interviews with mothers was based on obtaining an adequate number of participants in each of the sub-categories. As detailed earlier, I did not strive for saturation but ensured that I was able to get a representation of views of mothers along the length of the spectrum of toothbrushing behaviours ranging from high need of improvement in reaching the recommended level of toothbrushing, along with those in the middle, up to those who were already engaging in recommended level of toothbrushing for their children. Topic guides were used to conduct the semi-structured interviews with questions related to acceptability of the intervention and specific domains of the TDF to allow for exploration of the perceived

impact of intervention in relation to the specific behavioural determinants identified as TDF domains (Appendix 6.4). The topic guide for LHW interviews included additional questions regarding training and recruitment, intervention delivery and fidelity, and their views on perceived sustainability of the intervention. Participants were also asked about their recommendations for intervention improvement. Interviews were conducted in Urdu over the telephone and lasted 30-40 minutes on average. They were transcribed verbatim and translated into English for data analysis.

Upon completion of data collection, as a token of appreciation for their time and participation in the study, the LHWs were provided with Pakistani Rupees (PKR) 1000 cash gift (£4.75) each, and mothers were provided with PKR 100 (£0.48) calling cards for local talk time upon receipt of post-intervention survey responses, and an additional PKR 100 calling cards after the telephone interviews.

6.4.8 Data Analysis

As outlined in chapter 2 (aims and overall research design), the thesis follows the multiphase mixed-methods research design with the feasibility study utilising the sequential explanatory core design. Thus, the findings of the quantitative survey data were used to inform the qualitative post-intervention interviews.

Both the quantitative data and qualitative data analysis were used to report findings related to the study objectives. In addition, the data analysis of the acceptability of the intervention, and its perceived sustainability according to LHWs and its perceived impact in overcoming the barriers according to mothers, was guided by the theoretical domains framework (TDF) and COM-B model of behaviour change. Doing this helped provide an overview of how the intervention process links to the previously identified barriers and facilitators for children's toothbrushing practices (chapter 4), thus, indicating how the intervention could be refined for future testing.

6.3.8.1 Quantitative data

Due to the small sample size, it was intended to present the results of the quantitative data collected through text message-based surveys, as descriptive statistics. Children's ages were reported as mean and data on toothbrushing behaviours was reported as number and percentage of participants responding. Based on the reported change in children’s toothbrushing behaviour according to the recommendations of twice daily and supervised tooth brushing, four categories were created to allow selection of sub-sample of mother participants on the spectrum of

(A) no change in behaviour (B) some change in behaviour but not yet at the recommended level (C) improved behaviour to reach the recommended level (D) already following the twice daily parental supervised toothbrushing recommendations.

6.3.8.2 Qualitative data

Qualitative data from telephone interviews was analysed using thematic analysis. Thematic analysis is a "method for identifying, analysing and reporting patterns (themes) within data" thus organising the data set in a way that allows for presentation of rich detail (Braun and Clarke, 2006). Thematic analysis of LHWs' and mothers' interviews using the TDF and the COM-B model allowed for identification of several categories that grouped under 3 main themes pertaining to the acceptability of the intervention, its perceived sustainability and impact: *capability, opportunity* and *motivation.*

NVivo 12 Pro data management software (QSR International Pty Ltd. (2020)) was used and the 6 steps outlined by Braun & Clarke (2006) were followed for qualitative thematic analysis:

Step 1. Familiarisation with the data

In the initial step, data familiarisation was carried out by going through the data (interview transcripts and notes taken during the interviews) back and forth to get a sense of it and noting down the initial thoughts and ideas about the process.

Step 2. Generating initial codes

The next step entailed generating initial codes from the data at the semantic or basic level. Coding refers to identifying 'most basic segment or element of the raw data' inorder to organise the data in a meaningful way (Braun and Clarke, 2006).

Although the type of thematic analysis employed was predominantely theoretical or deductive approach which linked to the research objectives and the TDF domains, open coding technique was used in order to remain open to any other themes emerging from the data.

Examples of some of the descriptive codes used were "responsibility", "carelessness" "motivation", "engagement" and "having previous knowledge".

Step 3. Searching for themes

Once the raw data in the transcripts was coded, the codes were then collated and sorted into potential categories at the broader level as a precurser to identifying themes. The categories were based on the domains of the TDF. This process entailed categorisation of the codes based on their similarity or how connected (or unconnected) they are, to be able to be classified categorically as a theme. For example, for anaylsis of mother's interviews, codes such as "increase in knowledge", "brushing together" were categorised to link with the TDF's domains of 'knowledge' and 'behaviour regulation'.

Steps 4 & 5. Reviewing and naming themes

In this step of data analysis, Braun & Clarke's (2006) stage 4 (reviewing themes) and stage 5 (defining and naming themes) were combined together to produce an interpretative phase of the data analysis as detailed by Lochmiller (2021) (Lochmiller, 2021). The categories based on TDF domains with their individual codes were reviewed to analyse how they fit within the overarching themes of the COM-B model and linked to the objectives of the qualitative component, such as "acceptability of the intervention", "perceived impact of the intervention" and "perceived sustainability of the intervention". For example: the categories of knowledge and behaviour regulation were grouped under the theme of 'capability' based on mapping of TDF domains to COM-B model (Table 6.1).

Step 6. Reporting

The final step involved reporting the findings. Extracts from the data are provided along with an analytic narrative to give a sense of the data in terms of what it might or might not mean. Rigour for the qualitative study was supported by note taking during the interviews inorder to capture the overall impressions and also by actively seeking negative cases (Kessel et al., 2016). This was further supplemented by constant comparison between participants accounts inorder to reduce analysis bias (Smith and Noble, 2014).

Table 6.1 Table depicting mapping of COM-B components to TDF

COM-B component	Theoretical Domains Framework (Domains and description)
Capability (Psychological)	**Knowledge** (an awareness of the existence of something) **Skills** (an ability or proficiency acquired through practice) **Memory, attention and decision processes** (the ability to retain information, focus selectively on aspects of environment, and choose between two or more alternatives) **Behavioural regulation** (anything aimed at managing or changing objectively observed or measured actions)
Capability (Physical)	**Skills** (an ability or proficiency acquired through practice)
Opportunity (Social)	**Social Influences** (those interpersonal processes that can cause individuals to change their thoughts, feelings or behaviours)
Opportunity (Physical)	**Environmental context and resources** (any circumstance of a person's situation or environment that discourages or encourages development of skills and abilities, independence, social competence, and adaptive behaviour)
Motivation (Reflective)	**Social/Professional role & identity** (a coherent set of behaviours and displayed personal qualities of an individual in a social or work setting) **Beliefs about capabilities** (acceptance of truth, reality or validity about an ability, talent or facility that a person can put to constructive use) **Optimism** (confidence that things will happen for the best or that desired goals will be obtained)

	Beliefs about consequences (acceptance of truth, reality or validity about outcomes of a behaviour in a given situation) **Intentions** (a conscious decision to perform a behaviour or resolve to act in a certain way) **Goals** (mental representation of outcomes or end states that an individual wants to achieve)
Motivation (Automatic)	**Social and Professional role & identity** (a coherent set of behaviours and displayed personal qualities of an individual in a social or work setting) **Optimism** (confidence that things will happen for the best or that desired goals will be obtained) **Reinforcement** (increasing probability of a response by arranging a dependent relationship, or contingency between a response and a given stimulus) **Emotion** (a complex reaction pattern, involving experimental, behavioural and physiological elements, by which the individual attempts to deal with a personally significant matter or event)

6.4.9 Reflexivity

As explained in detail in chapter 4, the process of a reflexive practice was applied during data collection, analysis and reporting of the qualitative data for this study as well. Having worked as a clinical dentist in Pakistan, I had often treated young patients for dental caries. During this time, I had an opportunity to talk to their accompanying parent (who were mostly mothers) to understand their concerns and issues regarding dental care of their children, and to advise them on their children's oral health. As realistically it is not possible to completely detach oneself from their biases and prejudices, becoming more aware of them allows one to understand that there is a possibility of various meanings attached to the data. Thus, taking a stock of this, I drew upon on my background- both as a dentist and a mother to develop an understanding of the data during the data collection and the analysis process and to present the findings in the best possible way.

6.4.10 Ethics

Ethics approval for this study was obtained from University of York Health Sciences Research Governance Committee (HSRGC) and National Bio Ethics Committee (NBC) Pakistan.

6.5 Results

In this section, the results of the feasibility study are presented as quantitative and/or qualitative findings under key headings that link to the study objectives. For ease in readability, the results for the two main objectives: feasibility of the intervention and the feasibility of the evaluation design are presented in the reverse order to maintain a natural flow of events starting from participant recruitment into the study, feasibility of data collection procedures including results of pre and post- intervention text based survey training of LHWs, intervention delivery and its fidelity and exploration of intervention acceptability and perceived impact/sustainability.

6.5.1 Objective: Feasibility of the evaluation design

6.5.1.1 Feasibility of Participant recruitment

The study participants were recruited over a period of two months starting from October to November 2020. The target was to recruit six LHWs and 30 mothers and the study was able to recruit seven LHWs and 34 mothers which was slightly over the intended recruitment target.

Lady Health Workers (LHWs)

Contact was established with a LHS through a mutual contact. The LHS who has considerable experience of working in the study setting facilitated recruitment of a purposive sample of LHWs with different work experience levels.

The study required participation of six LHWs and based on the sampling criteria, all of the six LHWs approached by the LHS expressed their interest in taking part in the study and their details were passed on to me. They all consented to participate, after they were provided the study details and participant information sheet and consent form through the WhatsApp messenger. In addition, an extra participant was added to the group of LHWs on her express wish to join the study.

Mothers

As the LHWs have detailed information about the demographics of their community, they approached eligible mothers based on the study inclusion criteria. A total of 44 mothers were approached and were provided with the study details. Out of these 6 declined (reasons presented later) and 38 expressed interest.

For 38 who were interested in participation, with their consent, their contact details were passed on to me. Contact was then established with them over the phone, to explain about the study. Out of the 38 approached by me, four declined to participate: two declined stating they were busy, one said her child didn't have any teeth yet and there was not much that she had to say and one of the contact provided could not be reached despite multiple attempts to establish contact with her. The participant recruitment process is illustrated in figure 6.2.

The feasibility of recruitment of mother participants was further explored during the post-intervention interviews with LHWs. This helped to uncover any potential challenges that could be encountered for setting up and conducting a future pilot trial.

The use of LHWs as 'gate keepers' to reach a community of mothers was a fruitful approach. Although the majority of LHWs had no trouble in achieving the recruitment target which took place over a period of one month (5 mothers/families to be recruited by each LHW), one LHW whose catchment area consisted of predominantly rural area, spoke about how she had to approach 10 eligible participants before 4 agreed for their details to be passed onto the researcher.

> *"Remaining six of them, some said we don't have permission from home, we cannot speak like this with somebody. Some said that we don't know what questions they might ask and we might not know the answer and some said we don't have a mobile with us." (LHW R-2 with 17 years work experience).*

It is a common practice for the female members of the family to not to attend calls from unknown numbers or to hand the phone over to a male member of the family to answer such a call. This was apparent from the account of another LHW:

> *"We have a doctor madam who is doing a research for which she will ask you some questions, shall I give your number to her? Would you have any objection to that? So obviously they all know me so they said no, if it's a female then we have absolutely no objection, you can give it to her." (LHW M with 11 years work experience).*

I also had a similar experience when I called a potential mother participant to provide further study details. Due to my overseas number which was not recognised by the potential participant, I had to initially speak to a male member of the family, who first confirmed with the potential participant about expecting a call from me, before I could speak to her. Hence, this finding highlights an important cultural aspect to be considered while planning recruitment for a future pilot trial.

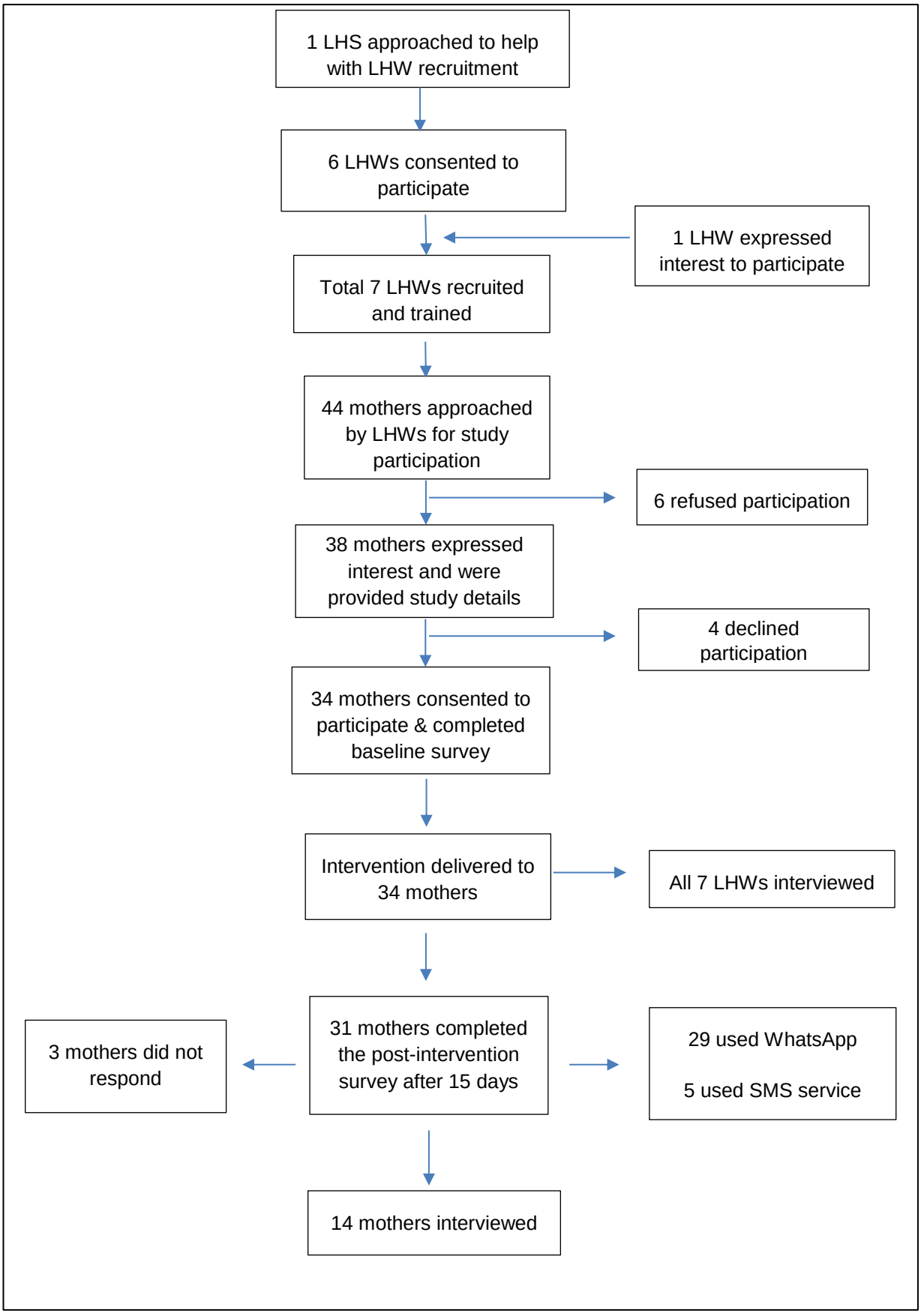


Figure 6.3 Participant recruitment flowchart

6.5.1.2 Feasibility of data collection methods

The feasibility of data collection methods was based on assessment of the feasibility of text-based survey to collect data on children's tooth brushing behaviours. The text-based survey was easy to administer, quick to complete requiring only two minutes and responses were received in real time. All 34 participants completed the baseline survey and 31 participants responded to the post-intervention survey with a response rate of 91%. For the participants who responded to the post-intervention survey, the time period for completion ranged from completing in one go to taking about two days to complete it when once started. A reminder was sent after 24 hours had elapsed without receiving a response. There was a need to send a reminder once to two participants after which they completed the survey. Out of the 31 participants who responded to the post-intervention survey, one participant did not respond to the latter half of the survey with questions related to the intervention despite reminders being sent.

The survey was administered at two points- once at baseline and then 15 days post intervention. Although it was intended to administer the text survey through the SMS service, on express wish of the participants, WhatsApp messenger was also used as the survey delivery medium.

Out of the 34 mothers recruited 29 mothers preferred WhatsApp messenger and 5 mothers used SMS service for responding to the survey questions. Findings of pre and post-intervention survey are provided in Table 6.2. As mothers were asked to consider the toothbrushing behaviour of their youngest child in case if they had multiple children, the ages of children whose behaviours were reported in the study ranged from 1- 6 years with a mean age of 3.2 years.

According to the survey responses, there has been a positive shift in number of mothers between pre and post intervention for considering importance of brushing children's teeth, frequency of toothbrushing and confidence in their ability to brush their children's teeth. However, for supervised brushing, there does not seem to be a remarkable difference in the numbers between pre and post intervention.

All the mothers either strongly agreed (77.4%) or agreed (19.4%) to have found the support session to be useful. One third of mothers in the sample (33.3%) reported to have considered about changing their child(ren)'s toothbrushing behaviour even before taking part in the study with 43.3% reporting to have considered it after the provision of the support session. Furthermore, 60% mothers reported to have started

working towards changing their child(ren)'s toothbrushing behaviour after having received the support session by the LHWs.

Table 6.2 Results of pre and post-intervention text survey of participants

Characteristics	N (%)	
Age of children in years (n, mean (SD))	n=34, 3.2 (1.5)	
	Pre-intervention (n=34)*	**Post-intervention (n=31)***
Importance of brushing children's teeth		
Less important	0	0
Not more not less	6 (17.6%)	3 (9.6%)
More important	28 (82.3%)	28 (90.3%)
Frequency of toothbrushing		
≥ Twice daily	6 (17.6%)	19 (61.3%)
Once daily	16 (47%)	7 (22.6%)
< Once daily	7 (20.5%)	3 (9.7%)
Not started	5 (14.7%)	2 (6.5%)
Supervised toothbrushing	n= 29	n= 31
Yes	15 (51.7%)	17 (54.8%)
No	14 (48.2%)	14 (45.1%)
Confidence in ability to brush	n= 34	n= 30
Strongly agree	11 (32.3%)	18 (60%)
Agree	20 (58.8%)	11 (36.6%)
Neither agree or disagree	1 (2.9%)	1 (3.3%)
Disagree	1 (2.9%)	0
Strongly disagree	0	0

Awareness regarding toothbrushing recommendations		n= 30
Yes	-	21 (70%)
To some extent	-	10 (33.3%)
No	-	0
Start thinking about changing behaviour		n= 30
Before taking part in the study	-	10 (33.3%)
After taking part in the study and before LHW's visit	-	7 (23.3%)
After LHW's visit	-	13 (43.3%)
Do not know	-	0
Started working towards changing behaviour		N= 30
Before taking part in the study	-	4 (13.3%)
After taking part in the study and before LHW's visit	-	7 (23.3%)
After LHW's visit	-	18 (60%)
Have not started yet	-	1 (3.3%)
The support was useful		N= 30
Strongly agree	-	24 (77.4%)
Agree	-	6 (19.4%)
Neither agree or disagree	-	0
Disagree	-	0
Strongly disagree	-	0

***unless specified in which case change in number is due to question not being applicable or because of no response received.**

6.5.2 Objective: Feasibility of the intervention

6.5.2.1 Training of LHWs and provision of study & support materials

Training was provided in the form of three short video segments that were delivered to the LHW participants through the WhatsApp messenger working group. The convenient, in-built features of the WhatsApp mobile application allowed for assessment of when a message, either in text or graphic/audio format, had been successfully sent in the group, delivered to all the recipients and whether messages had been accessed in the group by each of the recipients. Based on this feature of the application, it was noted that each of the video segments had been successfully accessed by all the LHWs.

Around the same time when training was delivered to the LHWs through WhatsApp, intervention materials and other supporting documents were also sent to the LHS contact and each of the LHW was instructed to collect their sets from the LHS.

The feasibility of providing training and supporting materials to the LHWs was also explored in the post-intervention interviews to inform planning for a future study. Although provision of training remotely was necessitated due travel restrictions and social distancing measures in place at the time, it turned out to be a favourable move and the training videos were very well received by the LHWs.

The idea was to have the videos of a reasonable time duration that would not cause the intended audience to lose interest, while at the same time being comprehensive enough to convey the key messages.

> *"They were not short, they had the full essence. Those books of yours that we spent time reading, we got all that information quickly from the videos." (LHW R-1 with 20 years work experience).*

Another advantage of providing training videos over WhatsApp mobile application, which was not considered at that time but was in fact highlighted by one of the LHW was that it provided information at their fingertips. This meant they could access the video at any time that they needed to, as it was stored on their mobile phones because of the default setting of WhatsApp that stores media files directly to the phone gallery.

> *"if there is one thing somewhere that you are confused about, so listening to it again and again makes it memorable" (LHW A with 23 years work experience).*

Furthermore, another LHW also indicated how she showed part of the training video clip, which was related to the study process, to a mother to help with the recruitment.

Although the training videos were very well received, when the LHWs were queried about whether they would also like to have a face-to-face training session. They all agreed that they would also prefer to have face-to-face training sessions, which has its own advantages such as more scope for discussion and interaction for them. This again highlights an important finding which points towards a preference for more interactive style-based training sessions with case-based scenarios that would stimulate discussion and reinforce problem solving skills.

6.5.2.2 Feasibility of delivering the intervention and its fidelity

The feasibility of intervention delivery was based on assessment of numbers of mothers to whom the intervention was delivered successfully. Assessment of intervention fidelity included analysis of intervention fidelity checklist filled by LHWs to record delivery of different components of the intervention. Qualitative exploration of the intervention delivery and fidelity checklists were also undertaken to uncover any barriers or hindrances to intervention delivery including delivery of different intervention components.

The intervention was successfully delivered by LHWs to all 34 mothers over a period of one month. All checklists were successfully completed during the intervention session. Analysis of filled checklists showed that the LHWs were able to deliver most of the intervention elements that linked to different intervention components i.e the BCTs. One element that was most often omitted was the information regarding primary tooth eruption in children as it was not applicable to that set of participants who did not have any young child in the family.

During the interviews it was revealed that although most of the LHWs were successfully able to deliver the intervention to all the recruited participants, this was not always straight forward and a simple task. In some cases, they had to call on 1-2 times before they got a chance to speak to the mother participant and deliver the behavioural support intervention.

> *"I went two times but the mother wasn't home…..so that checklist, not once, like I have told you, I could only fill it the second-third time" (LHW F with 5 years work experience).*

Getting a convenient time to visit those mother participants who were working especially, posed a challenge for the LHWs, who then visited them during the weekend- Saturday/Sunday so that the intervention could be delivered. Furthermore, even with non-working mothers, one of the LHW mentioned that she had to re-visit one of the mother participant in order to be able to initiate the delivery of the behavioural support session. This was mainly because of mothers being preoccupied or busy with routine household chores or attending to guests/others in the house.

This was also reflected in one of the fidelity checklists for a participant, when the LHW was not able to deliver the last element of the behavioural session. When further explored in the post-intervention with the LHW, it was explained that this was because the mother's children were consistently demanding her attention and she was not able to attend to the LHW anymore.

Timings for the routine home visits are at the discretion of the LHWs who are well acquainted with suitable visiting times for people in their community. Although LHWs stated that they do try and conduct home visits when people are most likely to spare time for them. However, the time of the visit is not usually formally set beforehand for which reason there are times when the person they need to see is unable to attend to them. This is an important contextual factor that needs to be considered when planning for a future trial, as this may mean allowing for additional time and reimbursement for travelling costs and work conducted out of normal working hours.

All the LHWs agreed that initiating conversation related to children's oral health was not at all difficult for them. This is was partly because of the expectation by the mothers about an impending discussion regarding children's oral health, when they agreed to participate in the study, and also because of the level of understanding and rapport that the LHWs share with their community.

6.5.2.3 Acceptability of the intervention and its perceived impact/sustainability

The post-intervention interviews with both the LHWs and the mothers also helped to elicit their views on acceptability and perceived impact/sustainability of the intervention in this setting.

Lady Health Workers

Once LHWs confirmed delivery of the intervention to their group of participants, a suitable time was arranged to conduct post-intervention interviews with them.

Interviews lasted 40 minutes on average and all 7 LHWs were successfully interviewed.

Thematic analysis of LHWs interviews identified 3 main themes pertaining to the acceptability of the intervention and its perceived sustainability using the TDF and COM-B model. The findings of thematic analysis are presented in the following section.

Theme 1: Capability

Knowledge and skills

Advising about general hygiene is a part of LHWs health promotion duties, however, there was not a particular focus on oral health promotion included as part of their work duties. For this reason, they had very limited knowledge on this topic and taking part in the study also helped increase their own knowledge regarding oral health and toothbrushing practices:

> *"this what you have taught us, this is very good. This is not in our books but for us this is a new chapter." (LHW R1 with 20 years work experience).*

> *"My knowledge has increased about a lot of things that we ourselves did not know" (LHW F with 5 years work experience).*

The LHWs were asked about whether they ever had any conversations with mothers regarding care of children's teeth and tooth decay in children, to which they stated that they mentioned to mothers about children's toothbrushing but it was mostly as part of the general hygiene advice. Other than this the conversation regarding oral health mostly initiated whenever there was a complaint of toothache, for which they referred the person to a dentist.

Although the LHWs are trained in counselling skills as part of their work, but without the essential background knowledge, they often found themselves at a loss when people countered them with false beliefs regarding children's primary teeth and toothbrushing in general. There was an expectation of this happening and for this reason there was a section in the handbook provided to the LHWs, explaining how to dispel false beliefs related to children's primary teeth and toothbrushing in children. Most commonly stated reasons for not brushing children’s primary teeth were that they do not require cleaning or cleaning them can weaken and damage the gums. Another frequently cited reason for not giving primary teeth due attention was

because they were considered to be temporary and would eventually give way to permanent teeth.

> *"There were one or two mothers who said to me that their [referring to children] gums would get damaged. I said to them it's a very soft brush it will not do anything like that. It is very important to clean their teeth. If they get decayed, that would spread very quickly to reach the nerves. It is said that these are milk teeth, they would fall off and that would be the end, but the problem would transfer to the new teeth. So, they listened to this very attentively." (LHW K with 9 years work experience).*

Behaviour regulation and memory attention & decision processes

As the LHWs had limited knowledge regarding dental care in children, it was essential to enhance their capability in this area by providing them with necessary support and resources which not only increased their knowledge but were also in a format that was accessible for them. Usually as part of their training process, they are provided with handbooks for reference on the health topic. Keeping this in mind and the need to provide training remotely, training videos along with a handbook were compiled.

> *"We did not say anything dental related, it was not included in our, for us, meaning we would speak about personal hygiene but we did not focus much on children but now what we were told in this research, we were made to understand, the training, the module that you provided, it increased our knowledge quite a lot" (LHW M with 11 years work experience).*

The development of the flipbook was based on findings of the exploratory focus group study during which the LHWs demonstrated to me how they used their flipbook to deliver health messages to the people in their community. The flipbook provided as support material to facilitate the delivery of the behavioural support session, was very positively received by the LHWs. They especially commented on how pictures in the front kept mothers and their children engaged while the text provided at the back helped them guide the delivery of the support session.

"I could understand everything very easily in the flipbook. You did not miss out anything in it. We would show the picture on one side and it was easy to read from the other side. Looking at everything the questions that we had to ask them and things to tell them, all the questions and answers were there in front of us" (LHW R1 with 20 years work experience).

The aim of the flipbook as part of the intervention session was to facilitate the delivery of the behavioural session whilst mirroring their current practice of using a flipbook to deliver health messages. The guidebook supplied along with the flipbook provided detailed guidance about the key messages contained in the flipbook.

"I liked it a lot for this reason too, meaning if a point slips your mind, so what happens is you get a review of it and you realise it. If something is slipping your mind, when you glance at it once, so you immediately remember it." (LHW A with 23 years work experience).

Theme 2: Opportunity

Social Influences

The LHWs agreed that tooth decay was a very common problem and welcomed the opportunity to incorporate toothbrushing advice as part of their health promotion activities. They are very well aware of their social standing and the level of influence that they have for promoting positive health behaviours in their community.

"In Pakistan we have increased need for such things. Another thing, like in routine we have all the other things included, similarly if we, if this is added to our routine program because we people have contact with every person, every household, every person has this problem. So, in routine we keep coming and going, if this extends to everyone [other LHWs] so this message can reach every person, every household" (LHW A with 23 years work experience).

The LHWs enthusiasm for their work and a sense of ownership for their community provides a favourable opportunity for promotion of positive oral health behaviours. Their willingness to incorporate children's oral health promotion speaks a lot about the acceptability of the intervention at the proximal level and their openness about scaling the intervention to reach others in their field, at the wider level.

Environmental context and resources

There was an expectation of display of some reservation on the part of LHWs to incorporate oral health promotion as part of their regular home visiting, due to potential reasons such as increased workloads or considering it to be something beyond the scope of their work duty. Hence, it was a pleasantly surprising finding when all the LHWs showed enthusiasm to continue with the oral health promotion sessions even after the completion of this research.

> *"We didn't know these things, we know them now so what will happen is as we go to every house, it's not like we just do it with five mothers, now whenever we do our visits, we will keep telling mothers, God Willing" (LHW S with 16 years work experience).*

There was no mention of increased workload or transport costs for repeated home visits which could make it difficult for them to incorporate oral health promotion as part of their routine home visits, in fact the findings were on the contrary. The LHWs affinity to promote healthy behaviours in their community despite the work challenges that they face and their steadfastness to work even in times of Coronavirus pandemic when they have to be extra careful and observe all the precautions, says a lot about their dedication and community spirit, thus, presenting a unique opportunity to utilise them for promoting positive oral health behaviours.

One significant point that was raised by a LHW during the interview, was lack of support provided by oral health professionals in terms of promotion of children's oral health.

> *"We say, like it happens in countries abroad, when children visit a dental clinic, they tell them like do this, so the doctors should also say a little something like this related to children. What happens is when they go, they have a toothache, so they just pull it out." (LHW S with 16 years work experience).*

As the payment for dental services in Pakistan is based on traditional out-of-pocket payment model, preventive oral health visits are non-existent with symptomatic dental visiting prevalent. The lack of focus on prevention by oral health professionals further exacerbates this issue.

Nevertheless, the LHWs stated that the behavioural support session was very well received by the mothers. The toothbrushes and toothpaste pack provided for the

whole family along with information leaflet elicited a very positive response from both the mothers and children who even committed to use them every day on a regular basis.

> *"They were very happy especially young children meaning those whom I gave, I gave them with my own hands, "brush your teeth, promise me that you would do it like this twice daily before going to bed and after breakfast before going to school or even if you stay at home you would brush your teeth, I will then give you brush and toothpaste." So then when I gave it to them, it was very good meaning they showed a very good response…..now as I visit or meet them again so the children tell me, "aunty we did as you told us and that chart we have stuck it there at the front so we remind each other that aunty has told us we have clean to our teeth"" (LHW R2 with 17 years work experience).*

Theme 3: Motivation

Beliefs about capabilities

It was estimated that the behavioural support session would last approximately 10-15 minutes, however, the LHWs indicated that it took them around 30 minutes to deliver the session or sometimes more especially when other things were brought into the discussion or to ensure mothers were able to understand the guidance provided to them.

> *"Yes, half an hour because then we have to perform our other work duties too with it [laughing] so then when I went, half an hour or sometimes thirty-five minutes too, this is how long it took me" (LHW F with 5 years work experience).*

Nevertheless, they did not find it difficult to dedicate this amount of time on discussing about children's oral health and dental hygiene, and mentioned they could easily manage it during their routine home visits.

However, they mentioned other challenges such as mothers being busy or not available at the time of visit for which reason, they had to visit again some other time. Another challenge for LHWs was remaining mindful of the social distancing and Coronavirus preventive measures during the session delivery.

"So it took me thirty minutes, I did not take a lot of their time, because nowadays you know because of Corona we kept a distance and delivered the session while sitting far away" (LHW R1 with 20 years work experience).

It was very reassuring to know that the LHWs were very observant of the Coronavirus safety protocol. They all mentioned about carrying hand sanitisers, washing hands regularly, wearing face masks and observing social distancing.

Intentions, goals and optimism

The LHWs expressed a keen interest in continuing to provide behavioural support sessions to mothers during their routine home visits. They also mentioned about incorporating children's oral health promotion as part of their heath sessions that they deliver to group of families and even at schools.

An interesting finding was the keen interest expressed by mothers for becoming a part of the oral health promotion activities. Thus, further highlighting the acceptability of the intervention.

"Many mothers say you give them brushes, talk to them about the teeth, why don't you come to our house too. I said to them I will visit you too and you will also get brushes, I will give them to everyone but gradually" (LHW K with 9 years work experience).

Emotion and reinforcement

The LHWs stated that being able to help people in their community with their health-related issues and being recognised for their work were the major motivating factors for them to continue working. They had to face many challenges in the beginning especially when few people in their community did not treat them amicably. However, their attitudes changed with time because of the LHWs dedicated service provision regardless of people's attitudes towards them.

Moreover, one LHW pointed out that in general motivating people could be a challenge when they seemed more interested in finding out about the material benefits of listening to the session or taking part in the research.

"When we mention about a research or say something similar so people ask "would they give us anything?" This is very wrong so then that is why our duration prolongs trying to motivate them and bring them at a level that not every department or organisation provides stuff, you have to do something for yourself too" (LHW M with 11 years work experience).

This links back to the finding of the FGDs with LHWs (chapter 4) in which they stated that providing incentives, no matter how big or small, can help with increasing people's motivation and reinforce the message that is being delivered.

Mothers

The results of the text-based survey facilitated selection of a purposive sample of mothers for post-intervention interviews, based on (1) frequency of tooth brushing, (2) supervised toothbrushing, and how it changed between pre and post intervention (Table 6.3).

The interviews were planned in a way that it allowed to sample participants from each of the category whilst ensuring an almost equal representation of the all of the LHWs who delivered the intervention to the participants, and also making sure to cover participants who had children in different age groups, such as very young to older children. Fourteen interviews were successfully conducted out of 15 attempted (one other participant in category C3 could not be reached even after multiple attempts to contact her).

Table 6.3 depicts the number of participants in each of the four categories based on the pre and post-intervention survey responses and the number of participants interviewed from each category.

Table 6.3 Sample selection for post-intervention interviews

Category	Category Code	Sample
Those who have improved to reach the recommended level for frequency and supervision of their children's toothbrushing (n= 9)	A	4
Those who changed their children's toothbrushing behaviour to some extent (but have not yet reached the recommended level):	B	
- In frequency only (n= 10)	B1	2
- In supervision only (n= 1)	B2	1
- In both frequency and supervision (n= 1)	B3	1
Those for whom there was no change in their children's toothbrushing:	C	
- No change in frequency (supervision already according to recommendations) (n= 4)	C1	2
- No change in supervision (frequency already at recommended level) (n= 3)	C2	2
- No change in both frequency and supervision (n= 2)	C3	1
Those whose behaviour was already according to the recommendations (n= 1)	D	1

Acceptability

On the whole, mothers universally showed a positive response to the behavioural support intervention. Many indicated that it provided them with information that would be very beneficial for their children, whereas others mentioned it helped them focus more on their children's oral health which they had mostly unwittingly ignored despite having sufficient knowledge and skills to care for their children's oral hygiene.

> *"It felt really nice that somebody also told us something about children's hygiene, I, especially liked it a lot" (Category A - mother of 9, 5 and 4-year-old children).*

Capability

Knowledge & skills

Mothers were of the opinion that the behavioural support session proved to be beneficial for them. Not only in terms of receiving new information and increasing their knowledge and skills but also making them realise the importance of teeth and helping them to engage more in their children's toothbrushing.

Many mothers stated that cleaning a child's mouth and gums even before the teeth erupt was completely new information for them. This is quite understandable given the common practice of children starting to brush their teeth when they are old enough to understand and coordinate their movements such as moving the brush in their mouth followed by rinsing, which amounts to 3-4 years of age.

> *"We did not have knowledge about young children, breast fed babies, that it is important to clean gums of even small babies those who are breast fed. This way they get into the habit of cleaning teeth. This was new for me" (Category A - mother of 9, 5 and 4-year-old children).*

Furthermore, having the child brush under supervision was also flagged as a new piece of information by some mothers. This also appeared to be a behaviour where there was not a noticeable shift in numbers of mothers engaging in this practice, as evident by the findings of the text-based survey.

“New was like she [LHW] told us to make them do it under my own supervision. I often used to apply it on the brush and give it to him [the child] and he would do it as he wished” (Category B1- mother of 12, 8 and 4-year-old).

One explanation for this could be that even when mothers were making an effort to incorporate twice daily toothbrushing in their child's daily routine, they could just manage it without being able to supervise their children during the process.

Some mothers confessed that they had no prior knowledge regarding the information related to the amount of toothpaste to be used according to the child's age. They commented on how it was shown on the TV and the toothpaste advertisements that were misleading in this regard, mostly showing people using toothpaste covering the whole of the brush head.

“Yes, toothpaste quantity, this thing, yes this thing. I did not know about the quantity, the age wise quantity” (Category C1- mother of 10, 6 and 3-year-old children).

Furthermore, mother's skills for guiding their children's toothbrushing were also mentioned to have improved after the intervention session.

"Now I tell them on a regular basis up and down, do it up and down and then I say, do them from inside too. Believe me now they themselves say this to me that there is a figure [referring to images on the leaflet provided], look at the figure how they are shown doing it." (Category C2- mother of 6 and 3-year-old children

Their toothbrushing skills were mostly learnt from their elders without ever having received any proper guidance on the best way to brush their teeth. The behavioural session along with the pictorial leaflet made them aware of the correct toothbrushing movements and increased their skills and capability in this regard.

<u>Behavioural regulation and memory, attention & decision processes</u>

It was evident that some mothers, especially those with older children, had them brush their teeth, but they were not consistent with it or did not follow a routine. The commonly cited reasons were being busy with household chores, general laziness, and a sense of apathy for a regular toothbrushing routine. After receiving the behavioural support session, many mothers explained how they have become more

aware of being regular with their children's toothbrushing and that they are better able to manage child behaviour around it. Moreover, they also mentioned how their children have now started to cooperate and are getting accustomed to a twice daily toothbrushing routine.

> *"Yes because of this chart [referring to the leaflet]. Before I was not doing it regularly, I would do it after one day, because I was not well too and also because of laziness. From the time we got the chart, I look at it and do it regularly for them now" (Category C2- mother of 6, 3 and 1-year old children).*

> *"If we get them in the habit right from the beginning itself, then it might not become a big problem later on…..now I have come to know it is very important because I have a niece, her teeth are very damaged….so as soon as I have heard this I told them this is very important otherwise your teeth would become like that of her" (Category A - mother of 9, 5 and 4-year-old children).*

However, two mothers shared their different experience and said it still sometimes proved a challenge to get some of their children to brush their teeth. As both these mothers had older children, they were asked whether their children had expressed any interest in the leaflet or showed any sense of motivation to brush their teeth to which both the mothers replied that they had not shown the leaflet to their children or placed it anywhere where it was clearly visible to them.

> *"Yes, I make children do it [referring to toothbrushing] but my older son he annoys a lot at the time of brushing, a lot. He wishes he doesn't have to brush at all….obviously then I make him do it forcefully but kids nowadays, you know, they do as they please" (Category B3- mother of 1, 3 and 5-year old children).*

> *"My middle child, he does this, that no I won't do it, not today no, so I get hold of him and bring him to the washroom but the younger one, as soon as I start to say come and brush your teeth, she runs towards the washroom before him and says, "I will brush, I will do it". She watches the older one so maybe that is why she is motivated. She has that in her mind that the older one does it and does it with a lot of interest" (Category C1- mother of 10, 6 and 3-year-old children).*

From their accounts, it can be deduced that mothers who find it difficult to manage their child(ren)'s behaviour, need further support to increase their capability to deal with the challenge of getting the children to brush their teeth.

Theme 2: Opportunity

Environmental context and resources

The previous focus group based exploratory study revealed that children's toothbrushing in the morning time was the common practice due to social reasons rather than the health benefits. There is a general lack of focus on oral health and more so about care of children's primary teeth and routinised toothbrushing in children.

Some mothers were of the opinion that lack of engagement from health and oral health professionals for oral health promotion was the reason for it being on a very low priority for most of the people. These views resonate with that of the LHWs who also pointed out the need for oral health professionals to play their part in promoting oral health.

> *"And even the doctors never said anything about toothbrushing, buy certain [tooth]paste it is good, nothing of the sort that this [tooth]paste is good or to get the children brushing two times or three times, they did not tell us anything. Doctors here, they have to call us again and again that is why [laughing]." (Category C2- mother of 6, 3 and 1-year-old children).*

Nevertheless, the intervention materials such as the toothbrushes and toothpaste provided for the whole family and the information leaflet were generally very well received by the participants and provided encouragement for them to routinise twice daily toothbrushing. The purpose of the leaflet was to provide a handy guide to all the information covered in the behavioural support session and also to act as a reminder for mothers to brush their children’s teeth. Although the decision to keep the leaflet more pictorial rather than textual was based on idea to provide a quick reference for the mothers especially considering those with limited ability to read, it turned out to be extremely productive. The children particularly found them very attractive and demonstrated great interest in following the toothbrushing instructions provided.

"Yes [children] were very happy to see them [toothbrushes and toothpaste] and that is, then use it so…..that card that she [LHW] gave us, it has all about the way and all about how to do it. I have explained him to brush like this. He has placed it [leaflet] exactly in the washroom and now does [toothbrushing] by looking at it. Now, as God has willed, he has come to know a lot about brushing" (Category C3- mother of 3-month-old and 6-year-old children).

Although the overall response to intervention materials such as the toothbrushes and toothpaste was very positive, however, there was one mother who had a different opinion. She was under the impression that the items have been manufactured outside of Pakistan and especially the toothpaste could contain ingredients that might be unsuitable for them from a religious point of view.

"But the toothbrushes that you sent, they don't seem right to me…..they are very hard……the toothpaste that they have sent for us doesn't seem quite right" (Category B2- mother of 6, 10 and 13-year-old children).

Upon enquiring what her concerns were regarding the toothpaste, she responded saying *"Don't know those companies what type of, you know we live in Pakistan, we have this big [concern] that they might give us such a thing no?"* (Category B2- *mother of 6, 10 and 13-year-old children).*

The participant was reassured that both the toothbrushes and toothpaste were supplied by a local based toothpaste company and could be used without having concerns of it containing any ingredients that would be unacceptable for them to use. This is an important finding to consider especially in terms of scaling up the intervention for future research, in order to avoid lack of engagement with the intervention materials by the participants.

Social influences

Many mothers commented on how well the behavioural support session was delivered by the LHWs. The rapport and special bond that the LHWs share with the mothers in their community greatly emphasised the suitability of this approach to promote children's oral health.

“This that you have done it through lady workers, I really liked this idea. These our health workers they are even there in villages, present in every corner…..so if its done through them then you will get access everywhere [for oral health promotion]” (Category B1- mother of 12, 8 and 4- year-old children).

“We don’t really face any problem because we have our sister [referring to the LHW attached to the family] who helps us.” (Category C2- mother of 8 and 4-year-old children).

However, an important point raised was again linked to lack of support from medical and oral health professionals. In Pakistan, doctors are highly respected and their word is given great importance. Having the initial level of support from them can provide the much-needed encouragement from the very beginning of a child's life and set the ground for development of healthy oral health behaviours with help of further support from the community.

"Our doctors, those who are in Pakistan, they have never ever told us. If I speak of my niece, for her they have said about hundred and fifty thousand rupees, that a hundred and fifty thousand rupees for getting her teeth cleaned and all. If from the start these doctors, like often our children are born in the hospital, if they tell us from the beginning itself, like they say about hygiene, do this, do that- like they tell us about pampers [diapers], breastfeeding, like this if they tell us about the teeth, then I think mothers would start right from the beginning." (Category A - mother of 9, 5 and 4-year-old children).

It was quite evident from accounts of some mothers that the intervention was already having a wider benefit. They mentioned how they were spreading the word to other nearby families to follow the guidelines for their children’s toothbrushing. This again highlights the acceptability of the intervention to the mothers.

“I have also told everyone in my household and also in my neighbourhood. It was their wish, they were saying it’s a good thing your kids are on it so we will also guide our children likewise…..we live in a joint family system and approximately we have 8 small little kids and all of them have now agreed to brush twice and to take care of their teeth” (Category C2- mother of 6, 3 and 1-year-old).

Theme 3: Motivation

Beliefs about capabilities

Many mothers confessed that the behavioural support session increased their capability to take care of their children's teeth by making them more aware of this aspect of their physical health. One mother was very emphatic about how much she was always concerned about her children's general hygiene and made significant effort to make sure her children were always neat and tidy and yet she only become aware, after delivery of the behavioural support session, that her care for her children's hygiene did not include regular toothbrushing. She stated that she now makes sure that toothbrushing is a part of their general hygiene.

> *"I always make sure my children are neat and clean. I really focus on these things for my children. I always try so that they are not unclean or have any problems. I have now found out [about regular toothbrushing in children] and make more effort now" (Category C1- mother of 6, 4 and 2-year-old children).*

Beliefs about consequences

Some mothers with children having dental problems were very vocal about how after following the toothbrushing recommendations, there has been a highly significant reduction in their children's dental complaints.

> *"So when we started brushing, and this paste, God has willed, is very good. Because of this my daughter's toothache has stopped and they do it with interest…..they are now in the habit of brushing at night and also in the morning. Because of this their complaints of pain in their teeth have reduced…..older daughter's mouth used to smell too, but not anymore" (Category C2- mother of 6 and 3 year-old-children).*

The reason for this significant improvement in their dental health condition could be attributed to scientific and/or psychological factors. The scientific explanation could be that regular toothbrushing removed debris from the tooth surfaces thus relieving the pressure exerted on the nerves leading to alleviation of the symptoms. On the other hand, knowledge of having followed toothbrushing guidelines properly could have brought on a level of satisfaction which could be related to the psychological reasons for experiencing improvement of dental problems.

Intentions, Goals, and Emotion

Mothers also mentioned that after receiving the behavioural support session, they have become more determined to take care of their children's teeth. It was quite evident, from these interviews as well, that those mothers who brushed their children's teeth, had mostly done it during the morning times. Moreover, they also discussed about how their older children have been motivated to follow the dental care guidelines and also prompt their younger siblings to follow suit, leading to a sense of satisfaction for the mothers.

> *"Actually you can say before this we did not at all know that cleaning children's teeth is so important, as they used to do it at one time only as they were going to school, during school time at breakfast time always after breakfast I used to clean their teeth but now that I know about two times, I have now in my life considered it very important that their teeth should be cleaned…… my older daughter she says, meaning after brushing teeth, she even stops her brothers from eating anything or drinking anything after brushing teeth. Even if they want to eat something, the older one refuses to let them saying that you have already brushed…..believe me I feel so happy that now even they understand how important it is to clean teeth " (Category A - mother of 9, 5 and 4 year-old-children).*

Having past negative experiences related to their own dental problems was another reason why mothers felt satisfied now that they were able to take care of their children's teeth without having to worry about their children's dental health suffering the same fate as their own.

> *"We don't clean children's teeth for which reason children's teeth get decayed….so now thank God I am very satisfied. Often I used to check his teeth because of my own teeth" (Category A - mother of 7, 5 and 2-year-old children).*

Reinforcement

The provision of toothbrushes and toothpaste was hailed by most of the mothers as a fruitful, motivating tactic especially for the older children. In order to establish a proper toothbrushing routine and to make the whole toothbrushing experience a pleasant one, it is important to motivate, especially older the children too to engage

in the process. Hence, this aspect of the intervention can be considered an important one.

> *"Nowadays children anyway get more attracted to the brushes with cartoons on them or children's toothbrushes, so meaning as compared to simple brushes, they like the others better. So what happens sometimes is if they are attracted to a brush and they like it, so for the sake of getting that brush, they start cleaning their teeth" (Category B1- mother of 12, 8 and 4-year-old children).*

Participants' future recommendations

Although the intervention overall seemed to have a positive effect in changing children's toothbrushing behaviours and seemed to increase parental engagement with their children's oral hygiene practices, there were some who seemed to require further support in this regard, especially those with older children.

As those participants with no positive change related to their children's toothbrushing behaviours were identified through the results of the text message-based survey, it was necessary to explore their barriers in order to provide an indication of how further support can be provided especially to those who might still find it difficult to routinise twice daily supervised toothbrushing for their children.

There was a recommendation to have an element of the intervention implemented in which older children could be directly addressed such as in schools or through informative sessions with them. This recommendation was picked up and further explored in subsequent interviews with mothers- whether provision of oral health promotion activities for older children, be it in schools or community settings with a focus on primary and secondary school aged children in order to motivate them, would help provide further support? Mothers agreed to this being a viable option.

> *"It is a very big challenge for us mothers to teach everything to our children. We cannot teach them everything like that because children they idolise their teacher, there is an environment, children catch everything that they say." (Category C1-mother of 10, 6 and 3-year-old children).*

“It should also be in schools and it should also be with meaning like with lady health workers, because they provide very good guidance and we have good relations with them and children also agree to listen to them and we people too. They guide very well.” (Category C2- mother of 6 and 3-year-old children).

This also linked with what was reported by one LHW who involved the older, school going children too (who were at home because of their school being off that day) during the delivery of the intervention session and reported that children were eager to listen and expressed great interest.

Furthermore, as previously presented findings, some mothers also highlighted the lack of support provided by both the dental and non-dental health professionals. This is very similar to what was pointed by the LHWs too. This lack of support from the health professionals was acutely felt by one mother who voiced her resentment saying that the reason they are never provided with any oral health preventive advice by dental professionals is because they want their patients to keep coming to them for treatment again and again.

The findings reported above, can be linked to two of the TDF domains- the environmental context and resources domain and the domain of social influences. It is quite evident that an environment that is conducive to good oral health including involvement from dental professionals, schools and community sessions can provide further support to promote oral health in the community. These findings indicate wider implications of the research.

There were no recommendations or suggestions forthcoming regarding any change in format or the content of the behavioural support session by both the mothers and the LHWs.

6.6 Discussion

This feasibility study had been designed to test the PROSPECT behavioural intervention developed to support parents in initiation and routinisation of children's supervised toothbrushing, by evaluating feasibility of its implemetation including training, acceptability and fidelity; and feasibility of its evaluation design such as recruitment startegy and data collection procedures. The results of this study are intended to allow for the refinement of the intervention and information about recruitment and data collection procedures that will help inform the design of a future trial to assess the impact of intervention in reducing caries prevalence in children in Pakistan.

6.6.1 Key findings

The intervention was on the whole very well received by both the LHWs and the mothers. Except for one mother, all the other mothers and the LHWs found the intervention materials both appropriate and acceptable. Many mothers agreed that although they were aware of the ‘twice daily brushing’ recommendation, they had not paid much heed to it or mostly had their children brush during mornings. With the delivery of the behavioural support session, they had realised the importance of twice daily toothbrushing and were now making a concious effort to routinise it.

The wariness regarding the toothbrushes and toothpaste exhibited by one mother was due to her conjecture about these being manufactured outside of Pakistan and so could quite possibly contain ingredients which are not acceptable from a religious point of view. This is a pertinant finding that makes it necessay to highlight from the beginning that the intervention items provided have all been sourced locally.

The leaflet provided to mothers was intended as a guide to children’s toothbrushing alongwith acting as a prompt or a reminder and was to be placed at a place where it was clearly visible to everyone at home. Many mothers commented on how their older children had taken quite an interest in it and prompted the mothers and their younger siblings to follow the instructions. However, a noticeable finding was those mothers who appeared to be less motivated to engage in their children’s toothbrushing also revealed about their underutilisation of the intervention materials provided to them to facilitate with their children’s toothbrushing routine. For example: one mother said she had put away the leaflet instead of placing it somewhere where it was clearly visible because she did not want her children to fiddle with it. Another mother reported that

she did not get a chance to use the leaflet because she had been away from her home and was visiting her mother for an extended stay.

From the analysis of the post-interventon interviews based on the TDF and the COM-B model, it was quite evident that intervention helped most of the mothers to overcome the barriers that they faced by inceasing their capability (TDF domains of knowledge; skills; memory attention and decision processes; behavioural regulation), motivation (TDF domains of beliefs about capabilities and beliefs about consequences; intentions, goals, emotion and the domain of reinforcement) and providing opportunity (TDF domains of social influences; environmental context and resources) for engaging in their children's supervised twice daily toothbrushing. The findings presented indicate how the TDF domains of knowledge; skills; memory attention and decision processes; behavioural regulation; social influences; environmental context and resources; beliefs about capabilities and beliefs about consequences; intentions, goals, emotion and the domain of reinforcement were covered by the intervention to help mothers overcome the barriers linked to these domains which were earlier identified through focus groups (chapter 4).

With regards to the capability domain, after analysing mothers' accounts according to their category based on change in behaviour (Table 6.3), it was evident that those mothers who spoke about increase in their knowledge and skills after the delivery of the intervention, had either changed their behaviour to reach the recommended level for children's toothbrushing, or had their behaviour changed to some extent (improvement in frequency of toothbrushing). However, there were others who reported an increase in their knowledge and skills but this was yet to translate into practice in terms of reaching the recommended level for their children's toothbrushing, as there was no change in their children's toothbrushing behaviour (they were already at the recommended level for either supervision or frequency).

Similarly, although there was an improvement seen for the TDF domains of the behaviour regulation and memory, attention and decision processes (capability domain of COM-B) with mothers reporting feeling more capable to manage children's toothbrushing and child behaviour around it, however, some mothers still struggled with difficult child behaviour, requiring further support.

For the opportunity domain related to environmental context and resources, and social influences, lack of guidance from oral and other health professionals was highlighted. It was apparent that LHWs providing the behavioural support to mothers

helped in changing their behaviour for their children's toothbrushing either to reach the recommended level (improvement in both frequency and supervision) or to improve it to some extent (such as improvement in frequency). Furthermore, a mother's account (who was already at the recommended level for frequency of toothbrushing) of how she was spreading the word in her extended family suggests that the intervention provided a validation for her children's toothbrushing behaviour, in the face of lack of availability of correct information from other credible sources such as the oral health and other health professionals.

The COM-B domain of motivation with beliefs about capabilities and beliefs about consequences, showed that mothers felt that their capability to brush their children's teeth has further increased and they were now more aware and well informed of the consequences of brushing/not brushing their children's teeth and so make a conscious effort to not miss it. The survey response based categorical analysis showed that these mothers were already at the recommended level for frequency of children's toothbrushing, and supervision, respectively. Furthermore, mothers who spoke about setting their intentions and goals after receiving the intervention, to incorporate in their daily routine children's twice daily supervised toothbrushing, were the ones that showed most improvement by reaching the recommended level for children's toothbrushing. Mother's account of children's interest in brushing with toothbrushes that were provided to them suggests reinforcement of the behaviour and was evident by improvement in their toothbrushing frequency to reach the recommended level.

However, as can be reasonably expected form any intervention, there were some mothers/families who needed further support to enhance their ability to engage in healthy behaviours. The domains of environmental context and resources, and social influnences were identified as key domains that can be further worked on, and along with their linked behavour change techniques, the existing intervention can be supplemented thus providing further *'opportunity'* (COM-B model) to support families to establish healthy oral hygiene behaviours for their children.

The findings also indicate that it was not just the case of lack of knowledge which needed to be addressed but a host of other contextual factors such low priorty given to oral health in general and to primary teeth in particular, difficulty with time and child behaviour management, and low sense of motivation springing from a low sense of capability. It was also apparent from the findings that the LHWs are a vital support system for the families in their community and an indispendable link between the

health services and the communities that can be used effecively for promotion of health and healthy behaviours in the community.

Comparison with existing literature

Need for oral health promotion

The focus groups (chapter 4) with mothers and LHWs had clearly highlighted a need for provision of support to caregivers of young children to help them establish and maintain healthy oral health behaviours for their children. This is in line with results of a survey based study conducted in 12-15 months old children and their caregivers regarding their feeding and oral hygiene habits in Pakistan. The study reported a large majority of mothers (80.9% out of 435 participants) did not brush their children's teeth at night (Awais, Naheed et al., 2019).

The need for behavioural support was further substantiated by LHWs expressing their concerns during post-intervention interviews, regarding tooth decay to be a household problem (similar to views reported earlier in chapter 4) and such an initiative would not only improve their knowledge but also be beneficial for the whole community (Villalta, Askaryar et al., 2019). The findings are in line with those reported by Oge et al (2018) in a web-based self administered survey study on knowledge, attitudes and practice among health visitors towards children's oral health in the UK. Almost all (99.8%) of the 1,088 health visitors who responded to the survey agreed that oral health advice or promotion should be part of their homevisting routine practice (Oge, Douglas et al., 2018).

The regular home visiting pattern of LHWs places them in an ideal position to facilitate habit development in parents for oral hygiene behaviours of their young children. Thus, helping to protect against low maternal self-efficacy, anxiety and difficult child behaviour which have been linked to poor oral health and hygiene in children (Pine, Adair et al., 2004, Trubey, Moore et al., 2015). Furthermore, the LHWs rapport building and counselling skills would be particularly useful to make mothers feel comfortable whilst discussing their child's oral health, as even though this study did not intend to touch on any sensitive topics, there is a possibility that some mothers might find discussing their child's toothbrushing habits or lack of it, uncomfortable or embarrassing.

In a qualitative study to explore behavioural determinants of brushing young children's teeth in the US, Huebner and Riedy (2010) reported that parents who brushed their

children's teeth twice daily were more likely to overcome barriers through utilisation of personal reminders or specific skills such as making toothbrushing a fun activity. On the other hand, those parents who reported less than twice daily toothbrushing of their children were found to describe external constraints, less social support and offered fewer ideas to overcome barriers (Huebner and Riedy, 2010). This is similar to findings reported in the current study as mothers who seemed to require further support to engage in their children's toothbrushing were found to have not taken advantage of the leaflet that was provided as a reminder and a guide to children's toothbrushing. Thus, indicating a low motivation level to overcome the barriers.

The lack of support or dental advice by both dental and other health professionals was another significant finding that emerged from the interviews. This again highlights the lack of importance given to oral health thus propagating development of dental diseases which are easily preventable. This finding is in line with that reported by Awais et al (2019) in their cross-sectional study of 435 mother-child pairs in Pakistan, in which only one mother reported to have received information from a paedatrician regarding oral health care for her child (Awais, Naheed et al., 2019). In a qualitative study exploring organisational barriers to oral health conversations between health visitors and parents of very young children in a depived area of UK, the authors reported a lack of in-depth oral health training for health visitors and limited availability of resources to supplement conversations in this regard (Eskyte, Gray-Burrows et al., 2021).

Similar findings were also reported regarding general practitioners having limited oral health related knowledge by a questionnaire based study conducted in Wales, UK, to explore perceptions of dental and general practitioners and lay health workers with regards to key oral health messages. This may be the reason why general practitioners may hesitate to initiate oral health conversations with parents (Richards, Filipponi et al., 2014) or may even end up providing conflicting advice (Eskyte, Gray-Burrows et al., 2021).

6.6.2 Methodological considerations

Reflections on methodology

1. Feasibility of the intervention

LHW training

The outbreak of Coronavirus pandemic had the world moving to work remotely and so is the case with this study too. There had to be changes put in place to ensure research activity moved forward in these unprecedented times. The LHW training session which was to be delivered in person had to be carried out remotely using short video segments. This was done to avoid sending bulky files which would have failed to be delivered to participants especially if they had limited storage on their phones. Short video segments also precluded the need for prolonged viewing time which could have caused participants to lose interest and/or developing a sense of being over-burdened with screen time.

Although this method of training delivery has limited opportunity for on the spot discussion, it has other advantages such as being less resource-intensive and more cost-effective by eliminating the need to travel and setting up a location, and an opportunity for immediate, repeat access to the information.

Furthermore, although web applications such as WhatsApp messenger provide a secure platform allowing exchange of encrypted messages to communicate with research participants, issues with internet connectivity can limit the possibility of carrying out work unhindered. Nevertheless, some of the convenient features of the app and its widespread familiarity and usage in Pakistan provided a unique opportunity to conduct research remotely.

Intervention delivery and its fidelity

Although there were some challenges faced by the LHWs for delivery of the intervention (through repeat visits), it is important to note that these were not intervention specific but were mostly their work related challenges that they usually encounter while working in the field. Furthermore, there was an expectation of LHWs being confronted by false beliefs regarding children's toothbrushing which have a very common presence in the existent society. For this reason, a section in their training and handbook was especially dedicated on how to tackle these situations by provision of evidence based findings whilst keeping it contextually relevant.

The intervention delivery checklist provided to LHWs to be filled during the delivery of the behavioural support session served the dual purpose of providing a measure of intervention fidelity and also acted as a prompt to guide LHWs in delivery of different elements of the support session. The use of a fidelity checklist was considered the most feasible option to assess the intervention fidelity given the circurmstances (of my fieldwork being carried out remotely), because of the three main reasons: firstly, use of a checklist as compared to audio recordings precluded potential for technical and logistical problems related to equipment failure, need to provide training in equipment handling, secure data storage and transfer. Secondly, given that the intervention delivery was carried out during the time of Coronavirus pandemic, direct observation through inclusion of a another person during the support session would have posed unnecessary health and safety risk for all parties concerned. Thirdly, the LHWs are familiar with the use of checklists as part of their routine work in which they are required to fill work related checklists and maintain upto date work logs. Hence, they did not require any special training except for some basic information that was incorporated as part of the training videos and in the form of written instructions provided for their reference.

There was an expectation of mention of increased wokload by the LHWs in relation to adding oral health promotion in their routine work activities, however, suprisingly this was not the case. The LHWs embraced this opportunity to promote oral health and committed to continue doing this even after the completion of the study. This is in line with the findings reported by Khan et al (2019) about intrinsic motivational factors for LHWs to be of much higher relevance than the financial incentives when it comes to promoting health in their communities (Khan, Mehboob et al., 2019).

Acceptability and perceived impact/sustainability

The use of TDF and COM-B model to guide the qualitative data analysis provided a robust method to structure the data analysis and also helped to link the findings of the intervention testing with the focus group study used to identify parental barriers and facilitators for engaging in their children's supervised toothbrushing. This allowed for comparision of the findings and also to identify what worked well and things that need changing for further refinement of the intervention.

2. Feasibility of the evaluation design

Participant recruitment

Participant recruitment during this feasibility study highlighted both opportunities and challenges that can be expected, and thus planned for accordingly in a future study. The recruitment of LHWs can be facilitated through involvement of their supervisors who act as 'gatekeepers' in this case. Furthermore, the recruited LHWs then act as 'gatekeepers' providing access to large number of potential participants and their families. It is important to mention here that although the recruitment process for LHWs and majority of mothers went smoothly, there was one LHW who mentioned that she had to approach 10 potential participants before she was able to recruit four participants. The cultural reasons such as having reservations about having their contact number passed to someone unknown to them (the researcher in this case), lack of access to a personal mobile phone or no permission to get involved in any externally conducted activities are some of the important challenges that could surface and need to be considered for the conduct of a future study. Nevertheless, these challenges are all mostly linked to use of mobile technology for communication with potential research participants for the purpose of research. There is less expectation of such a hindrance, if circumstances permitting, a conventional face-to-face approach for recruitment of participants and data collection is employed in a future study.

Data collection procedures

Self-reported measures although remain the most practical means of gathering population data (Prince, Cardilli et al., 2020), they can be subject to desirability bias and over or under estimation by the participants. Having an objective measure of health or disease parameters can provide a balance and opportunity to gain deeper understanding of a phenomena. Initially it was decided to incorporate an objective measure of toothbrushing behaviour by assessing children's oral cleanliness through oral examination by a dentist using food dye to indicate plaque deposits. However, safety risks due to Covid times meant this idea had to be discarded. Instead, a text message-based survey was conducted, which has the potential to reduce desirability bias especially around self-reported measures such as toothbrushing behaviours through provision of results directly to the researcher without the need (such as in the case of a paper-based survey) to be collected by the LHWs, thus, also lessening the

paperwork for LHWs and providing results in real time as soon as the participants respond.

Quality and study limitations

Qualitative research has often faced criticism for lacking scientific rigour: interpretation based on researcher's perspective- researcher bias, lack of reproducibility with different researchers reaching different conclusions and lack of generalisability to other settings (Mays and Pope, 1995). In order to enhance quality of the qualitative data generated through the post-intervention interviews, steps were taken such as: using purposive sampling to enable even representation of different views and diversity of perspectives, seeking negative cases and employing constant comparison across cases. Maintaining field notes, a reflexive journal, and going back and forth through interview data allowed opportunity for constant reflection on the findings. Although qualitative research offers indepth exploration of people's lived experience or a phenomena, this does not necessarily preclude generalisability to similar set of cases or settings. For example, when comparing findings of challenges faced by parents/caregivers for engaging in their children's toothbrushing across different parts of the world, there were many commonalities that were apparent.

Although during the design of the testing phase of the intervention, a number of steps had been taken to ensure rigour and quality of the data generated, the study had limitations that warrant acknowledgement.

Validity/credibility

The pre and post-intervention survey was used to gauge any change in mothers' toothbrushing behaviour for their children. Due to time constraints, it was possible to follow up once only, i.e. 15 days post intervention. Even though questions used in the survey were those that had been previously validated and were forward and back translated into Urdu and pilot tested on five mothers, conclusions cannot be based on how the findings related to change in behaviour, would persist over longer duration follow up. For this reason, only descriptive statistics were presented in order to demonstrate whether intervention had any effect at all without drawing any inferences based on the findings.

Validity of self-reported measures is almost invariably threatened by social desirability bias. Use of an objective proxy measure for behaviours can eliminate this to a large extent. Given the current circumstances around social distancing measures due to

the Coronavirus pandemic, it was not possible to assess children's oral cleanliness (as an objective measure of toothbrushing behaviours) as was initially proposed. However, use of text-based surveys was intended to allow participants' responses to directly reach the researcher. Furthermore, it was reiterated to participants that there are no right or wrong answers, and their honest responses would help understand how better to support parents/mothers in improving oral health outcomes for their children.

Credibility in qualitative research refers to the extent to which findings reflect participants' experiences or perspectives (Lincoln and Guba, 1985). Participants' knowledge of researcher's background as a dental professional could have influenced them to respond with 'socially acceptable' responses. Encouragement to participants for being honest and emphasis on there being no right or wrong answers was therefore intended to combat this to some extent. Furthermore, the fact that interviews were conducted over the telephone, could have afforded a sense anonymity to participants thus eliciting more honest answers (Novick, 2008).

Reliability/dependability

It is common practice to have at least two coders for qualitative data analysis and their inter-rater reliability presented as an objective measure of their level of agreement. The current study being a part of PhD research, it was practically not possible to involve a second coder. However, I discussed findings with my PhD supervisors at regular intervals to allow for alternative perspectives, in an attempt for some form of reliability.

Dependability is a concept in qualitative research which is equivalent of reliability in quantitative research. Dependability implies the consistency with which various research processes have been conducted. Following a categorisation matrix based on the TDF and the COM-B model to analyse interviews allowed for consistent and transparent approach to analysis of the data.

Generalisability/transferability

The current study being a feasibility study, no formal power calculations were performed, in fact, number of participants recruited into the study was dictated by what was considered a feasible and practically possible task whilst managing the study remotely.

One of the objectives of this study was to test the feasibility of the data collection methods. The text-based survey, although proved to be a practical (due to conducting research remotely) and feasible option particularly in terms of avoiding social desirability bias, it does have the potential to exclude non-mobile phone users. This needs to be considered in the design of a future trial.

Similar to the concept of generalisability is transferability according to the qualitative criteria, and refers to applicability of findings to other contexts. The objective of qualitative research is not primarily to generalise findings but to further the understanding of a phenomena or people's actions and behaviours. The aim of the post-intervention interviews was to explore the acceptability of the intervention and to capture different sets of viewpoints, for example, based on change in behaviour- full improvement, some change or no change; participants belonging to different age groups such as mothers of younger and older children etc. This ensured themes were well developed and provided a good representation of mothers who are at different point of spectrum for their children's toothbrushing behaviours. In addition, in order to present sufficient context to enable other researchers to decide how transferrable the findings are to other settings, numerous illustrative quotes have been provided.

In addition, findings from this study suggest that a similar approach utilising community health workers to promote early initiation and routinisation of toothbrushing in children can be applicable to other resource constrained settings. These include those settings where there is a shortage of adequate specialist workforce, and/or lack of accessibility to primary preventive services either due to non-availability of a national oral health programme/policy or due to physical (e.g. transport) or cultural barriers (decreased movement of women outside their communities). Furthermore, as described previously, provision of peer support to mothers/families in child rearing during the early years of a child's development has been reported to be beneficial from numerous studies, and this can be said to have universal applicability to other contexts.

Confirmability

Confirmability is similar to concept of objectivity and refers to the extent to which findings are shaped by interviewee's responses and not by researcher's bias (Lincoln and Guba, 1985). After each interview, a summary of the things discussed was shared as a form of respondent validation. In addition, other best practice approaches were also used while conducting interviews and during data analysis. These included

asking open ended questions and prompting them to elaborate as required, going back and forth the recorded interviews and taking notes during and at the end of interviews to allow for reflection and use of better probing questions in subsequent interviews.

6.6.3 Implications

Based on the findings of this feasibility study, following recommendations have been put forth to consider before taking the PROSPECT intervention to next stage of testing.

- With regards to providing further support to those mothers who find it difficult to routinise twice daily toothbrushing for their children, other strategies such as engaging older children may be considered. Depending on the practicality and keeping it within the remit of this research, it may be in the form of oral health promotion sessions in the community, or provision of additional materials as part of the intervention for engaging children such as toothbrushing activity recording calendar, stickers, fun games etc.

  During the interviews with LHWs, they mentioned about delivering health sessions in their community as part of their work duties. Although these sessions are aimed at mothers but if they can also be delivered to include the school going children such as during their holidays, in addition to the home visits by LHWs aimed at the mothers, this can provide the opportunity to target the 'social influences' and 'environmental context & resources' domain of the TDF that were highlighted as needing further consideration in future for refinement of the intervention.
- A notable finding during the interviews with both LHWs and mothers was their incliniation to spread the word related to children's toothbrushing and oral health, to their peers. As part of their routine work, LHWs periodically (once in a month or two) conduct health sessions in their community on various health related topics in which they invite 15-20 mothers to attend at their health house. This can provide an opportunity to build on the 'social influences' by bringing mothers collectively to discuss and share tips and advice regarding their children's twice daily supervised toothbrushing.
- Involvement of staff at the managerial and administrative positions to elicit views on perceived sustainability of the intervention can help refine the intervention by removing those elements that may deem to be unsustainable in the long run. Furthermore, co-development of face- to-face training and any

additional intervention materials/elements, through engagement of these stakeholders can ensure that oral health training follows their in-practice format which would be easier to upscale for a multi-centre trial and has the potential to be sustainable.

- As previously mentioned, it was apparent from this study that mothers tended to discuss with their relatives, friends and peers about any new information that they gained. It is important to consider this finding to inform the design of a future trial to avoid ‘contamination’ between intervention and control groups by opting for a cluster randomised trial design

6.7 Conclusion

The results of this early phase feasibility study show that the PROSPECT intervention developed to support mothers for engaging in their children's toothbrushing is feasible and acceptable to both LHWs and mothers/parents of children. The findings indicate that discussions around oral health were welcomed by both the LHWs and the mothers. It was also evident that lack of knowledge was not necessarily always the case when it came to twice daily toothbrushing of children's teeth but a general sense of low motivation and low priority given to children's oral heath which can be enhanced through provision of regular support to the mothers/families.

The results of the current study have also helped in uncovering any challenges that can limit successful delivery of a future trial, and findings shall be used to design a larger pilot study to evaluate the effectiveness of behavioural support to mothers/parents through LHWs in reducing caries prevalence in children in Pakistan.

Section 3: Discussion and conclusion

Chapter 7: General Discussion

7.1 Overview

The research contained in this thesis makes a number of important contributions to new knowledge in this field. This PhD research has made an important contribution to area of public health dentistry in Pakistan. It has developed a scalable intervention that can be delivered by an existing national public health service, namely the Lady Health Workers programme. A systematic review was conducted and results from this (BCTs) were combined with contextual factors (barriers and facilitators), and PPI to produce an intervention that was theory and evidence based and was tested to be feasible and acceptable to both LHWs and mothers of young children. As the research was led by a mother, who is a dental professional from Pakistan, this too ensured that the intervention was clinically accurate and culturally appropriate. Research from this PhD has laid the groundwork for a cluster randomised trial for promoting children's oral health through LHWs in Pakistan. In this chapter key aspects of the PhD research are summarised and discussed along with some of the unique challenges (Coronavirus pandemic) that had to be overcome.

7.2 Summary and integration of key findings

The main output from this thesis was the development of PROSPECT behavioural intervention, delivered by the LHWs to mothers of young children in Pakistan to support them for engaging in their children's toothbrushing practices.

1. Systematic review

The systematic review identified interventions that were effective in achieving the clinical and/or behavioural outcomes such as reducing caries/gingival disease experience, and improving dietary behaviours and dental service utilisation, as specified according to the individual studies. Many interventions used a combination of BCTs and unsurprisingly, two most commonly used BCTs identified were the *'information about health consequences'* and *'instructions on how to perform the behaviour'*. This can be explained by the fact that traditionally there has been a focus on improving knowledge to change behaviour, and that the majority of the studies that were included lacked a theoretical basis for their interventions. Providing information regarding health behaviour is an important component of any behaviour change intervention, because to enable people to change their behaviour, it is vital to equip

them with knowledge for them to understand why behaviour change is needed. However, there is a general consensus that it is rarely enough to translate into behaviour change. (Arlinghaus and Johnston, 2018). Furthermore, having a theoretical basis for interventions allows one to develop an understanding of why interventions succeed or fail, through analysis of how intervention components or the BCTs act to enable behaviour change.

2. Focus group study

For the next step and in order to develop a context specific intervention to promote children's oral health, it was important to identify the barriers and facilitators that mothers face for engaging in their children's toothbrushing. This was done through qualitative exploration using focus group discussions. Most of the findings were similar to what has been reported by the previous similar studies in different settings (Elison, Norgate et al., 2014, Marshman, Ahern et al., 2016, Trubey, Moore et al., 2014). For instance, the barriers and facilitators were found to be spread over multiple levels including the individual level such as knowledge, skills and memory; the parent-child level such as parent-child relation and child's behaviour management; and the context or the external environment such as availability of resources, social norms, social support etc.

Although most of the aspects explored provided results that were similar to previous qualitative studies published, there were some novel findings that emerged from this study that need to be highlighted. While mothers were generally aware of twice daily toothbrushing recommendation for maintenance of good oral hygiene, they lacked awareness about brushing children's primary teeth which linked to the question of when should toothbrushing in children be initiated. These contextual findings are in contrast to those reported by Marshman et al (2016) in their study on qualitative exploration of parents' experience of children's toothbrushing for an ethnically diverse sample of families living in a deprived area of UK. The results of their study indicated that parents had a good overall knowledge of children's toothbrushing behaviours such as age of toothbrushing initiation, frequency of toothbrushing and use of fluoride toothpaste (Marshman, Ahern et al., 2016). Although their study participants belonged from one of the most deprived areas of the UK and the sample was ethnically diverse (also containing a sizeable portion of those from Pakistani ethnicity), the disparity in results is quite evident. This can be attributed to the fact that although families belonged to deprived areas, the majority of them (21/27) had taken their children to visit the dentist. The availability of free dental service including

preventive visits for children could have provided parents with the essential knowledge regarding children' toothbrushing behaviours (Marshman, Ahern et al., 2016) .

One of the most significant barrier regarding children's toothbrushing that has been reported by parents relates to difficult child behaviour (behaviour regulation domain). This includes either child's uncooperative behaviour with regards to reluctance for toothbrushing, and/or exerting independence by wanting to brush their teeth themselves (Aliakbari, Gray-Burrows et al., 2021a). Study by Elison et al (2014) which explored maternally perceived barriers and facilitators for toothbrushing in very young children- infants and pre-schoolers, reported that the most common non-compliant behaviour was related to child attempting to man-handle the toothbrush and brush their own teeth (Elison, Norgate et al., 2014). Child development studies report that children in their second and third year of life start to gain independence and a sense of autonomy which may manifest as overt resistance to parental control (Kuczynski, Kochanska et al., 1987). Interestingly, findings of my focus group study with mothers indicated that difficult child behaviour mostly pertained to children's reluctance for brushing their teeth rather than insisting or wanting to brush themselves. A possible explanation for this could be that because of initiation of toothbrushing in children at an older age (around 4-5 years of age), after a few demonstration sessions by the parent(s), the children are considered old enough to manage their own toothbrushing with parent(s) mainly taking the role of reminding them.

In a survey-based study consisting of 239 parents of 0 to 4-year-old children in Australia, which investigated association of the child, parental and family level factors with children's toothbrushing, the authors reported that parental level factors that contributed most uniquely to the hierarchical regression model of toothbrushing frequency was knowledge and routine. An explanation provided is that those with increased knowledge have better parenting skills and can thus implement a regular toothbrushing routine for their children (Berzinski, Morawska et al., 2020).

Whereas it would be beneficial to equip families with knowledge about importance of children's primary teeth, and providing correct and evidence-based information to improve knowledge and skills is a significant part of any health intervention, there should also, essentially be a focus on how mothers and the families can be supported to translate this knowledge into practice.

A cross-sectional study in Netherlands with 630 families of 5 and 6-year-old children, reported that families performing poorly on family functioning measures based on dimensions of responsiveness, communication, organisation and social network, were more likely to engage in less favourable oral hygiene behaviours (Duijster, Verrips et al., 2014). Homes with chaotic or disorganised ways of performing day-to-day activities may have parents who find it difficult to implement a regular toothbrushing routine for their children. This can be further exacerbated by child's uncooperative behaviour resulting in a vicious loop of events in which parents finding it hard to manage child's behaviour problems may feel compelled to surrender to their demands which can result in inconsistency with toothbrushing behaviours and a lack of set routine. Therefore, in order to support parents for engaging in their children's toothbrushing, contextual factors which link to the TDF domains of social influences and environmental context and resources also need to be considered.

In the systematic review by Aliakbari et al (2021) on barriers and facilitators for home-based children's toothbrushing, social support was identified as both a barrier and a facilitator (Aliakbari, Gray-Burrows et al., 2021b). Lack of support or interference with family's set rules regarding children's oral health behaviours can prove to be a hindrance for parents to adopt and implement positive oral health behaviours. Although not specifically focusing on toothbrushing behaviours, study by Duijster et al (2015) on parental views of barriers and facilitators for establishing oral health promoting behaviours in children, reported that grandparents' indulgent behaviours with regards to their grandchildren's sweet consumption often times disrupted parental control over children's dietary intake (Duijster, de Jong-Lenters et al., 2015). In my focus group study, although the mothers reported that they were primarily responsible for children's toothbrushing and had little or no help from other family members such the fathers or grandparents, the LHWs pointed out that elders in the family were accustomed to more traditional methods for teeth cleaning such as use of *dandasa* (walnut tree bark). This was an important finding and in order to bring all family members onboard regarding children's toothbrushing behaviours, it was decided that LHWs would also include them, as appropriate, to be a part of the toothbrushing advice session delivered to mothers through home visits.

In a study by Trubey and colleagues (2014) exploring reasons for parents brushing or not brushing their children's teeth involving interviews with 15 parents of children 3-6 years of age, they reported that parents' perception of other parents' routines or social comparison was the biggest motivator for them to get their children brushing

(Trubey, Moore et al., 2014). Social reasons for toothbrushing were also apparent in the current focus group study whereby mothers compared their children's toothbrushing habits with that of family and friends around them and also cited social or cosmetic reasons for their toothbrushing routine more than the health benefits.

The importance of social reasons more than the health benefits of toothbrushing in the study setting is also supported by the fact that toothbrushing in children was initiated after all their primary teeth had erupted or they had started going to school. Not wanting their child to feel embarrassed because of the condition of their unclean teeth, most mothers stated that they made sure that children brushed before going to school. The findings suggest that mothers felt complacent about their children's (morning only) toothbrushing routine because they considered primary teeth to be temporary (Riedy, Weinstein et al., 2001) that would eventually fall out and once the permanent teeth erupt, the child would be old enough to understand the importance of and get in the practice of twice daily toothbrushing. Similar findings related to low importance given to primary teeth have also been reported by studies conducted in Pakistan (Khawaja Khail, Ronis et al., 2021), and other neighbouring countries such as India (Chhabra and Chhabra, 2012, Setty and Srinivasan, 2016) and Iran (Hashemi, Manzuri et al., 2019). However, evidence suggests that habits form early in life and caries in primary dentition are the strongest predictors of caries in permanent dentition irrespective of other predictors (Skeie, Raadal et al., 2006, Tagliaferro, Pereira et al., 2006, Zemaitiene, Grigalauskiene et al., 2017). For this reason, it is crucial to convey to the mothers the importance of, and to provide support to them for initiation and routinisation of twice daily toothbrushing early in a child's life.

In a study by Hoeft and colleagues (2009) about Mexican American mothers' initiation and understanding of home oral hygiene for their young children, wider support from health professionals and parenting support groups was reported as an important motivating factor for them to initiate and routinise their children's toothbrushing (Hoeft, Masterson et al., 2009). However, in the focus group study as part of this research, there was a sense of lack of support expressed by the mothers and according to them there was not much priority given to oral health by the health professionals, which in turn trickled down to the individuals in the community and this was one of the reasons cited for general lack of engagement with children's healthy oral health behaviours. This was a vital, and significant context-relevant finding. In many developed nations, children are provided with free dental care and parents are encouraged to utilise dental services for their children as early as their first birthday, so they are able to

receive support and guidance related to their child's oral health. This is not the case in Pakistan. Unlike these settings, there is no national oral health coverage for children or adults and the traditional 'out-of-pocket' mode of payment for dental services prevails. This has resulted in symptomatic dental visiting pattern throughout the country without any inclination for preventative visits. Nevertheless, this is not a justification of why health professionals including non-dental professionals cannot be involved to provide simple oral hygiene guidance to mothers as part to general hygiene advice. One major criticism for this has been that the non-dental health professionals do not consider themselves trained or skilled in providing oral health related guidance.

Mothers' views about lack of wider support regarding caring of children's oral health were validated by the accounts of the LHWs in separate FGDs which explored their barriers and facilitators for promoting children's oral health with special focus on provision of toothbrushing advice and support. The LHWs admitted that they did not have much knowledge about oral health and specifically children's oral health and although they are regularly consulted by mothers for health advice pertaining to their child, however, they never advised or initiated conversations with mothers about children's oral health. Although they were aware of the twice daily toothbrushing recommendation as healthy oral health behaviour, it was apparent that they were not sure about the right time to initiate toothbrushing for children. They all agreed tooth decay was a 'household problem' shared their willingness to incorporate provision of toothbrushing advice and support in their work duties and expressed their interest to be trained for this purpose.

These findings are similar to the ones reported by Filipponi and colleagues (2016) in their qualitative study on views of school nurses and health visitors for children's oral health promotion in Wales (Filipponi, Richards et al., 2018). In their study they explored participants' awareness of risk factors for dental diseases, appropriate oral health behaviours and willingness to perform oral health promotion in their setting. The authors reported findings related to lack of priority given to oral health and need to adopt a 'cohesive' approach to involve health professionals from child's early years for their oral health promotion. On the other hand, in a scoping review of evidence synthesis on barriers to integration of oral health into primary care, Harnagea and colleagues (2017) identified barriers linked to implementation challenges such as increased workload, time constraints, staff turnover and lack of availability of adequate staff (Harnagea, Couturier et al., 2017). These barriers can have

implications for primary professionals and community health workers' willingness to be involved in oral health promotion in their settings.

Khan et al (2019) explored motivation drivers for LHWs to engage more actively in tuberculosis case finding in Pakistan, through semi-structured interviews with 20 LHWs and 12 programme managers. They reported that internal drivers of motivation such as religious rewards (prayers and well wishes) and social recognition took precedence over financial incentives (Khan, Mehboob et al., 2019). The findings of focus group qualitative study as part of this PhD, supports the results reported by Khan et al (2019). Thus, the study adds to the existing literature that looks to answer the question of amenability of LHWs to be involved in health promotion activities in their communities.

3. Intervention development

Once the barriers and facilitators have been established, in the next step it was important to develop an intervention that would, by large, address these barriers whilst enhancing the facilitators. As the focus was to develop a theory and evidence-based intervention, this process was facilitated by use of previously tested and validated intervention development processes such as the Behaviour Change wheel and the method outlined by French et al (2012). The systematic step-by step process on how to develop an intervention, provided a clear roadmap and guidance on all the vital things to consider when developing an intervention. This study adds to the ever-growing literature on development of theory and evidence-based interventions to inform policy and practice, as strongly advocated by research bodies such as the Medical Research Council (Craig, Dieppe et al., 2008, Skivington, Matthews et al., 2021). Furthermore, involvement of stakeholders in the research has gained significant momentum over the past years. This is now considered an essential part of the intervention development process in order to ensure the 'utility, usability and acceptability' of an intervention (Hudson, Moon et al., 2020). For the current research, consultation with stakeholders such as mothers and LHWs to finalise the intervention components (BCTs) and proofreading of the subsequently developed intervention materials satisfies the valid criteria of ensuring the utility, usability and acceptability of the intervention in the study context.

4. Feasibility study

After the intervention was developed and all the materials compiled, it was time to implement it in the study setting to test its feasibility and acceptability. Initial feasibility testing of the developed intervention allowed to uncover those implementational challenges and understand the cultural nuances that could have caused significant setbacks had this step been passed over for a larger study. This step of feasibility testing of the intervention is in concordance with the MRC framework for development and evaluation of complex interventions.

The feasibility study as part of the current research, was well able to establish the acceptability of the intervention by both the mothers and LHWs. I present below some of the key findings that emerged from the feasibility study and also some important findings that can help with refinement of the intervention for future testing using a pilot trial.

The intervention being delivered by the LHWs was intended to provide social support to the families with regards to their children's toothbrushing. This was evident from the accounts of many mothers that they found it very useful to receive toothbrushing advice from the LHWs. As part of the intervention delivery, although the advice was focused on mothers as the primary carer of the child, the LWHs were asked to involve other family members (such as fathers, grandparents) in the discussion during the home visits. Furthermore, the LHWs also encouraged mothers to share the information with their own social circle- family and friends in order to spread the knowledge. The importance of social support for home-based toothbrushing behaviours was also reported in the systematic review by Aliakbari and colleagues in which 29 studies out of total 68 studies identified social support as a facilitator. This was one of the highest domains identified in their analysis, second only to the knowledge domain which was reported as a facilitator in 30 studies (Aliakbari, Gray-Burrows et al., 2021b).

Although the LHWs found the remote video- based training provision (along with written materials) acceptable and useful, they stated that a face-to-face training has its own advantages and would be more preferable. This finding is supported by the results reported by Muke et al (2020) for a randomised pilot trial to evaluate effectiveness of digital training provided to non-specialist health workers in India for delivery of brief psychological treatment for depression. In their study participants were randomised to three groups: digital training group, digital training with remote

(telephone) support group and conventional face-to-face training. The authors reported that competency outcome improved more for the face-to-face, and digital training with remote support group as compared to the only remote training group (Muke, Shrivastava et al., 2019).

Given the advantages of remote training in terms of potential cost-effectiveness, such as related to money and time spent travelling to the venue, and also the necessity in some cases (such as during COVID times), it may be fruitful to incorporate it in other ways. For example, in a study by Atif et al (2019), they used a cascaded training and supervision model to sustain delivery of a peer-led perinatal depression intervention in Pakistan. This incorporated training the trainers (non-specialist university graduates) remotely, who then trained and supervised (with the help of LHS) peer support workers in delivery of the intervention (Atif, Nisar et al., 2019). This model- training the trainers can be especially beneficial in providing training in resource-constrained settings, as it combines the advantages of a face-to-face training with that of remote training without the need for specialised equipment or high level of technological literacy for every participant.

The feasibility study was able to not just achieve the recruitment target, but was able to over-recruit participants into the study. This highlights two main points- the trust that LHWs share within their communities and significance of LHWs and LHS as essential gate-keepers. Choi et al (2016) in their focus group study to explore community health workers' perspectives on recruitment and retention of recent immigrant women into a mammogram and pap test study trial, reported that one of the strategies used by community health workers to recruit participants was building on the trust and respect that they shared with the people in their communities (Choi, Heo et al., 2016). This indicates the importance of community health workers as gatekeepers for their communities. In the current study, even if mothers of young children were approached for recruitment through other means such as seeking permission from schools to approach mothers, or holding conversations with mothers in faith-based settings, that element of approval from someone they knew and trusted, would have been missing.

The information leaflet provided as part of the intervention was intended as a prompt and reminder of key messages delivered during the home visit session. A very positive response especially from the children was received, who found the leaflets very engaging. A systematic review and meta-analysis on use of pictures to convey health messages to patients and consumers, reported that information with pictures

can help improve knowledge and recall especially in individuals with lower health literacy (Schubbe, Scalia et al., 2020). This is a pertinent finding and provision of additional materials with simple activities for children in order to sustain their engagement with the behaviour may be considered in the future study.

Although the intervention was well received overall, the negative case seeking approach for the post-intervention qualitative interviews to include mothers on the spectrum of complete change in children's toothbrushing behaviour to those who clearly required more support, helped uncover those context specific challenges that can hinder uptake of the intervention. Such as the case with one mother participant who shared her mistrust of the toothpaste provided as part of the intervention, thinking that it has been manufactured abroad and may contain certain ingredients that are not suitable from both the religious and the health point of view. This misconception and a sense of mistrust can be linked to what is usually encountered by the polio eradication teams in Pakistan, thus affecting the vaccine uptake and presenting challenges to tackle the burden of the disease (Ali, Ahmad et al., 2019). Therefore, it is important to highlight in the future research, for the benefit of the participants and the intervention implementation, to provide clear messages regarding materials being sourced locally.

7.3 Methodological considerations

7.3.1 COVID related impact: challenges and opportunities

All research is influenced by certain methodological considerations that should be acknowledged to provide readers with a broader view of the real-life challenges faced during the conduct of research. This PhD research was conducted during the unprecedented times of Coronavirus pandemic which necessitated certain changes to initially planned research methodology.

After the systematic review and focus group study had been completed, the initial plan was for me to conduct in-person stakeholder consultation sessions in Pakistan to (i) finalise the intervention components (BCTs), and intervention and training materials (ii) have them proofread for clarity, appropriateness and comprehensibility that matched the level of understanding of the intended recipients. This was to be followed by a feasibility trial- a cluster randomised controlled trial to test the developed intervention with randomisation at the LHS level. This entailed arranging provision of face-to-face training sessions by dental and oral health experts for the LHWs

randomised to the intervention group. Audio-recordings of the intervention delivery sessions were to be undertaken as part of the assessment of fidelity of the intervention delivery process. In addition to the self-reported toothbrushing behaviour survey that was to be administered pre and post intervention, an objective proxy measure of toothbrushing in the form of plaque/oral hygiene index was also to be recorded at the baseline and post-intervention by a trained dentist. This was to be followed with post-intervention interviews with the LHS, LHWs and mothers to explore acceptability of the randomisation process, training, intervention and data collection methods and procedures. If found feasible and acceptable, it was intended that fidelity assessments and post-intervention interviews would provide information regarding how intervention could be refined before a full-scale cluster randomised controlled trial could be planned.

Due to the ensuing lockdown all over the world, it was necessary, in order to move forward, to continue carrying out the research remotely. As during that time, I was working on intervention development, the changes that had to be made were related to the part of stakeholder consultation and the subsequent phase of feasibility testing of the intervention.

Even when it was possible to push forward with the research process, working remotely, through the help of advanced internet and communications technology, there were a number of challenges that warrant acknowledgement. This meant that the PPI in the form of stakeholder consultation during the intervention development process had to be conducted remotely. Due to the widespread use and familiarity of the WhatsApp communication platform, a working stakeholder group was created. Although technical difficulties such as unstable internet connection meant that a live online discussion was not possible, there were other options that were utilised. The documents prepared outlining the purpose of the meeting and activities required to be done, were uploaded to the WhatsApp working group and all the members were contacted individually to gather their input. In the end all the feedback was fed back to the group as a summary with group members asked to comment on the findings in case of any disagreement. The members were contacted again once the intervention materials such as the leaflet, LHW handbook, flipbook and advice guide were drafted to help with proof reading and assessment of understandability of the materials to ensure that they are easily comprehensible by the target population.

The next step was to deliver training to LHWs in provision of behavioural support and advice to mothers regarding children's toothbrushing. This was done via development

of training video clips as provision of in-person or live online training was not a feasible option.

The biggest challenge was to carry out the field work associated with feasibility testing of the intervention remotely. The study design was changed to non-randomised feasibility study instead of a feasibility cRCT to keep it as manageable as possible whilst coordinating remotely. Method of data collection for intervention fidelity assessment was changed from use of audio-recordings to that of a checklist. This change was considered necessary for safety and practical reasons as it precluded the need for provision of training to LHWs in device handling and troubleshooting. It also prevented the risk of infection transmission through sharing of audio recording devices between LHWs and avoided the need to transfer confidential data (ensuring that it was done safely and securely) to me with subsequent erasure of physical recordings from the devices.

The clinical measure of oral cleanliness as part of a proxy toothbrushing objective measure had to be removed due to health and safety concerns at that time. The study protocol was updated to reflect the changes and both the ethics and research committees (University of York Health Sciences Research Governance and Pakistan National Bio Ethics Committee) were updated and their approval obtained on the revised version before commencing the study.

All communication with the LHS, LHWs and mothers, from the stakeholder consultation to feasibility study, including recruitment, administration of text-based survey, to post-intervention interviews, took place either via WhatsApp messenger or telephone calls. Some of the logistical challenges associated were: internet connectivity issues precluding online group meeting, document file format (word or pdf) unsupported by recipient's mobile device during stakeholder consultation meant photos of the documents had to be sent, formatting and optimising text-based survey in Urdu for delivery through WhatsApp messenger or SMS. Furthermore, as responses to text-based surveys were received in real-time and to ensure participants had full opportunity to complete the short survey in one go if they wished to, it was necessary for me to remain active once responses to the survey were initiated. In order to accommodate for the time difference, this sometimes meant starting work as early as 2 am in the UK (7 am in Pakistan) as quite often participants responded first thing early morning in Pakistan.

In addition, for health and safety concerns of all the participants and keeping in line with local standard operating procedures as stated and implemented in Pakistan, it was necessary, given the uncertain times, to act swiftly but cautiously to ensure that the intervention was delivered as soon as it was safe to do so. This was after the intervention materials were compiled and received by LHWs and they had resumed their work duties and home visits.

My family were instrumental in facilitating the research process on ground, such as getting the intervention materials (leaflet) and other documents (flipbook, handbook, advice guide, fidelity checklists etc) printed and their subsequent delivery including the toothpaste and toothbrushes to the LHS from where they were collected by the LHWs.

Every challenge also brings with it its own set of opportunities which can off-set some of the obstacles encountered, hence it is equally important to acknowledge them. Due to the travel bans although it was not possible to conduct in-person training and fieldwork, it did open up an opportunity to provide training cost-effectively, without having to arrange for the training workshop, provision of refreshments, travel reimbursements and printing and associated costs. The necessity to work remotely also afforded another opportunity in terms of testing different data collection methods using text-based surveys and phone-based interviews. Although both methods have been previously used in numerous studies and carry their own set of pros and cons, they did provide a convenient way to not only effectively collect data, but do so without generating any health and safety concerns in the midst of a global pandemic.

7.3.2 Strengths and limitations

In terms of the whole programme, there are number of strengths and limitations to be considered for in respect to the validity of the findings. In terms of originality, this research, in the study setting, has been one of its kind attempting to provide evidence to address the research gaps for tackling high caries prevalence in children in Pakistan. In terms of rigour, firstly, an important strength was using a systematic approach to develop a behavioural intervention that was both theory and evidence based. Secondly, the use of a comprehensive and previously validated framework, such as the TDF, provided a firm structure to this research by identifying the theoretical underpinnings. Thirdly, the intervention development process included a very essential component of PPI relating to stakeholder consultation in order to finalise the intervention components to ensure their usability and acceptability in the

study context. Related to the importance of work, the results of this PhD research will provide the basis for a future randomised trial, the results of which if found positive, can provide evidence to advocate for policy change with regards to children's oral health promotion through the LHWs.

The overall limitations of this research project in terms of internal validity are risk of self-report bias with regards to children's toothbrushing behaviours. An objective measure of toothbrushing behaviours had to be removed due to the current situation around the Coronavirus pandemic, which otherwise could have provided a validation of the findings. In terms of external validity, reliance on mobile phone technology although an advantage to allow remote working at the time, it may have excluded non-mobile phone users.

In the following sub-sections, I present the strengths and limitations of each study conducted as part of this PhD.

Systematic review

The systematic review involving identification of effective interventions and their individual intervention components (BCTs), enabled this research to draw upon the evidence of what has been previously shown to be effective. However, it might be said that the BCTs that were shown to be previously effective could have been influenced by a number of individual study related factors such as the study design, confounders, risk of bias etc. This may very well be likely and for this reason those BCTs that were part of at least two effective interventions were labelled as 'promising' and shortlisted to be considered for intervention development, following the approach used by Brown et al (2019) in their systematic review on BCTs in smoking cessation interventions and by Campbell et al (2018) in their study for improving behavioural support for smoking cessation in pregnancy (Brown, Hardeman et al., 2019, Campbell, Fergie et al., 2018).

Furthermore, selection of BCTs to inform development of the behavioural intervention was not limited to those identified as effective in previous effective interventions. They were also considered based on how the BCTs identified as part of effective interventions, addressed the barriers and facilitators identified from the focus group study with the mothers and finalised using the stakeholder consultation.

Focus group study

The qualitative exploration of mothers' barriers and facilitators for engaging in their children's toothbrushing provided valuable data to answer questions about "why is" and not just "what is", in order to identify context specific aspects which were lacking from previously published studies in a similar low-and-middle income country (LMIC) setting. With conflicting reports of health professionals and health workers' willingness to incorporate oral health promotion as part of their work duties, it was necessary to explore the views of LHWs regarding the provision of toothbrushing advice and support to mothers in their communities, in order to assess their amenability. However, a limitation of the focus group study is the number of focus groups conducted- two each with mothers and LHWs. As the purpose of the FGDs was to broadly identify the barriers and facilitators using a priori framework as opposed to generation of theory using the grounded theory approach, this was deemed to be sufficient for the study context, as an initial exploratory study.

Intervention development

As the field of behaviour science is an ever evolving one, at the time of this PhD research, the latest version of the specially developed tool, the theory and techniques tool to map BCTs to the TDF and consequently the barriers and facilitators was used. Furthermore, involvement of stakeholders added another layer of effort to make the intervention contextually relevant.

The use of communications technology indeed helped with progress of the research even during the lockdown days due to the Coronavirus pandemic, however, the methods used are not without their limitations. It was not possible to convene an online group meeting due to technical difficulties and this precluded the opportunity for brainstorming and holding a more face-to-face dynamic discussion. Nevertheless, in terms of practicality, the group members were encouraged to share their thoughts via voice or text message into the WhatsApp group to generate an online discussion. The group members shared their thoughts in the group through a mix of both voice and text messages. A summary of the discussion was fed to the group in the end to confirm the results with the members.

Feasibility study

Development of training videos and materials and conducting the feasibility study along with exploration of its acceptability whilst working remotely is one of the strengths of the study.

The utility of 'gatekeepers' to recruit participants cannot be understated in relation to this research. Without the help of LHS and LHWs as gatekeepers, recruitment of participants (mothers) could have been a slow and tedious process especially coupled with lack of face-to-face interaction.

The data collection methods based on text-based survey and telephone interviews were again a practical and a feasible choice in the current circumstances but they have their own set of limitations such as risk of self-report bias and social desirability bias. As all self-report measures are at risk of self-report bias, a clinical measure of oral cleanliness was also initially included as part of data collection, in order to bring in an objective measure of children's toothbrushing behaviours. This assessment would have also allowed an opportunity to test its feasibility for inclusion as part of outcome measures for the future trial. However, unfavourable circumstances due to the Coronavirus pandemic meant this step had to be eliminated due to health and safety concerns.

Nevertheless, the fact that the text message survey responses were directly received by me without having to be collected through the LHWs, and use of non-face-to-face telephone interviews might have afforded a sense of anonymity to the participants which might have elicited honest responses.

Another limitation of using text-based survey was possibility of exclusion of people who are non-mobile phone users. This includes those who do not have access to a personal mobile phone and also those who are not communications technology/mobile phone use literate. As this was a feasibility study with a relatively small sample size as compared to a future larger study, recruiting mother participants who were mobile phone users did not pose a significant challenge. Also, my being a female researcher worked in my favour during participant recruitment. However, keeping in view the cultural aspects related to hesitancy around sharing mobile phone numbers of female members of the family with people not known to them, especially with outsiders of male gender, can significantly hinder recruitment of mobile phone user participant base for a larger study. Perhaps giving participants choice around

different data collection methods including but not limited to: text-based survey, paper-based survey or even automated/non-automated voice-based phone surveys, can allow for more efficient data collection with a potential of largely eliminating the risk of self-report bias.

As part of the feasibility study, the main stakeholders- mothers and LHWs were interviewed for their views on intervention's acceptability. Negative case seeking based on toothbrushing behaviour categorisation matrix allowed to identify those mothers/families who required further support based on no or slight change/improvement in toothbrushing behaviours. Also, although, LHWs' views regarding acceptability and perceived sustainability of the intervention were explored, a limitation is not being able to explore views of LHS and project/programme managers regarding intervention's sustainability. With the necessary change in study design from feasibility cluster randomised controlled trial with randomisation at the LHS level to a non-randomised feasibility study, it was decided, at the time of the study, to focus on exploring the views of the main actors in the study with a possibility of involving the LHS and project/programme managers to explore their views in the next stage of intervention testing during a larger study.

Nevertheless, my doctoral research presents both strengths and limitations, some of which relate directly to the unique circumstances (Coronavirus pandemic) at the time. These need to be considered in the design of a future study.

7.3.3 Reflections on learning

Throughout the conduct of this PhD there were opportunities for learning and self-development. My thesis is based on a mixed methods research approach and although I always considered myself to be more of a quantitative research person, I can safely say that I thoroughly enjoyed using the mixed methods approach. Moreover, having myself experienced application of this approach, I can now understand why it is said that mixed methods research has the ability to produce stronger evidence by balancing out limitations of each individual method.

However, as a novice researcher in the field of qualitative research and behaviour change science, it was important to undertake necessary training to be able to gain skills before putting them into practice. Attending the qualitative research module and workshop on conducting focus groups helped gain theoretical knowledge which was applied in conducting the focus groups and interviews with the research participants.

In agreement with the cliched but true statement, 'practice makes a man perfect', I could feel getting more confident as the study progressed.

Furthermore, use of a reflexive journal at the time of qualitative data collection and analysis helped in analysing my thoughts and reflections, and how the interpretation of data has been inevitably shaped, to some extent by my- the researcher's subjectivity.

Although not having a background in psychology or behaviour change science, development of a behavioural intervention did seem a daunting prospect in the start but the availability of training resources (behaviour change taxonomy) and guidance on developing interventions made the whole process a smooth learning experience. Furthermore, I also had the opportunity to consult two behaviour change experts (Lou Atkins and Ian Kellar) at different stages of my research for guidance.

Other skills learned during this PhD included digital skills such as related to graphic designing applied for designing the intervention materials such as the flipbook and the leaflet, and the video making and editing skills which helped with compilation of the training videos.

One of the most important learning experiences was adapting research according to unfavourable circumstances. Living in unprecedented times of Coronavirus pandemic, adapting the research accordingly was inevitable. Focusing on the positives instead of the negatives, as advised by my supervisors, was a very important motivating factor to ensure this research reached its completion within the scope of this PhD.

7.4 Implications and recommendations for research, policy & practice

7.4.1 Research Implications

One of the important aspects for any intervention to work is to ensure that it meets the needs of people, by helping them to overcome the barriers and enhancing the facilitators for the target behaviour. In this research, it was found that mothers, as the child's primary caregiver faced a range of barriers that were identified as being spread over the domains of the TDF.

Over the years there has been a shift in focus from only imparting knowledge to provision of further support in order to enable people to adopt healthy behaviours. As it has now been well established that young children's oral health is influenced at multiple levels including the individual level, parental and contextual level, it is crucial that these factors are considered to develop strategies for providing support to parents for engaging in their children's toothbrushing behaviours.

Previous studies have suggested that parents with better parenting skills have better oral health knowledge and are better able to implement a routine for their children's toothbrushing. Furthermore, child related factors such as difficult child behaviour was reported as a significant contributor to parents' perception of difficulty with their child's toothbrushing (Berzinski, Morawska et al., 2020). It was apparent from the focus group study as part of this research, that children missed brushing at night mostly because they were tired or sleepy and did not cooperate well. This can be judged as having a lack of set routine which includes toothbrushing as part of the preparation for children to retire for the night. Parenting strategies including how to set a predictable routine for their children's toothbrushing can provide that necessary support to the parents.

Using a family-based approach that ensures the whole family is involved in children's toothbrushing can have positive outcomes in terms of adoption of healthy oral hygiene behaviours for the children (Duijster, de Jong-Lenters et al., 2015). This can be linked to the technique called 'role-modelling' where parents engage with their children's toothbrushing by brushing themselves at the same time so that the children could follow their example, and has the potential to encourage children by making toothbrushing time a family 'fun' activity.

Interestingly, in the current research, it was found that, in contrast for the night time toothbrushing, the morning brushing followed a routine more or less, when children brushed as part of their daily routine getting ready for school. The importance given to cosmetic reasons or social aspects of having clean teeth was cited by mothers as the reason for following up with morning toothbrushing. Thus, it would be advisable to frame oral health messages in a such a way to draw their engagement based on their priorities such as short-term cosmetic benefits and/or long-term health benefits. This would mean delivering the messages as 'gain-framed messages' (highlighting the positive effects of performing the behaviour) or 'loss-framed messages' (signifying the negative effects of not performing the behaviour) depending on their individual receptiveness to such messages (Trubey, Moore et al., 2015).

In the end, this again is linked to the importance of provision of tailored messages that considers the individual family's circumstances. There cannot be an expectation of a 'one-size-fits all' approach that can be effectively used to support parents for their children's toothbrushing. There has to be a shift from what Watt described as the 'victim-blaming' (Watt, 2007), paternalistic approach to providing parents supportive environment through community wide action that can enable them to make informed choices for their children's oral health.

7.4.2 Research, policy & practice recommendations

Research recommendations

The work presented in this thesis has laid the groundwork for a pilot cluster randomised controlled trial (cRCT). The research has shown that the intervention was well received by mothers and the LHWs. The trial would, almost certainly, need to be of a cluster design to avoid 'contamination' between the intervention and control group families (Eldridge, Kerry et al., 2009, Puffer, Torgerson et al., 2005). Whilst, in theory, randomisation of families would be possible to trained and untrained LHWs, in practice this would not be logistically feasible as LHWs have an established geographical catchment area. Consequently, the unit of allocation would be either at the LHW level or at a higher level of LHS. Randomising at the level of a LHW has the advantage that it is statistically a more efficient design compared with that of a LHS. On the other hand, there is the potential of contamination between the LHWs through (inadvertent) sharing of the intervention related details as they often have their team meetings and allocated training days, whereas, this is less likely if the unit of allocation is the LHS. Furthermore, 'training the trainer' model to provide oral health training to LHWs can be tested if randomisation takes place at the LHS level, as this way LHS randomised to the intervention group would be trained first and would then subsequently provide the training to the LHWs working under their supervision. Therefore, a pilot element of a cRCT may be appropriate to identify whether there is significant contamination at the LHW level.

Process evaluation (using a mixed methods approach) embedded in the future study design will allow assessment of the context and mechanisms that determine the effectiveness of the intervention (Scantlebury, Cockayne et al., 2020). As part of this, exploration of views of those in the supervisory (LHS) and managerial position (project/programme managers) will allow ascertainment of intervention's scalability and future sustainability to inform relevant policy change recommendations.

Inclusion of objective measures such as assessment of plaque index/oral cleanliness, along with self-report measures can provide evidence for intervention effectiveness. A pilot trial can inform the feasibility of undertaking clinical examination as part of the definitive trial. This will be especially important as a full-scale trial would have assessment of caries as its primary outcome measure for intervention effectiveness. In addition, a longer follow-up period as opposed to the feasibility study, will allow us to study the sustainability of the effect of the intervention in a full-scale trial.

Thus, the next steps would be to consider taking the findings from this PhD for post-doctoral research and applying for research funding grants for a pilot/feasibility cluster trial. The expertise of my supervisory team in developing and testing interventions in large scale trials and the well-established York Trials Unit can provide the necessary support to proceed to the next level of research.

Finally, future research with robust study design of a theory and evidence-based intervention that provides tailored support can present important lessons to learn from for children's oral health promotion.

Policy & practice recommendations

The development and feasibility testing of children's toothbrushing support intervention presented in this thesis indicates that such an intervention is both acceptable and appropriate to the needs of the stakeholders- the families and the LHWs. The research has highlighted the issue of oral health care in Pakistan, its salience to the people- families and health workers and an urgent need to push forward the agenda of oral health promotion in the country. Further research in terms of a (cluster) randomised controlled trial with economic evaluation will enable assessment of the effectiveness and cost-effectiveness of the intervention. Should further research demonstrate a meaningful impact, it will provide the basis for advocating policy change to include oral health promotion as an integral part of general health promotion through the well-established Lady Health Worker programme. In the meantime, policy makers in Pakistan should invest in raising awareness about the importance of oral health in children, the need for parents to intervene and support their children in maintaining good oral hygiene at an earlier age, and the role that health professionals can play in reinforcing good oral hygiene behaviours among families.

7.5 Conclusion

The work presented in this thesis has led to the development and feasibility testing of a behavioural intervention for providing support to parents for engaging in their children's toothbrushing (PROSPECT) delivered through LHWs in Pakistan. The results of this initial feasibility study indicate the intervention to be both feasible and acceptable to the mothers and LHWs in Pakistan thus indicating its potential to take it a step further for future testing of the refined intervention in a pilot cluster randomised controlled trial.

Appendices

Appendix 3.1: Systematic review search strategy (Medline)

Set	Search Statement
1	exp child/ or exp child, preschool/ or exp infant/ or exp parents/
2	child*.mp.
3	infan*.mp.
4	toddler.mp.
5	mother*.mp.
6	pregnan*.mp.
7	pregnan*.mp.
8	parent*.mp.
9	dyad.mp.
10	famil*.mp.
11	newborn.mp.
12	early childhood.mp.
13	or/1-12
14	oral health education.ti,ab.
15	oral health education.tw.
16	oral health education.mp.
17	oral health promotion.mp.
18	exp Health Promotion/ or exp Dental Care/ or exp Oral Health/ or exp Health Education, Dental/ or exp Dental Caries/
19	community intervention.mp.
20	community outreach.mp.
21	exp Primary Health Care/
22	Preventive Dentistry/
23	oral health advi?e.mp.
24	(health adj2 (promot* or advi?e or educat* or practic* or improv*)).mp.

25 or/14-24

26 dental decay.mp.

27 exp Dental Caries/

28 caries.mp.

29 exp Dental Plaque/

30 toothbrush*.mp.

31 exp Oral Health/ or exp Periodontal Diseases/ or exp Dental Care/ or exp Dental Plaque/ or exp Gingivitis/ or exp Dental Caries/ or exp Oral Hygiene/ or exp Toothbrushing/

32 (oral health adj knowledge).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

33 (oral health adj knowledge).mp.

34 exp Oral Hygiene/

35 oral care.mp.

36 dental health.mp.

37 oral health.mp.

38 exp Oral Health/

39 (oral health adj2 behavio*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

40 (oral health adj2 behavio*).mp.

41 exp Oral Hygiene/ or exp Dental Plaque/ or exp Toothbrushing/ or exp Gingivitis/ or exp Dental Devices, Home Care/

42 Oral health related quality of life.mp.

43 Oral health related quality of life.ti,ab.

44 OHRQoL.mp.

45 or/26-44

46 health visit*.mp.

47 health visit*.ti,ab.

48 community health worker*.mp.

49 exp Community Health Services/ or exp Community Health Workers/

50 exp Health Personnel/

51 exp Midwifery/ or lady health visitor*.mp.

52 exp Community Health Nursing/ or community health visitor*.mp.

53 health aide.mp.

54 exp NURSE PRACTITIONERS/ or exp NURSE MIDWIVES/

55 exp Midwifery/

56 exp Nurses' Aides/ or exp Allied Health Personnel/

57 exp Nurses' Aides/ or support worker.mp. or exp Allied Health Personnel/

58 home visit.mp.

59 nurse*.mp.

60 Education, Nursing/ or Nursing/ or Public Health Nursing/ or Neonatal Nursing/ or Pediatric Nursing/ or Maternal-Child Nursing/ or Community Health Nursing/ or Primary Care Nursing/ or Obstetric Nursing/ or Nursing Staff/

61 ((nurs* adj2 educat*) or (midwi* adj2 educat*) or nurs*adj2 train or (midwi* adj2 train*) or (nurs* adj2 practic*) or (midwi* adj2 practic*)).mp.

62 home visit*.mp.

63 lay health worker*.mp.

64 or/46-63

65 randomized controlled trial.pt.

66 randomized.ab.

67 randomly.ab.

68 trial.ab.

69 groups.ab.

70 exp Feasibility Studies/

71 feasibility study.ti,ab.

72 pilot study.ti,ab.

73 exp Pilot Projects/

74 or/67-75

75 exp animals/ not humans.sh.

76 74not 75

77 pretest-posttest study.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

78 pretesting.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

79 pre-post tests.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

80 quasi experimental design.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

81 quasi experimental study.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

82 quasi experimental study design.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

83 repeated measurement.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

84 repeated measurements.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

85 repeated measures.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

86 time series.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
87 79or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88
88 78or 89
89 15 and 27 and 47 and 66 and 90

Appendix 3.2: Summary Table of studies included in the systematic review

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
Randomised Controlled Trials							
(Kowash, Pinfield et al., 2000) **RCT (4 arms + 1 control)**	**United Kingdom** To determine the effect of dental health education (DHE) on caries incidence in infants, through regular home visits by trained DH Educators over a period of 3 years.	***Intervention: Baseline (n= 228 dyads)*** Group A: 60 Group B: 59 Group C: 60 Group D: 49 ***Followup*** Group A: 45 Group B: 47 Group C: 51 Group D: 36 ***Control:*** n=55 dyads ***Children*** Intervention group A-D: Mean age (SD): 11.4 (3.4) months at baseline Comparison group E Approached only at 3 year follow up ***Mothers*** Mean age (SD): 29 (5.3) years	2 Dental Health Educators specially trained every year. One was a Dental Therapist and the other a Paediatric Nurse	***Intervention*** Oral health education Diet and Oral hygiene (OH) advice given using structured interview and counselling for 15 mins. The main message was to substitute bottle with feeder cup; brush child's teeth twice a day with fluoride toothpaste and visit a dentist regularly. Each mother, on every visit, was given the opportunity to ask questions and further advice given accordingly ***Intervention group*** Group A: DHE on diet + briefly OH Group B: DHE on OH + briefly on diet Group C: DHE equally on diet and OH Above groups received intervention every 3 months for 1st two years. and then twice a year in the third year Group D: DHE on diet and OH once a year for 3 years. ***Comparison group*** Did not receive anything. Those initially eligible but not selected were traced and if living in the locality were examined at 3 year follow up to act as controls.	***Clinical*** Caries status, periodontal status Measured at 3 yrear follow up ***Behavioural*** Frequency of drinking and sweet consumption Frequency of toothbrushing and dental visits	***Clinical*** There was significant difference reported in mean dmfs for Group A vs. Group E (0.29 (1.64) vs 1.75 (5.09) (p <0.001) Effect size (d): -0.37 (-0.77, 0.03) not significant. Only (3%) in the study groups had gingivitis (all in diet group A) Effect size Group A vs. Group E: OR 0.27 (0.07, 1.05) not significant Poor oral hygiene (debris +calculus) (three in group A and six in group D) Effect size Group A vs Group E: OR 0.08 (0.02, 0.28) Group D vs Group E: OR 0.31 (0.13, 0.77). ***Behavioural*** Significant differences between each intervention group with Group E for all reported behaviours (p <0.001). Effect size (OR): not significant for any behaviours for intervention groups vs control group E except for frequency of toothbrushing (more than once/day) for which OR was highly significant (<0.0001) for each intervention group vs. group E.	Unclear risk
(Davies, Duxbury et al., 2005)	**United Kingdom**	Baseline, n=839 in intervention group	Health Visitor or Practice Nurse	***Intervention group*** Oral health education + OHP Kit 5 stages of intervention:	***Clinical*** Oral examinations at	***Clinical***	Unclear risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
Clustered RCT	To assess the effects of a multi-stage dental health promotion programme in reducing Early Childhood Caries (ECC)	and n= 706 in control group Total 1545 children examined at follow up ***Intervention:*** Out of the total 649 children had attended the clinic at intervention site Mean age 3.97 Males: n=432 (51.5%) Females: n= 405 (48.3%) ***Control:*** Out of the total 558 children attended clinic at control site. Mean age: 4.02 years Males: n= 359 (50.8%) Females: n= 344 (48.7%)		1. At 8 months visit to health centre a gift bag containing trainer cup, leaflet was given and oral health advice by HV. 2. At 12-15 months visit parents were given by HV or practice nurses gift bag containing 1450 ppm fluoride TP and TB. 3. at 18 months children were invited by post to attend local dental clinic and where they were provided Fluoride TP and TB. If not attended within 2 months then it was posted to them 4, 5. Fluoride TP and TB + leaflet posted to them when they were 26 and 32 months old. ***Control group*** Received usual care	3-4 years of age for mean dmft, mean dmfs and proportion of children with caries and nursing caries ***Behavioural*** Questionnaire at 21 months' age to asses: Use of bottle, trainer cups, sugared drinks Age of initiation of toothbrushing and frequency of toothbrushing	Mean dmft of intervention children vs control was significantly lower (1.17 vs 1.72, p= 0.001) Effect size (d): -0.19 (-0.3, -0.08). Mean dmfs of intervention vs control was significantly lower (2.58 vs 3.75, p= 0.008) Effect size (d): -0.15 (-0.27, -0.04). ***Behavioural*** Significant differences reported between intervention and control group for ceased Bottle use, only sugared drinks given in cup when used, toothbrushing started before 1st birthday and brushing twice daily (p= 0.04, 0.02, 0.02 and <0.01 respectively). Effect size (OR) was found to be significant only for use of sugared drinks given in cup when used (OR 0.35 (0.16, 0.77) p= 0.0089.	
(Vachirarojpisan, Shinada et al., 2005) **Clustered RCT**	**Thailand** To evaluate process and outcome of a participatory Dental Health Education programme for preventing ECC	***Intervention***: Baseline n= 11 health centres, 270 children Mean age (SD): 12.09 (3.66) months Males: n= 120 (56.3%) Females: n= 93 (43.7%)	17 staff members at 11 health centres	***Intervention group*** <u>Oral health discussion + TB and TP</u> Group discussions by trained health centre staff with a group of 6-8 parents/caregivers on their children's oral health and causes and prevention of ECC, based on empowerment model of Health Education and distribution of free toothbrushes toothpastes of 500	***Clinical*** Caries increment reported as mean cavitated, mean non-cavitated and combination of both as ECC ***Behavioural***	***Clinical*** No significant differences reported for mean cavitated, non-cavitated and ECC between intervention and control groups (p>0.05). ***Behavioural*** Statistically significant improvement for all oral hygiene behaviours assessed (p<0.001). Effect size (OR) significant as well.	Low risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
		Mother's n= 183, age (SD): 27.64 (6.42) years Follow up n= 213 children ***Control:*** n= 10 health centres, 250 children. Mean age (SD): 12.24 (3.78) months Males: n= 96 (50.3%) Females: n= 95 (49.7%) Mother's n= 166, age (SD): 27.49 (6.39) years Follow up n= 191 children		ppm. Provided at 3 times at 3 months' interval. ***Control group*** <u>Routine DHE programme</u> based on didactic teaching about ECC prevention and distribution of free toothbrushes Coinciding with vaccination programme at age of 9 months and 18 months.	Habit of falling asleep with bottle, night time feeding and sweet food consumption between meals of drinking and sweet consumption Performance of any toothbrushing, parents' brushing their children's teeth, use of fluoride TP and use of proper amount of TP	The dietary behaviours were not found to be significantly different between intervention and control groups (p >0.05). Effect size (OR) non-significant as well.	
(Harrison, Benton et al., 2007) **Randomised Controlled Trial**	**Canada** To test motivational interviewing (MI) to prevent early childhood caries; and to use Poisson regression for data analysis	***Intervention:*** Baseline n=122 dyads Follow up n= 105 dyads ***Control:*** Baseline n= 118 dyads Follow up n= 100 dyads ***Children:*** <u>Intervention:</u> mean age (SD) 10.8 (5.3) months	3 local South Asian women trained as 'MI counsellors'	***Intervention group*** <u>OHE- MI counselling + pamphlet and video</u> One 45-minute counselling session, 2 brief follow-up telephone calls at 2 weeks and 1 month after initial contact. Then four follow-up telephone calls up to 6 months after the initial contact and 2 postcard reminders. A pamphlet on infant oral health designed by the local health unit dental staff but modified to include strategies	***Clinical*** Oral examination done at 2 years follow up reporting mean dmfs and mean dmfs+white spots.	***Clinical*** Statistically significant difference of mean dmfs between intervention and control group (3.35 (7.8) vs 7.59 (14.2) p= 0.001 Effect size (d)= -0.37(-0.65, -0.09) and for dmfs + white spots (3.52 (8) vs. 7.91 (14.2) p= 0.01 Effect size (d)= -0.38 (-0.66, -0.11).	Low risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
		Boys: n= 122 (57%) Control: mean age (SD) 12.1 (5.3) months Boys: n= 118 (52%)		to prevent ECC appropriate to the South Asian community. Mothers also watched an 11-minute educational video, "Preventing Tooth Decay for Infants and Toddlers." Both pamphlet and video, available in English and Punjabi, also recommended that parents take their child to PICS for fluoride varnish applications. ***Control group:*** The pamphlet + video same as in intervention and recommendation to take their children for fluoride varnish application to PICS.			
(Whittle, Whitehead et al., 2008) **Randomised Controlled Trial**	**United Kingdom** To determine the effect of oral health education carried out by a specially trained health visitor on the dental health of young children	***Intervention:*** 250 children 3 year follow up n= 181 5 years follow up n= 147 Mean age: 5.13 years ***Control:*** 251 children 3 year follow up n= 171 5 year follow up n= 129 Mean age: 5.20 years	Health visitors	***Intervention-*** Home visits with dental advice + kit First visit comprised of dental advice and leaflet along with toothbrush and tooth paste being given. In the 2nd visit when child was 20 months old discussions focused on child's diet and toothbrushing, giving of the leaflet and toothpaste and toothbrush. The dental advice reinforced through leaflets was based on reduction of sugars and increased consumption of fruits and vegetables, initiation of toothbrushing and advice on toothbrush and toothpaste. ***Control*** Routine home visits Usual dental advice relating to getting child registered, toothbrushing and avoiding sugary	***Clinical*** dmfs at 3 years and 5 years of age of children	***3 year's age follow up*** No statistically significant results reported for difference in mean ds, ms and fs in intervention vs control groups. ***5 years' age follow up*** A census group was also used for comparison. Statistically significant differences were reported in the study for INT vs. census group for mean ds, ms and mean dmfs (3.35 vs. 4.71, 0.37 vs. 0.87 and 3.99 vs. 5.94 respectively). However, the effect size (d) calculation for INT vs. census at 5 years of age was not statistically significant. ds: -0.17 (-0.33, 00) ms: -0.14 (-0.31, 0.03) dmfs: -0.21 (-0.50, 0.08)	Low risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
				drinks in face to face. No printed material provided			
(Mohebbi, Virtanen et al., 2009) **Cluster RCT**	**Iran** The study evaluated the impact of the 6-month educational intervention aimed at preventing dentinal and enamel caries in 12- to 15-month-olds.	***Health centres:*** n= 18 (6 in each group) ***Group A:*** n= 77 dyads at baseline and n= 55 at follow up ***Group B:*** n= 85 dyads at baseline and n= 59 at follow up ***Control:*** n=80 dyads at baseline and 63 at follow up ***Children*** Mean age 12.3 months with 50% males.	Vaccination Staff (n= 36)	***Intervention groups*** Oral health education Pamphlet in local Persian language written in plain simple language illustrated with baby pictures and use of 'happy colours'. **Group A** received pamphlet with 5 minutes verbal instructions + 2 phone call reminders 2 months apart + instructions to be on time in order to reduce drop outs. **Group B** received only the pamphlet without any other verbal instructions or phone reminders. ***Control group*** After the trial, mothers received the same pamphlet on caries prevention from the vaccination health staff.	***Clinical*** Difference in caries increments at baseline and 6months follow-up by assessment of number of dt and de and percentages of children developing new dt and de. ***Behavioural*** Brief interviews conducted to explore mother's perception of intervention effectiveness for changing behaviours.	***Clinical*** No significant difference in dt for Group A vs. C (0.1 (0.6) vs. 0.2 (0.7), p= 0.188 and Group B vs. C (0.1 (0.1) vs. (0.2 (0.7), p= 0.265) Effect size (d): A vs. C -0.29 (-0.65, 0.08), B vs. C -0.20 (-0.55, 0.16). Significant difference for de between group A 0(0) vs Control (0.4 (0.7), p <0.001 Effect size (d): -0.78 (-1.15, -0.40) Group B was 0.2 (0.6) vs. 0.4 (0.7) in controls, p=*0.06*. Effect size d: -0.31 (-0.66, 0.05) Logistic Regression analysis controlling for background factors: OR for developing new de or dt was 0.1 (95% CI 0.0–0.4) for group A and 0.4 (95% CI 0.2–1.0) for group B.	Low risk
(Feldens, Giugliani et al., 2010) **Randomised controlled trial**	**Brazil** To investigate the effectiveness of home visits advising mothers about healthy feeding practices during the first year of life on the occurrence of early childhood	***Intervention:*** n=200 dyads at baseline and 157 at follow up Mean age (SD): 50.6 (1.7) months Males: n= 85 (60.3%) ***Control:*** n=300 dyads at baseline and 219 at follow up.	12 Field workers	***Intervention group*** Oral health education Verbal dietary, healthy breast-feeding and weaning advice (based on WHO recommendations) was given to mothers within 10 days of child's birth and monthly upto 6 months then 8,10,12 months, in informal manner considering mother's opinions and concerns. Instructions on preparation and recipes of	***Clinical*** Proportion of children with ECC (presence of any decay) Secondary outcomes: Occurrence of severe early childhood caries (S-ECC)	***Clinical*** The proportion of children with ECC (main outcome) was 53.9% (76/ 141) across the intervention group and 69.3% (138/199) among controls Effect size: RR 0.78 (0.65–0.93) for children ECC) S-ECC was present in 41 (29.1%) intervention group children and 85 (42.7%) controls.	Low risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
	caries and severe early childhood caries at 4 years of age.	Mean age (SD): 50.4 (1.7) months Males: n= 110 (55.3%) ***Mothers*** Mean age at child's birth 25.7y		complementary and healthy food were provided. ***Control group*** Received routine assistance by paediatrician and dietary advice related to oral health upon completion of research period.	The number of affected teeth (d1+mft). Assessment carried out within 1month after the 12month home visit. ***Behavioural*** Dietary behaviour (onset, duration and frequency of feeding practices) at 6 and 12months collected during interviews by nutrition students.	RR (0.68 (0.50–0.92) for SECC (reported in study. Mean number of affected teeth (dmft) was found to be significantly different between intervention vs. control group (3.25 vs. 4.15, p= 0.023) Effect size (d): -0.20 (-0.42, 0.01). ***Behavioural*** Significant differences reported between proportion of children in intervention and control groups for 'age of sugar introduction (>6 months or more)' (p= 0.010), 'no. of daily meals or snacks at 1 year (>8)' (p= 0.035) and 'consumption of high density of sugar in foods at 1 yr' (p= 0.002). ES (OR): 2.37 (1.26. 4.44), 0.51 (0.30, 0.85) and 2.4 (1.41, 4.08) respectively. No significant difference was reported for 'night time bottle use at 1 year' p= 0.382) ES (OR): 0.80 (0.51, 1.24).	
(Neumann, Lee et al., 2011) **Cluster RCT**	**Australia** To evaluate the effectiveness of a community-	***Intervention*** n= 482 at baseline and n= 146 at 3 years' followup	Maternal and child health nurses (MCHN)	***Intervention group:*** <u>Oral health promotion</u> An oral health starter kit (OHSK), which included an age-appropriate toothbrush,	***Clinical*** Proportion of children with caries reported through number	***Clinical*** When adjusted for age (children in intervention group were slightly younger than those in the control group), there was no statistically	Unclear risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
	based intervention to improve the oral health of children in non-fluoridated rural Victoria, Australia.	Females (baseline) n= 224 (46%) ***Control*** n= 433 at baseline and 246 at 3 years' follow up. Females (baseline) n=207 (48%).		toothpaste and educational information for parents outlining key evidence-based oral health promotion messages. These kits were distributed to all families with infants/toddlers in the intervention LGAs (regardless of whether they agreed to participate in the study or not). In addition, an oral health promotion training programme was provided for the MCHNs in these LGAs along with posters, pamphlets and a video/DVD where required. ***Control group:*** Usual care	of decayed, extracted or filled surfaces (defs), and the Significant Caries Index (SiC^{10} and SiC^{30}), which is the mean defs in the 10% and 30% of the children with the highest caries experience, all calculated both including and excluding the pre-cavitated surfaces at each of the subsequent annual exams (exam 1, 2 and 3)	significant difference between the intervention vs. control groups for mean defs, SiC^{30} qnd SiC^{10} index.	
(Chaffee, Feldens et al., 2013) **Cluster RCT**	**Brazil** To estimate the caries impact of providing training in infant feeding guidelines to workers at Brazilian public primary care clinics.	***Intervention*** 9 clinics, 360 children enrolled and 237 children in follow up. Mean age (SD) 3.2 (0.2) years Males: n= 119 (50.2%) Mother's mean age at delivery: 27.1 (6.7) years ***Control:*** 11 clinics, 355 children at baseline and 221 children	Healthcare professionals including physician, nurses and administrative staff	***Intervention group*** Oral health education Dietary counselling for pregnant/lactating women aimed to improve oral health outcomes of their children. Pamphlets were also distributed. ***Control group*** Usual practice of maternal counselling at practitioner's discretion.	***Clinical*** dmfs, and Severe ECC (S-ECC) at 2-3 years of age. ***Behavioural*** Dental visiting at 2-3 years of age of child.	***Clinical*** • The Relative Risk (RR) for ECC 0.92 (0.75, 1.12); S-ECC 0.87 (0.64, 1.19) and cavitated decay 0.88 (0.66, 1.17) was not statistically significant. • No statistically significant difference in mean dmfs (any decay) between intervention vs. control groups (2.8 (5.4) vs. 3.6 (6.9), p=0.25). Effect size (d): -0.13 (-0.13, 0.05). • No statistically significant difference in mean dmfs (cavitated decay only) between intervention	Low risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
		in follow up. Mean age (SD) 3.2 (0.2) years Males: n= 114 (51.6%) Mother's mean age at delivery: 25.7 (6.6) years				vs. control groups (2.1 (5.0) vs. 3.0 (6.8), p= 0.18). Effect size (d): -0.15 (-0.33, 0.03). ***Behavioural*** • 26.6% reported previously visiting a dentist, and this was not significantly different between the 2 groups.	
(Mattheus, 2014) **Randomised controlled trial**	**USA** To investigate the effects of oral health promotion provided by primary care providers on parental oral health beliefs and behaviours.	***Intervention***: n= 44 ***Control***: n= 40 Parents of children aged 6-15 months	Paediatric Nurses	Both the groups received standard care including caries risk assessment, oral health examination, fluoride varnish application, anticipatory guidance, attempt to refer to a dental home and a toothbrush provided to the child. ***Intervention group*** In addition, received enhanced oral care including: extensive oral health history and caries risk assessment, medical history, and an oral health examination, Detailed child and family oral health education was discussed Detailed child and family oral health education was discussed with a handout focusing on common ECC risk factors. A tooth brush was provided during the child's first enhanced oral health visits, along with education on how to brush, proper use of fluoride toothpaste and the importance of regular brushing. Additionally, a sippy cup was provided at the second visit to reinforce proper oral health beliefs and behaviors, which included	***Behaviour and Knowledge*** Parental beliefs about oral health and parental oral health behaviours for their children 6 to 15 months of age assessed at 6 months follow up	Only p values for difference in scores provided for both the groups for which reason it was not possible to perform the effect size calculations.	High risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
				information of foods to avoid for the prevention of caries development. At each visit the family was given dental provider information with an attempt to refer them for future assessment and care.			
(Hallas, Fernandez et al., 2015) **Randomised controlled trial**	**USA** To determine the oral health hygiene knowledge of mothers of newborns and the effectiveness of an oral health education program on the oral health of infants at 6 and 12months	***Intervention:*** 47 dyads ***Comparison:*** 47 dyads ***Children*** Infants between 1-5 days old when mother-child enrolled in the study	Not explicitly mentioned but possibly nurses/midwives	***Intervention group*** <u>Oral health education + goody bag</u> Mothers watched 8-minute DVD in postpartum rooms and after that they received the goody bag containing Oral hygiene kit for newborn and oral health brochure ***Control group*** Standardized 8-minute DVD on nutrition for newborns and infants and oral hygiene kit for newborn and oral health brochure.	***Clinical*** Oral health assessment and Caries Risk Assessment Tool (CAT) used to assess overall risk of caries At 6- and 12-months post-partum. ***Behavioural*** Questionnaire at baseline and 6 months follow-up to assess mother's oral health knowledge, beliefs and practices. .	***Due to high level of attrition, assessments could not be carried out fully as planned.*** ***Clinical*** • Results of oral health assessment at 6 and 12 months showed infants (n=10) to be cavity free although they were at high risk of ECC as assessed by Caries Risk Assessment Tool (CAT). ***Behavioural*** • Baseline results indicated mother's lack of oral health knowledge about infants oral health care.	High risk
(Leung, Tsang et al., 2015) **Cluster RCT**	**Hong Kong** To reported the effectiveness The Healthy Start Home Visit Program based on and expanded from HOPE	***Intervention:*** Baseline n= 12 preschools, 84 dyads with 79 dyads at followup. Children's mean age (SD): 3.78 (0.75) years Boys: n=43 (51.2%)	Parent Ambassadors (PA) visiting in pairs	***Intervention group*** <u>Health education – Home visits</u> • Structured lesson plans including Mini lectures, flipcharts Role play to enable participants to master parenting micro skills. Parents required to complete homework activities 5 days a week	***Behavioural*** <u>Oral health</u> questionnaire developed by Department of Health, Hong Kong SAR Government with three questions	***Oral Health- tooth brushing*** Statistically significant difference found between the mean tooth brushing of intervention vs. control groups (10.55 vs 9.29, p= 0.003) Effect size (d): 0.52 (0.18, 1.50). ***Feeding practice***	Low risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
	(Leung et al., 2011) to include physical development issues, in addition to learning and psychosocial areas	Mother's Mean age (SD) 34.52 (6.38) years n= 77 (91.7%) Father's mean age (SD): 39.54 (8.23) years n= 4 (4.8%). ***Control:*** n= 12 preschools, 107 dyads with 95 dyads at follow up. Children's mean age (SD): 3.77 (0.72) years Boys: n= 69 (64.5%) Mother's Mean age (SD) 33.76 (6.94) years n= 98 (91.6%) Father's mean age (SD): 40.62 (8.71) years n= 4 (3.7%).		with their children in order to put parenting skills into practice ***Control group*** Six series of parent talks in group sessions at preschool	on teeth brushing, and parents rate each item on a 5-point scale. A higher score indicates more frequent teeth brushing. <u>Feeding practices</u> Knowledge, attitude and practices assessed using Hong Kong Parent Feeding Questionnaire using 3 point Likert scale. High score indicates desirable feeding practices	Statistically significant difference between mean feeding practices scores for intervention vs. control groups (50.98 vs. 47, p <0.001) Effect size (d): 0.56 (0.26, 0.85).	
(Braun, Quissell et al., 2016) **Cluster RCT**	**USA** To assess the effect of an OHP program on caries, as delivered in Navajo Nation Head Start by trained Navajo community oral health specialists.	***Intervention:*** 20 HS, 528 dyads at baseline with 518 at follow up. Children mean age (SD) 3.7 (0.03) years with 51% females. 77.5% mothers with mean age of 32.7 (SE 0.5) years	8 trained tribal community members called Community Oral Health Specialist (COHS).	***Intervention group*** <u>Oral health promotion (OHP)</u> highly personalized set of oral health–focused interactions (5 for children and 4 for parents), along with 4 fluoride varnish applications delivered each year during academic years of 2011 to 2012 and 2012 to 2013. Caregiver's OHP activities began with a kick-off event for caregivers and children that introduced the project. The remaining three parent	***Clinical (Primary outcome)*** dmfs in primary teeth at baseline+3 years follow up ***Secondary outcomes (clinical + behavioural)***	***Clinical*** dmfs, ds and DMFS: No statistically significant difference for mean dmfs, ds and DMFS between intervention and control groups for all three years of follow up (p>0.05). Effect size (d): dmfs at Year 3: -0.04 (-0.30, 0.22) ds at Year 3: 0.13 (-0.13, 0.39) DMFS at Year 3: 0.0 (-0.26, 0.26)	Low risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
		Control: 19 HS, 502 dyads at baseline with 498 at follow up. Children mean age (SD) 3.7 (0.04) years with 49.1% females. 76.5% mothers with mean age of 31.1 (SE 0.5) years		events, which occurred at various times and locations to maximize attendance, included 1) an overview of the importance of primary teeth, prevention of tooth decay, consequences of tooth decay, and caregivers' roles in prevention; 2) two small-group OHP activities; 3) a simple goal-setting activity; and 4) a fruit basket raffle for enrolled caregivers who attended. <u>Fluoride Varnish (FV)</u> FV and child OHP events were delivered in the Head Start classroom <u>TB & TPs</u> All families received toothbrushes and toothpaste for all family members at enrolment; intervention children and participating caregivers received additional supplies throughout the study period during data collection events. ***Control group*** Received TB and TP for the whole family s at enrolment	Longitudinal assessments of ds and decayed, missing, or filled surfaces (DMFS; permanent dentition) counts, caries prevalence, and validated survey items assessing caregiver oral health knowledge	***Behavioural*** Statistically significant difference between mean scores of intervention vs. control group in first follow up when original caregiver completed the survey (62.7 vs. 58.2, p=0.003) Effect size calculation (d): Year 3: -0.04 (-0.31, 0.22) ***Oral health Knowledge*** No statistically significant difference was reported for intervention vs. control group in mean knowledge scores for all three years. Effect size calculation (d): Year 3: -1.06 (-1.34, -0.78)	
(Batliner, Tiwari et al., 2018) **Randomised Controlled Trial**	**USA** To evaluate the effectiveness of MI to reduce caries occurrence and progression among AI	***Intervention*** n= 301 at baseline with 232 at follow up dental screening Children mean age (SD): 0.62 (0.89) months with 47.9% females	Local people with at least a college degree. The were called 'MI interventionists' and were provided with 2 days of training.	***Intervention group:*** Received 4 MI visits and the mother selected 2 topics from a list of 8 options. For the 2 topics chosen at each visit, the mother worked with the MI interventionist to discuss her ambivalence, concerns, or hesitations and to establish goals and a plan of action. In subsequent visits, the	***Clinical (Primary outcomes))*** dmfs measure of decayed, missing, or filled primary tooth surfaces (white spot lesions were not	***Clinical*** Difference between intervention and control groups for mean dmfs (10 vs 10.4, p= 0.7), mean ds (3.2 vs 4.1, p= 0.38) was reported to be not significant. Effect size (d) was found to be not significant dmfs: -0.02 (-0.21, 0.16) ds: -0.13 (-0.31, 0.05)	Low risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
	children < 3 y of age	96.9% mothers with mean age (SD): 28.2 (15.2) years ***Control*** n= 299 at baseline with 238 at follow up dental screening. Children mean age (SD): 0.73 (0.91) months with 54.3% females 95.8% mothers with mean age (SD): 27.5 (13.7) years .		mother and interventionist discussed progress and obstacles and then amended goals and action plans, discussing new topics as needed. At a mother's request, the same topic could be repeated in a subsequent session, although at least 1 new topic was added in these cases. ***Control group:*** Enhanced Community Services (ECS) included public service announcements on the tribal radio station, billboards, distribution of brochures focused on behavioural risk factors for ECC and oral health topics covered in the MI sessions. Each participant received oral health brochures according to age group and toothbrushes and toothpaste for all family members. ECS was provided to both intervention and control group.	considered) at enrollment and when the child was 12, 24, and 36 mo of age. ***Clinical + behavioural (Secondary outcomes)*** Longitudinal assessments of decayed surfaces (ds) and caries prevalence at 12, 24 and 26 months. Survey assessing mothers' oral health knowledge and parental oral health behaviours at baseline and 12, 24 and 26 months.	***Behavioural*** <u>Oral Health Behaviour</u> No significant difference reported between intervention and control for mean oral health behaviour score (53 vs 51.3, p= 0.86) Effect size (d): 0.09 (-0.09, 0.26). <u>Oral Health Knowledge</u> Difference between intervention and control groups for mean oral health knowledge scores was reported to be significant (82.1 vs 80.1, p= 0.03), however effect size calculation showed no significant effect (d)= 0.15 (-0.03, 0.33).	
(Henshaw, Borrelli et al., 2018) **Cluster RCT**	**USA** To assess the 2-y effect of MI on caries increment in primary teeth, as delivered by trained public housing residents to caregivers of children aged 0	***Intervention*** Enrolled n= 574 with 379 dyads at follow up Children's mean age (SE): 2.8 (0.09) years with 50.7% males. Caregivers mean (SE) age: 32 (0.32) years with 97.9% females	Local people living in (PHDs) recruited and trained as Oral Health Advocates (OHA) They received 8h classroom training followed by written test and 4 wk training on delivery of MI sessions.	***Intervention group*** <u>Clinical examination and dental referral</u> On-site child clinical examinations to collect data on dmfs, with a report on current oral health status and a dental referral list; and fluoride varnish application. <u>MI and other materials</u> Participants were presented with a menu of ECC prevention strategies	***Clinical*** dmfs over time measured at baseline, 12 and 24 months ***Behavioural*** Oral health behaviours and knowledge measured at	***Clinical*** No significant difference reported in mean dmfs scores between intervention and control groups at 24months (3.1 vs 3.1, p= 0.53) Effect size (d)= 0.00 (-0.14, 0.14) ***Behavioural*** <u>Oral Heath Behaviours</u> No mean difference reported between intervention vs control group in mean sugar sweetened	Low risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
	to 5 y living in Public Housing Developments (PHDs).	***Control*** Enrolled n= 847 with 686 dyads at follow up. Children's mean age (SE): 2.8 (0.04) years with 51% males. Caregivers mean (SE) age: 31.8 (0.46) years with 98.5% females		to discuss with the OHA: bottle and sippy cup use; cleaning your child's mouth; drinking fluoridated water; good-bye bottle, hello sippy cup; healthy snacks, keeping germs away; lift the lip; sleep time routine; and visiting the dentist. Toothpaste and toothbrush along with written handouts were also provided. ***Control group*** They received the same clinical examination and dental referral, written handouts and toothpaste & tooth brush except the MI sessions.	baseline, 12 and 24 months	beverage intake (2.1 vs 2.3, p= 0.43). Effect size (d): -0.13 (-0.26, 0.02), and proportion of children with twice daily tooth brushing (OR 1.3 (0.89, 1.93, p= 0.22) at 24 months follow-up. <u>Oral Health Knowledge</u> Significant difference reported between mean scores for intervention and control groups (77.3 vs 75.9, p= 0.03) at 24 months. ES (d): 0.07 (0.07, 0.35).	
Quasi-experimental study designs							
(Bentley and Holloway, 1993) **Pre-Post test**	**United Kingdom** To evaluate the effectiveness of health visitors in encouraging dental attendance of children aged 0-2 years	7/9 districts agreed to participate 255 HVs 362 dentists agreed to accept infants. 3165 parents of children contacted during the study period	Health Visitors	***Intervention*** <u>Oral health advice and dental referral for registration</u> Every mother that HV saw was to be advised about importance of oral health and provided with simple guidelines about care of erupting teeth and importance of registering with a dentist. Any mother who was not an attendee was asked to select a dentist from the list of those accepting infant patients and then HV filled the details on a pre-printed referral letter and handed to the parent and entered the details on an evaluation form for record	***Behavioural*** Dental registration rate	2412 out of 3165 contacted were referred to General Dental Practice and out of these 1872 could be traced so registration rate was found to be 21%	Moderate risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
(Sgan-Cohen, Mansbach et al., 2001) **Quasi-experimental**	**Israel** To measure the effect of a community health education program on reported infants' bottle-feeding practices and infants' toothbrushing behavior, with or without distribution of toothpaste and toothbrushes.	***Total sample (baseline):*** 883 infants, 6-12 months old. ***Intervention (n= 412 at follow up)*** Program 1 (OHE+ TP & TB): n= 169 at follow up Program 2 (OHE only): n= 118 at follow up ***Comparison (n= 239 at follow up)*** Control 1 (TP & TB): n= 82 at follow up Control 2 (Without TP & TB): n= 80 at follow up.	Nurses at MCH centres	***Intervention group*** <u>Oral health education +TP & TB</u> OHE to be provided during health education on dietary, toothbrushing and dental visiting behaviours. Toothpaste and Toothbrush for children were also provided thrice during the study period. ***Comparison group*** <u>HE with TP & TB distribution</u> No structured OHE education provided but nurses were instructed not to deny knowledge if any caregiver specifically asked about oral health.	***Behavioural*** • Bottle use during and between meals and during sleep; toothbrushing behaviours. • Measured 6 months later through questionnaires administered during interviews of parents.	***Behavioural*** <u>Bottle Use</u> • No significant difference between intervention and control group was reported and found in effect size calculation for 'during meals' bottle use (OR 1.12 (0.81, 1.56), p= 0.23) and bottle use with added sugar (OR 1.69 (0.92, 3.13), p= 0.06); 'during sleep' bottle use (OR 1.04 (0.72, 1.52), p= 0.62) and bottle use with added sugar (OR 1.11 (0.53, 2.35), p= 0.91); 'between meals' bottle use (OR 1.04 (0.72, 1.52), p= 0.64). • Significant difference was reported for between meals bottle use with added sugar (p= 0.03), however effect size calculation was not significant (OR 1.11 (0.53, 2.35). <u>Toothbrushing behaviours</u> Significant differences were reported between P1 and P2 (p=0.012), P1 vs C1 (p= 0.044), P1 vs C2 (p= 0.00016). No significant differences were reported for P2 vs C1, P2 vs C2 and C1 vs C2. Effect size calculation: P1 vs P2: OR 1.68 (1.05, 2.71) P1 vs C1: OR 1.85 (1.09, 3.15) P1 vs C2: OR 3.16 (1.80, 5.54)	Serious risk
(Harrison and Wong, 2003)	**Canada**	Baseline n= 14 Children's age (SD): 25.3 (6.2) months	Vietnamese Lay health worker termed 'Community Dental	***Intervention group*** <u>Oral health education – Counselling+ kits+ follow-up</u>	***Clinical*** Presence of visual decay	***Clinical*** • Significant difference in mean defs between INT vs baseline at	Moderate risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
Quasi-experimental with comparison group	To design, implement and evaluate a culturally sensitive oral health promotion program to improve dental health in Vietnamese preschool children in Canada.	***Experimental:*** n=16 Children's age (SD): 22.1 (5) months ***Comparison:*** Similarly aged Vietnamese children from a neighbouring municipality (n= 9). Children's age (SD): 22.7 (5.8) months. Baseline examinations conducted in 1994 and then comparison made of similar aged children in baseline with children in intervention groups at 1996, 1998, 1999 and 2001. However due to very small number of participants attending the oral examinations, it was excluded from analysis.	Health Worker' (CDHW)	• CDHW provided counselling at each recommended immunization schedule (at 2, 4, 6, 12 and 18mo) and provided Oral health promotion kits provided for infant at each visit. • Follow-up phone calls to mothers for coaching and support. <u>Community-wide initiatives</u> • Dissemination of videos and articles through community-wide initiatives and other activities such as: child dental health booths at local festivals, window displays near bus stops and child oral care brochure for nurses. ***Comparison group*** Did not receive Oral Health Education initiatives.	through defs index. ***Behavioural*** Brief questionnaires during baseline and follow-up to determine parenting practices, awareness of community outreach activities and suggestions for improving oral health of children.	1st follow up in 1996 (1.1 (4.3) vs. 5.1 (7.2), p= <0.05). Effect size (d): -0.69 (-1.40, 0.07) not significant. • Significant difference between INT vs baseline at 2nd follow up in 1998 (0.06 (0.2) vs. 9.5 (10.9), p= <0.05). Effect size (d): -1.18 (-1.85, -0.45). • Significant difference between INT vs baseline at 3rd follow up in 2001 (2.6 (2.8) vs 9.5 (10.9), p <0.05). Effect size (d): -0.83 (-1.49, -0.12) significant ***Behavioural*** • Significantly less use of day time and sleep-time bottle use for children 12-60 mon of age, reported by mothers with > 1 counselling sessions, (p<0.005). Effect size: Daytime bottle use (OR): 0.03 (0.005, 0.18) Sleep time bottle use (OR): 0.07 (0.01, 0.36)	
(Yuan, Kerr et al., 2007)	**Ireland** To evaluate the effectiveness of a	***Intervention:*** 9 wards out of which 3 were urban and 6 rural.	Community-based nurses (health visitors) (n=12) and General	***Intervention group*** <u>Oral health education+ Dental referral: Home visits</u>	***Behavioural*** Dental registration rates for preschool	***Behavioural*** T1: The mean registration rate of children 0-2yr in the intervention	Low risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
Quasi-experimental non-equivalent two group comparison	community-based program to promote dental registration and access to dental services for preschool children residing in areas of high social deprivation using monthly registration data provided by the Central Services Agency (CSA).	***Comparison:*** 14 wards out of which 6 were urban and 8 rural	Dental Practitioner (GDPs) (n=44)	Health visitors providing dental health education + oral health promotion kit containing feeding cups, toothbrushes and fluoride toothpaste+ registration vouchers and list of dental practices taking part in the initiative. GDP appointment GDP provided advice on how to care for baby's teeth, regular dental attendance and maintenance of child's dental registration. Vouchers provided to mothers were exchanged for motivational materials such as wipe-clean table mat and a height chart). ***Control group*** Received usual care.	children (0-2y and 3-5y) Measured rates at 3 time points: baseline (6months before program), T1 (during the program), and T2 (5months after program completion).	wards was not significantly different from controls Mean difference 0.03 (-0.02, 0.09) p 0.21). During the programme, the rate of change of registration (slope) for 0-2 year old children was significantly greater compared to rate of change in control wards Mean difference: 0.005 (0.002,0.007) • T2: Statistically significant difference between mean registration (mean difference 0.04 (-0.08, 0.00): P <0.05). • There were no statistically significant effects for the 3-5yr group.	
(Kressin, Nunn et al., 2009) **Quasi-experimental design**	**USA** To assess the effects of training paediatricians in providing patient centered counselling intervention on provider ECC counselling practices, and on children's subsequent development of ECC.	***Intervention:*** Baseline n = 635 with n= 607 parent child pairs at follow up. ***Comparison:*** Baseline n = 452 with n= 438 at follow up. Children: Intervention: 1.93 y, 51% males Control 1.87 y, 53% males	13 Paediatricians 14 Clinic Nurses (RNs and NP)	***Intervention group:*** 3 components: (1) Communication skills training to enhance clinicians' ability to counsel participants and they were trained to address 3 primary dimensions with caregivers: advice about diet, hygiene and tooth monitoring to detect development of caries. Providers were asked to implement 4A's: Assess parents' status on each dimension, Assist with addressing the barriers, Advise about ECC and Arrange follow up (2) Edits to EMR to include age appropriate information for each dimension and (3) educational brochure to be handed out by	***Clinical*** Incidence of ECC at 1 year follow up	***Clinical*** No statistically significant difference between proportion of children with ECC in intervention and comparison site (17.7% vs. 31.7%) p= 0.086. Survival analysis using Hazard Ratio shows significant results: 0.23 (0.09, 0.62), p= 0.004.	Moderate risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
				clinicians during consultation with caregivers. ***Comparison*** Brochures were made available.			
(Nair, Renjit et al., 2009) **Pre-post test**	**India** To evaluate the effectiveness of a community oral health awareness program given to mothers through trained community level workers (Junior Public Health Nurses (JPHNs) and Anganwadi workers (AWWs).	232 mothers of children aged 0-6 years.	Junior Public Health Nurses (JPHNs) and Aganwadi Workers (AWWs) n= 115	***Intervention*** Training materials for health workers included: audiovisual aids such as modules, charts, posters and brochures in regional language. Modules and booklets were used to help impart health sessions to mothers during sessions at Aganwadis.	***Behavioural*** Mother's knowledge regarding children's oral health	***Behaviour*** Questions on knowledge about oral hygiene such as when to start toothbrushing in children (p= 0.002), knowledge about importance of milk teeth: conservation of milk teeth is essential (p <0.001), reason for conserving milk teeth (p= 0.006) and knowledge about causes of dental disease: Causative factor in caries (p <0.001) showed significant improvement in scores, all showed significant improvement Effect size (RRR 0.28 (0.13, 0.40), 0.69 (0.54, 0.79), 0.21 (0.07, 0.33), 0.27 (0.19, 0.33) respectively	Serious risk
(Maupomé, Karanja et al., 2010) **Quasi experimental**	**USA** To outline caries changes after 18-to-30 months of follow-up in children from AI communities who were exposed to family-based and/or community-wide interventions, or served as a	Post-intervention sample ***Intervention*** Community A: Female: n= 23, mean age (SD) 23 (3.6) months Male: n= 23, mean age (SD) 24.3 (3) months. Community B	Community health workers (CHWs) provided the family interventions based on home visiting model	***Intervention*** Community based and family interventions Media based community-wide interventions were designed in six-month cycles, using five strategies: (i) raising awareness, (ii) providing health education, (iii) facilitating individual behaviour change, (iv) augmenting public health practice, and (v) modifying environments or policies related to breastfeeding, sugar-sweetened beverages, and water consumption. A sample	d1 and d2 components of dmft index as no teeth were missing or filled.	All three intervention communities showed substantial improvements in d1t and d2t. Effect size (d): d1t: A vs D: -0.52 (-0.94, -0.09) B vs D: -0.64 (-1.09, -0.18) C vs D: -0.35 (-0.76, 0.06) d2t: A vs D: -0.42 (-0.84, 0.01) B vs D: -1.17 (-1.64, -0.68) C vs D: -0.18 (-0.59, 0.23)	Moderate

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
	regional comparison group.	Female: n= 17, mean age (SD) 26.6 (2.9) months Male: n= 20, mean age (SD) 22.9 (2.8) months. Community C Female: n= 23, mean age (SD) 23.1 (2.8) months Male: n= 27, mean age (SD) 23.3 (2.7) months. ***Comparison*** Community D Female: n= 17, mean age (SD) 24.7 (3.3) months Male: n= 25, mean age (SD) 25.1 (3.1) months.		community-wide intervention plan targeting sugar-sweetened beverages. Family Interventions were delivered in eight visit clusters by community health workers (CHWs) using a home-visiting model. CHWs created a client-specific plan for initiating and maintaining breastfeeding along with water and sugar-sweetened beverage interventions in clusters 1–3. Cluster 1 occurred before the baby's birth, to facilitate counseling that would encourage early decisions to breastfeed. Clusters 2–4 occurred within 0–3 months of the baby's birth. Clusters 4–7 consisted of intervention implementation and final data collection was done in cluster 8. ***Comparison*** No intervention			
(Vichayanrat, Steckler et al., 2012) **Quasi exp pre-post-test with comparison group**	**Thailand** To demonstrate the application of the SEM to oral health interventions and to evaluate its effects on oral health practices among caregivers and their	***Intervention:*** 62 parent child pairs Children's mean age (SD): 19.16 (8.74) months. Caregiver's mean age (SD): 31.74 (10.61) years. ***Comparison:*** 52 pairs	Health Centre staff and Lay Health Workers (LHWs)	***Intervention*** 1. Oral health education & services at health centres: Health centre staff provided 4 main activities: oral health screening, structured oral health education, prescribing fluoride supplements and giving toothbrush and/or toothpaste. 2. Home visits by LHWs to provide social support:	***Clinical*** Caries status in children assessed by dmft. ***Behavioural*** caregiver's oral health knowledge and behaviour	***Clinical*** No significant improvement in mean dmft was reported for intervention and comparison group (3.04 vs 3.49, p=0.993). Effect size (d): -0.11 (-0.48, 0.26). ***Behavioural*** Tooth brushing***:*** Significant improvements were seen for 'any toothbrushing during the previous week' between INT	Serious risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
	determinants at multiple levels	Children's mean age (SD): 18 (9.30) months. Caregiver's mean age: 34.50 (11.52) years.		Trained LHWs visited every 3 months to provide social support: informational, appraisal and emotional support for caregivers. 3. Community mobilisation process: members of Tambon Administrative Organisation and Day care teachers and village health volunteers were invited to meetings during the programme to educate them and group discussions to better understand ECC problem and its prevention ***Comparison*** Received routine health services from local health centres, and toothbrushes pre- and post-test.		and comp group (93.5% vs. 80.4%, p= 0.035) Effect size (OR)= 3.45 (1.01, 11.76) Use of fluoride tooth paste. Brushing with adult supervision was not found to be significant. Bottle Feeding: No significant improvements seen for behaviours of 'falling asleep with bottle' and 'putting sweetened milk, juice or soda in the bottle'. 'Use of fluoride supplements' showed significant improvement 80.3% vs. 13.7%, p <0.0001) ES (OR) 24.23 (8.88, 66.13). Cariogenic snack consumption (>4 days) There was a significant decrease in low cariogenic snack consumption only for INT vs. comp group 46.8% vs. 65.4%, p= 0.058) Effect size: (OR) 0.46 (0.22, 0.99). ***Knowledge*** Significant improvement for only two knowledge items such as 'method of using fluoride supplements' (57.6% vs. 13.5%, p <0.0001) and 'not putting juice in bottle' (66.1% vs 34.6%, p 0.001) was reported. Effect size (OR) 8.9 (3.47, 22.85) and 3.69 (1.70, 8.02) respectively.	
(Raj, Goel et al., 2013) **Pre-post test**	**India** To evaluate the short-term impact of Oral Hygiene Training Package	***Pretest (n= 534 children)*** Females: n= 263 (49.3%) Males: n= 271 (50.7%)	Aganwadi Workers (AWWs) n= 21	***Intervention*** AWWs imparted oral health education to mothers in weekly meetings in their respective AWCs for 12 weeks. Meetings were conducted guided by the training	***Clinical*** Changes in plaque index scores, gingival index scores,	***Clinical*** No significant differences reported between pretest and posttest for mean dmft scores (2.1 vs.1.9, p= 0.06). Effect size (d): -0.08 (-0.20, 0.04).	Serious risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
	(OHTP) to AWWs on improving oral hygiene of preschool children.	***Posttest (n= 538 children)*** Females: n= 246 (45.7%) Males: n= 292 (54.3%)		module , posters and stories given to AWW as part of OHTP	debris index and caries activity. ***Behavioural*** Improvements in oral hygiene practices (frequency of tooth brushing, mouth rinsing after meals)	Significant reduction reported in caries activity (n) between pre and post-test assessed through Snyder's test (241 vs. 168, p<0.05). Effect size: RRR 0.35(0.24, 0.45). Significant improvements in debris index (as objective measure of toothbrushing) also reported (n) (418 vs. 291, p <0.001), Effect size: RRR 0.31 (0.24, 0.37). ***Behavioural*** 1. Significant improvements in pre-test vs post-test for brushing twice or more (%) (4.1 vs. 9.9, p <0.001). Effect size: RRR 0.06 (0.03, 0.09); and those that never brushed (13.9 vs. 7.2, p <0.001). Effect size: RRR 0.48 (0.24, 0.64) 2. Significant improvements also seen in use of medium of cleaning between pre and post-test: Use of tooth brush (85.2 vs. 90.2, p 0.017). Effect size: RRR 0.33 (0.08, 0.52); use of nothing to clean (13.9 vs. 7.2, p <0.001). Effect size 0.48 (0.24, 0.64).	
(Wilson, Debaryshe et al., 2013) **Quasi exp pre-post test**	**USA** The research hypothesized that family-centered, peer to-peer videos would be more effective than	Total 91 BFS video group 48 BOH video group 43 ***Children*** 52% boys 48% girls	Health Visitors (n= 19) with at least 6 months experience and atleast 6 attached families.	***Intervention*** Each video was divided into eight segments lasting four to seven minutes in duration. The segments were to be shown on an overlapping schedule. Home visitors were asked to complete the series within eight to ten weeks. During the video intervention period, home visitors continued to	***Behavioural*** Family oral health knowledge, attitudes and behaviours related to young children's oral health	***Oral health Behaviours/attitudes*** When evaluated individually, the BOH or BFS did not have any statistically significant effect in changing behaviour/attitudes between pre and post-test. (Effect size (d): 0.27 (-0.16, 0.69) and 0.36 (-0.04, 0.76) respectively).	Serious risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
	didactic, lecture based videos in achieving positive changes in family knowledge, attitudes and behaviours related to young children's oral health among families with young children living in rural Hawai'i.			implement the ongoing EHS protocol. How and when to incorporate the video during each home visit was left to the home visitor's discretion. To minimize differences in presentation, home visitors were asked to simply play the video and to provide only brief answers to any questions from family members. Home visitors were asked to refrain from showing the non-assigned video or from designing and implementing any supplementary curriculum. When each family had completed the video series, the home visitor was asked to give the participant a copy of the assigned video and encourage the family to share the video with other parents in their social circle.		When mean scores were evaluated between pre and post test for both videos, there was a significant improvement reported in oral health behaviours/attitudes (Mean scores pre vs. post for total: 103.70 vs. 107.02). Effect size (d): 0.31 (0.02, 0.61), p= 0.0005). ***Oral health Knowledge*** Significant improvement in mean knowledge scores were seen between pre and post scores for BOH and BFS individually and also for the effect when both scores were averaged. Mean scores: BOH pre vs. post: 15.30 vs. 17. 01; BFS pre vs. post 15.08 vs. 16.95 and for total: 15.19 vs. 16.98. Effect Size (d): BOH pre and post: 0.52 (0.09, 0.95), BFS pre and post: 0.52 (0.11, 0.92) Total: 0.52 (0.23, 0.82) p= 0.0005	
(Van den Branden, Van den Broucke et al., 2013) **Quasi experimental with control group**	**Belgium** To evaluate the effectiveness of a multi-component oral health intervention in preschool children in a non-randomized intervention study with a	***Intervention*** Baseline n= 1284 and n= 1080 at follow up. at 3 year's age follow up: mean age 3.1 year at 5 year's age follow up: mean age 5.20 years 52.4% boys.	3 home visits by a nurse and 11 consultations by a physician and a nurse up to child's 3 years of age. Oral health education provided by a specifically trained nurse.	***Intervention*** <u>Home visits+ oral health kits</u> 3 Home Visits: at 2, 4-6 and 10 weeks 11 consultations: from 3-6 weeks until the child is 30 months old Oral health promotion was developed and added to the standard programme by adding oral health education on 14 topics like breast-feeding, pacifier use, parental oral hygiene, water consumption, and	***Clinical*** Decay experience assessed through dmft and dmfs ***Behavioural*** Dietary and oral hygiene behaviours,	***Clinical*** No significant differences reported for proportion of children caries free in intervention vs control group assessed by d3mfs at 3 years follow up (97.5 vs 95.7, OR 1.25 (0.63–2.49) Significant difference between intervention vs control for d1mfs at 3yr follow up (91.9 vs 77.9, OR 2.47 (1.70-3.59), p <0.001).	Moderate risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
	complementary baseline control	Mother's mean age (at child's birth): 28.7 years. ***Control*** Baseline n = 1171 and n= 1057 at follow up. at 3 year's age follow up: mean age 3.2 year. at 5 year's age follow up: mean age 5.2 year. 50.9% boys Mother's mean age (at child's birth): 29.9 years.		brushing behaviour. Child health booklet, toothbrush and fluoride containing TP sample, cup and placemat were also given to parents. All health care professionals practicing in the intervention region were informed about the project and posters were provided to inform their patients. ***Control*** Standard programme	dental attendance Assessed at 3 and 5 years of age of child	No significant difference between intervention vs control for d3mfs at 5yr follow up (76.5 vs 76.1, OR 0.99 (0.77–1.26) p= 0.92). No significant difference between intervention vs control for d1mfs at 5year follow up (61.3 vs 60.6, OR 0.99 (0.80–1.22) p = 0.91). ***Behavioural*** Significant differences in proportion of children who visited the dentist less than a year ago, brushed more or more with fluoride tooth paste and were assisted with brushing once or more. However better behaviours were seen for the control region both at 3 and 5 years' follow up. Significant difference favouring intervention was reported for less than daily consumption of sugared drinks in between meals both at 3 y (53.2 vs.38.9, p <0.001) and 5 years (54.4 vs. 42.4, p<0.001). Effect size OR at 3 years: 0.53 (0.43, 0.67), RR 0.78 (0.71, 0.85), OR at 5 years: OR 1.62 (1.33, 1.98), RR 1.28 (1.15, 1.42) No significant difference was reported between intervention vs control group for less than daily consumption of sugared snacks in between meals both at 3 and 5 year follow up. When only comparing the intervention and control group, no effects of the intervention were observed, as the control group	

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
						generally performed better. However, when comparing the data with a historical cohort, some small effects of the intervention program could be observed in the short term. Thus, the intervention seems to have had limited success in improving oral health-related behaviours such as visiting the dentist", tooth brushing more than once with fluoride tooth paste, assisting with tooth brushing more than once, consumption of sugared drinks and snacks in between meals at 3 years and except consumption of sugared snacks for 5 years follow up.	
(Biordi, Heitzer et al., 2015) **Quasi exp pre-post test**	**USA** To provide oral health care services at 2 sites using a nurse practitioner–dietitian team to increase dental workforce capacity and improve access to care for low-income preschool children.	***Visit 1*** Total n= 4360 Rural: 2493, Urban: 1867 ***Visit 2:*** Total n =1832 R = 1127, U= 705 ***Visit 3***: Total n=728 R= 492, U= 236 <u>Age</u> **Visit 1:** 2.31 y**ears** **Visit 2:** 2.79 years **Visit 3**: 3.15 years <u>Gender</u> **Visit 1** Female= 49%, Male= 51% **Visit 2**	1 Dietician and 1 Nurse Practitioner	***Intervention*** Fluoride varnish application, oral health education discussion with parents and provision of written information and oral health assessment. Parents or guardians were also given a list of paediatric dentists who accepted public insurance, and the children received a bag containing a toothbrush, toothpaste, and age-appropriate oral health education materials, including a dental colouring book and crayons at 3 or 6 months visit depending on WIC procedure for 3 visits between the study period of 2010-2013.	***Clinical*** Mean decayed, discoloured or filled teeth ***Behavioural*** Oral hygiene and dietary habits Dental visits Assessed at 3 visits between 2010-2013	***Clinical*** No significant differences reported for mean decayed, discoloured or filled teeth between visit 1, 2 and 3 ***Behaviour*** Significant differences reported between rural and urban sites for child drinks > 1 cup of sweet drink/day; child uses bottle for milk and other drinks; child uses sippy cup for milk and drinks; child eats fruits/veggie at least 1time/day and child snacks on high sugar foods more than 1 time/day for all 3 visit except for child uses sippy cup for visit 3. Effect size: calculation not possible with the provided information.	Serious risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
		Female= 48%, Male= 52% **Visit 3** Female= 47%, Male= 53%					
(Gibbs, Waters et al., 2014) **Community Trial**	**Australia** The aim of the exploratory trial was to establish a model for feasible, replicable and affordable child oral health promotion for culturally diverse Local Government Areas (LGAs) in Australia	***Intervention*** Baseline n= 288 families/ 378 children and n=154 families with 197 children at follow up. Caregivers: mean age: 33.2 years Females: n= 164 (83%) Males n= 33 (17%). Children: Females: n= 100 (51%) Males n= 97 (49%). ***Control*** Baseline n= 233 families/314 children and n=110 families with 144 children at follow up. Caregivers: mean age: 33.5 years Females n= 112 (78%) Males n= 32 (22%) Children: Females: n= 76 (53%) Males n= 68 (47%).	Peer educators who were members of the community and fluency in both English and their ethnic language.	***Intervention- 'Teeth Tales'*** <u>OHE + OH pack + reminders</u> Two 3 h sessions of oral health education followed by a site visit to the local community health dental service to be familiarised with the service and other local family services. Provision of OH pack containing oral health information, toothbrush and toothpaste for the whole family. Reminders (1 message per month for 4 months) either by text or post according to preference. ***Comparison*** Families recruited from outside the study area were treated as the comparison group	***Clinical*** Assessment of debris and gingival index as proxy measures of oral hygiene. Decay assessment using dmfs index. ***Behavioural*** Self-reported measures of child's tooth cleaning frequency and oral health knowledge and use of dental services	***Clinical*** No significant difference reported for mean dmfs scores between INT and comp. groups (p >0.05). Effect size (d): 0.15 (-0.08, 0.38). Significant differences between INT and comp group were reported for presence of tooth debris (OR 0.44 (0.22, 0.88), p= 0.021), and presence of gingival inflammation (OR 0.34 (0.19, 0.61), p <0.001). ***Behavioural*** <u>Toothbrushing behaviours</u> No significant difference was reported for twice daily toothbrushing behaviours between INT and comp groups (OR 1.41 (0.77, 2.58), p= 0.259). <u>Dietary behaviours</u> No significant difference for frequency of consumption of cariogenic drinks several times/day (OR 1.17 (0.76, 1.80)), Freq of cariogenic foods served/day (OR 0.65 (0.40, 1.05)), Addition of sugar to child's drink sometimes/always (OR 1.00 0.62, 1.62)), addition of sugar to child's food sometimes/always (OR 0.97 (0.61, 1.56))	Serious risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
						Dental visiting No significant difference for child's dental visit (OR 0.96 (0.64, 1.45). Oral Health Knowledge Oral health knowledge did not show any significant effect of the intervention (OR 0.53 (0.26, 1.05)).	
(Hoeft, Barker et al., 2016) **Pre-post test**	**USA** To determine the effectiveness of the Contra Caries Oral Health Education Program (CCOHEP) for improving low-income, Spanish speaking parents' oral health knowledge and behaviours for their young children.	Parent/caregiver and their child closest to 3 years of age, n= 105 with n= 79 at follow up. Caregivers mean age (SD:) 33.7 (8) years with n=81 (77%) of them mothers. Children Mean age (SD:) 3 (1.3) years with n=47 (45%) being females.	Lay People with parenting/childcare experience hired and trained as *promotoras* or community health outreach workers	***Intervention- Contra Caries Oral Health Education Program (CCOHEP)*** OHE+ TP and TB provision Four 2 h sessions on oral health education delivered in interactive manner. Sessions included information about importance of primary teeth, good dietary behaviours and oral health behaviours and establishment of early dental visiting routine. Toothpaste and tooth brushes were also provided for the whole family.	***Behavioural*** Self-reported oral health behaviours such as dietary and toothbrushing behaviours and oral health knowledge. Verbal questionnaires were administered by bilingual researchers at baseline, 1 month later (post-test 1) and then 3 months later (post-test 2).	***Behavioural*** Toothbrushing behaviours Significant improvement was reported between baseline and post-test (p= 0.0001) for average number of correct toothbrushing behaviours, and also between post-test 1 and post-test 2 were reported (p= 0.0004). Effect size (d): 1.55 (1.20, 1.88) Dietary behaviours Significant improvement was reported between baseline and post-test 1 for dietary behaviours such as child's consumption of sweet drinks once a day or less (p= 0.0082), however this decreased non-significantly between post-test1 (77%) and post-test 2 (63%), p= 0.1306. Effect size (RRR): 0.45 (0.23, 0.60) However, no significant improvements in child's consumption of sweet foods less than everyday was reported from baseline and post-test1 (0.2568) and also between post-test 1 and post-test 2 (p= 0.8575).	Moderate risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
						Effect size (RRR): 0.14 (-0.13, 0.34). <u>Oral Health Knowledge</u> Significant improvement was reported for mean knowledge score between baseline (12.8) and post-test 1 (15.2), p= <0.0001 and insignificant reduction between post-test 1 and post-test 2 (15.2), p= 0.1797. Effect size (d): 1.89 (1.52, 2.24).	
(Smith, Blinkhorn et al., 2018) **Quasi experimental with historic control**	**Australia** To assess the effectiveness of dental health education program 'Smile not Tears' in preventing early childhood caries in young Aboriginal children	***Intervention*** Baseline n= 147 and n= 107 at follow up. mean age (SD): 2.6 (5.7) years girls n= 53 (49.1%) ***Control*** n = 82 mean age: 2.8 years girls n= 36 (43.9%), boys n= 46 (56.1%).	Aboriginal Health Workers (AHW) from 8 Aboriginal Community Controlled Health Services	***Intervention*** The AHW met with parents over 5 visits to deliver age appropriate messages at 6, 9,12, 18 and 24 months of age. Sessions included didactic and interactive delivery style. Magnets and leaflets distributed in 1st visit at 6 months of age, Fluoride toothpaste and toothbrush given at every subsequent visit including 6th visit which also included dental examination.	***Clinical*** The caries prevalence at 30 months of age as compared to similar aged children in the control group.	***Clinical*** The mean dmft and dmfs scores greatly differed between the intervention vs. control group (0.1 vs. 2.1 and 0.5 vs. 2.7). Effect size (d): -0.75 (-1.04, -0.45) and -0.63 (-0.92, -0.33) respectively	Moderate risk
(Yuan, 2019) **Quasi experimental**	**Northern Ireland** To evaluate a culturally appropriate community-based home visiting oral health education intervention for	***Intervention*** Recruited 18 mother child pairs with 17 mother-child pairs at follow up. Children: Females n= 8 (44%) Males n=10 (56%)	1 Chinese Health Visitor	***Intervention*** Advice about breast feeding and weaning and children's and mother's oral health advice at 8 weeks followed up by phone call at 4 months and then visit again at 6 months with oral hygiene and diet advice given to mothers then follow up call at 9 months. Breastfeeding and weaning leaflets+ teething	***Behavioural*** Mothers' oral health related knowledge, attitudes and behaviours with regard to baby toothbrushing, sugar consumption and	***Behavioural*** <u>Toothbrushing behaviours</u> Significant differences between mean scores of intervention vs control group were reported for importance and intention to brush child's teeth at 6 months 22.61 vs 18.83, p <0.001) and 12 months (22.82 vs 18.76, p <0.001).	Serious risk

Author & Study design	Study location & aims	Participant characteristics	Intervention delivery personnel	Intervention	Outcome measures	Findings	Quality
	Chinese, undocumented migrant mothers to promote their infants' oral health, by focusing on their oral health related knowledge, attitudes, and behaviours.	***Control*** Recruited 18 mother child pairs with 17 mother-child pairs at follow up. Children: Females n= 7 (39%) Males n=11 (61%)		ring+ mother's TP and TB provided at 4 weeks and then Baby trainer cup; Oral health pack containing baby toothbrush and fluoride toothpaste; Mother's toothbrush and fluoride toothpaste at 6 months and baby feeding cup and mother's and child's TP and TB at 1 year.	baby tooth decay as well as maternal dental health behaviours, measured at eight weeks, six months, and 12 months	Effect size (d): 1.71 (0.92, 2.43) and 1.62, (0.84, 2.33) <u>Dietary behaviours</u> Significant differences between mean intervention vs control group scores were reported for importance and intention to control sugar snacking at 6 months (31.11 vs. 27.22, p <0.001) and 12 months (32.59 vs 27.82, p <0.001). Effect size (d): 1.35 (0.60, 2.03) and 1.36 (0.61, 2.06).	

Appendix 4.1: Focus group participant information sheets

Lady Health Workers for oral health promotion in children in Pakistan: Feasibility of developing and testing a behavioural intervention

Information Sheet for Participants (Parents)

Please read this document carefully. We would like to invite you to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please ask us if there is anything that is not clear. If you decide you would like to take part then you shall be asked to sign a consent form and will be given a copy of this information sheet

You are being asked to participate in a research study on promoting parental oral hygiene practices for their children. The purpose of this study is to understand parents' knowledge, perceptions, beliefs and practices regarding children's oral health and the barriers that they face for engaging in tooth brushing of their children in everyday life. Results of this study will help us in developing ways to support parents for routinising tooth brushing for their children.

The study involves a group discussion with 8-10 mothers about oral health of children. It will take place in the nearest Health House/Primary Health Centre or any other local community meeting rooms. The session will last about 90-120 minutes with refreshment break in between and lunch provided at the end. The discussion will be audio taped and notes taken during the session.

You are free to choose whether or not to participate in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect you in any way. Should you wish to withdraw from the study, we may use data collected from you for the purpose of research, if you consent to it.

There is no known possible risk or discomfort that you can encounter connected to the activities in this study. Although there is no direct benefit to you for participating in this research, however, you shall be reimbursed your travel cost for coming to take part in the study and as a token of appreciation for your time, you shall be given PKR 100 prepaid calling card for local talk time.

Your identity and location in this study will remain strictly confidential. The data obtained from audio recording shall be transferred securely to a software for the purpose of analysis and all identifying information of participants such as their names will be removed and given an ID instead. The results of the study, including data, may be published for scientific purposes but will not give your name or include any identifiable references to you.

If you have any questions or would like further information, please contact:

Research student Mehreen Faisal, E: mrf516@york.ac.uk

Department of Health Sciences, University of York

Lady Health Workers for oral health promotion in children in Pakistan: Feasibility of developing and testing a behavioural intervention

Information Sheet for Participants (LHWs)

Please read this document carefully. We would like to invite you to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please ask us if there is anything that is not clear. If you decide you would like to take part then you shall be asked to sign a consent form and will be given a copy of this information sheet

You are being asked to participate in a research study on promoting parental oral hygiene practices for their children. The purpose of this study is to understand how children's oral health promotion can be incorporated in Lady Health Workers (LHWs) routine home visits. Results of this study will help us in developing ways to support parents for routinising tooth brushing for their children.

The study involves a group discussion with 8-10 LHWs and LHS about oral health promotion training needs. It will take place in the nearest Primary Health Centre or any other local community meeting rooms. The session will last about 90-120 minutes with refreshment break in between and lunch provided at the end. The discussion will be audio taped and notes taken during the session.

You are free to choose whether or not to participate in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect you in any way. Should you wish to withdraw from the study, we may use data collected from you for the purpose of research, if you consent to it.

There is no known possible risk or discomfort that you can encounter connected to the activities in this study. Although there is no direct benefit to you for participating in this research, however, you shall be reimbursed your travel cost for coming to take part in the study and as a token of appreciation for your time, you shall be given PKR 100 prepaid calling card for local talk time.

Your identity and location in this study will remain strictly confidential. The data obtained from audio recording shall be transferred securely to a software for the purpose of analysis and all identifying information of participants such as their names will be removed and given an ID instead. The results of the study, including data, may be published for scientific purposes but will not give your name or include any identifiable references to you.

If you have any questions or would like further information, please contact:

Research student Mehreen Faisal, E: mrf516@york.ac.uk

Department of Health Sciences, University of York

Thank you

Appendix 4.2: Focus group topic guides

Mother FGD Topic guide

Introduction

• Outline study aims: Purpose is to talk to parents about their children's oral health and what they do to help their child look after their teeth.
• Talk the participants through the FGD methods
  • Session will last for about 90-120 minutes including refreshments and lunch
  • Use of audio recorder by researcher
  • No right or wrong answers
  • Participation is voluntary
  • Obtain written informed consent
  • Assure about confidentiality

Background

- How old are you?
- How many children do you have?
- How old are they?
- What are the first things you think of when you think of 'healthy teeth'? How important are healthy teeth to you and your family?
- How are your children's teeth?
- Is there anything you do to try and help your child/children have healthy teeth?

Current toothbrushing practices of child

• Talk me through a normal day with respect to your child's current toothbrushing practices? (allow the parent to describe the process in their own words)

• Prompts: where is the toothbrushing carried out, at bedtime what do they do after toothbrushing, use of toothpaste, use and strength of fluoride toothpaste, does the foaming or flavour cause a problem with using certain toothpastes, do you use a manual or electric toothbrush, post brushing rinsing

• How are you or another adult involved in your child's toothbrushing (child brushes his/her own teeth without adult watching, child brushes his/her own teeth and the adult watches, adult assist child with toothbrushing, adult does all toothbrushing)

• How did you / your child establish their current toothbrushing regime? Why did you establish this routine?

• What age did toothbrushing start? What prompted you to start at this age?

Managing child's toothbrushing

- How do you manage or negotiate with your child when they do not want to follow their toothbrushing routine? Bedtime? Already asleep?

- What behaviours do they show? How easy do you find managing these? How insistent are you with ensuring that toothbrushing is undertaken?

- Child getting older, how will you manage giving them more control (may or may not be applicable)

- You have explained how you and your child established your current toothbrushing regime, how do think it will change as they get older (what age did /will they start brushing, as they get would the child to have more of a role in toothbrushing, need reminding?)

Specific questions based on the Theoretical Domains Framework

- Do you know how to brush/supervise your child's tooth brushing? How would you do this? (knowledge)

- How confident are you that you can brush/supervise your child's tooth brushing? (beliefs about capability)

- How much do you want to brush/supervise your child's tooth brushing? Are there any incentives for doing so (for you and/or you child/ren)? (motivation and goals)

- How do you feel about brushing/supervising your children's tooth brushing? Prompt: How about if your child does not want to have their teeth brushed? (emotion)

- What do your friends /family members think about brushing/supervised tooth brushing? Prompt: Do they do it themselves with their own children? Prompt: How often do they brush/supervise their child's toothbrushing? Do they help? (social influence)

- Are there any environmental factors that help or hinder your child's toothbrushing/supervised tooth brushing? E.g. Staying with friends / family / late bedtimes / other children / family members and morning school times (environmental context and resources)

- Is toothbrushing/supervising your child's tooth brushing twice a day something you find easy to remember to do? Might you consciously decide not to brush/supervise your child's tooth brushing? If so, why? (memory, attention and decision processes)

- What do you think will happen if you do not brush/supervise your children's toothbrushing? (beliefs of consequences)

- Do you think the benefits of toothbrushing/supervising toothbrushing is worth the effort? (optimism)
- To what extent do you feel it is your responsibility to brush/supervise your child's tooth brushing? (social role and identity)

- How easy or difficult do you find it is to brush/supervise your child's toothbrushing? Prompt: do you feel you have the skills to do this? (skills)

- What are the things that you would need to prepare you to brush/supervise your child's toothbrushing? What prompts you to brush/supervise your child's tooth brushing? (behaviour regulation)

- In the past week, how often did you brush/remind your child to brush their teeth (intentions?)

Have you ever been shown how to brush your child's teeth (e.g. dental professional, dental camps, health workers)

- Who showed you?

- Was this helpful, did it change your child's toothbrushing routine?

- How were you shown, hands on, on a model, positioning of child and you, amount of toothpaste, frequency?

- If parent answers 'no' ask: how did you learn to do it your way? Would it be useful if somebody showed you?

If we developed a resource to help parents with toothbrushing

- Do you think there is anything we could do to help parents with toothbrushing their children's teeth? What should this look like? When would it help you the most?

- How would you feel about having a resource which is designed to help you establish a toothbrushing regime with your child?

- What would you imagine this help would look like (video, workbook, booklet, website, app)? What should it have in it?

Closing

- Covered everything or is there anything else that you want to discuss?
- Is there anything else that you wish to mention about children's oral health or any help or support that you require to help you with looking after your children's teeth?
- Thank the participants
- Reassure about confidentiality

Discuss that findings will be used to develop an intervention to support parents with brushing their children's teeth.

Lady Health Worker FGD Topic guide

Introduction

• Outline study aims: Purpose is to talk to LHWs and LHs regarding inclusion of children's oral health promotion in their duties and understand their training needs for this purpose.
• Talk the participants through the FGD methods
  • Session will last for about 90-120 minutes including refreshments and lunch
  • Use of audio recorder by researcher
  • No right or wrong answers
  • Participation is voluntary
  • Obtain written informed consent
  • Assure about confidentiality

Activity (to be discussed later)

Please write down what you think are the main causes of children's poor oral health

Background

- How long have you been working in your position?
- Reasons for joining?
- Reasons for staying?

Current work duties

- Please describe your typical work day

Prompts: How many hours do you work, how many families do you visit? How much time is spent on average per family?

- What motivates you to work as LHW?
- What are the main challenges that you face at work?
- What is that you most like about your work?

Perceptions about children's oral health

- What do you think about oral health? Children's oral health?
- Discuss about the activity done in the beginning-What do you think are the main causes of children's poor oral health?
- Have you ever been asked for advice regarding dental pain?

Prompts: How often? How do you respond?

Questions based on TDF

- When do you think children's tooth brushing should be initiated? Do you about the guidelines for children's tooth brushing? supervised tooth brushing? (Knowledge)

• If you have to, would you feel confident in giving tooth brushing advice to mothers for their children? Prompts: correct tooth brushing method, which tooth paste and amount of tooth paste to be used? What skills do you think are needed? (Skills)

- Do you discuss children's oral health with mothers? Do you think you could be giving oral hygiene advice to mothers as part of your role? (Professional role & identity).
- How easy/difficult would you find it to talk to mothers about children's toothbrushing? Do you think you have the knowledge/skills? (beliefs about capabilities).
- What benefits and disadvantages can you see if you were to give toothbrushing advice to mothers? How do you think mothers would receive the oral health advice? (Beliefs about consequences).
- How much would you like to advice mothers about children's toothbrushing? (motivation & goals).
- Do you think giving oral hygiene advice is something that you could do easily routinely? (memory, attention and decision processes).
- What support would you need to give toothbrushing advice to mothers? Do you have enough time? (Environmental context & resources).
- What do you think are the views of your colleagues/ management regarding promotion of oral health of children? (Social influences).
- How do you feel about giving toothbrushing advice to mothers? Does it give you any particular feelings or emotion? (Emotion).
- What would you need to prepare before you give toothbrushing advice to mothers? Are there procedures or ways of working that would encourage you to give oral hygiene advice? (Behaviour regulation/Action planning).

<u>Oral health related training needs</u>

• What aspects a training about oral health should focus on?

• How often should there be refresher training about oral health?

<u>Views about oral health resource</u>

• How can parents/mothers be better educated about oral health of their children?

- If you are to give tooth brushing advice for children to mothers, how much time can you spend on it on average, during your routine home visits?

• If we develop a resource to help parents undertake their child's tooth brushing, in what form should it be? (booklet/leaflet, text/pictorial etc)

Closing

- Has everything been covered?

- Ask participants if they would like to add something or ask any questions

- Thank them and reassure about confidentiality

Appendix 5.1: Intervention materials

Flipbook

Importance of teeth

Chewing food

Speaking

Smiling

1

Importance of teeth

Purpose: To talk to mothers about the importance of teeth and assess how important they consider children's milk teeth

Discuss:

Why do you think teeth are important?

How do you take care of your teeth?

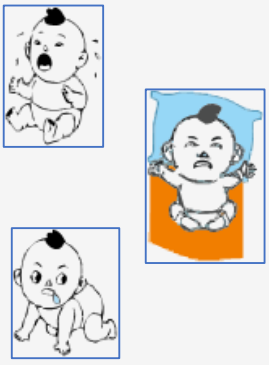
What do you think about the milk teeth? Do you think they are important?

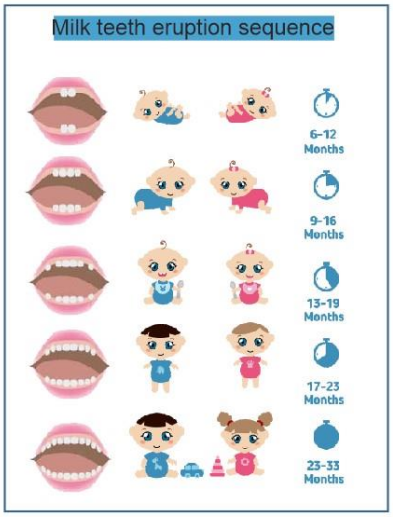
Have you ever cleaned your child's teeth? Ask about the reason if they answer in yes or no.

If they say no: then prompt them to think about cleaning their children's teeth.

If they say yes: then ask about the frequency, technique etc.

Tooth eruption in children





2

Tooth eruption in children

Purpose: To educate mothers about the tooth eruption sequence and the symptoms associated with it

Discuss:

Depending on the age of the child, ask about how many teeth does their child(ren) have?

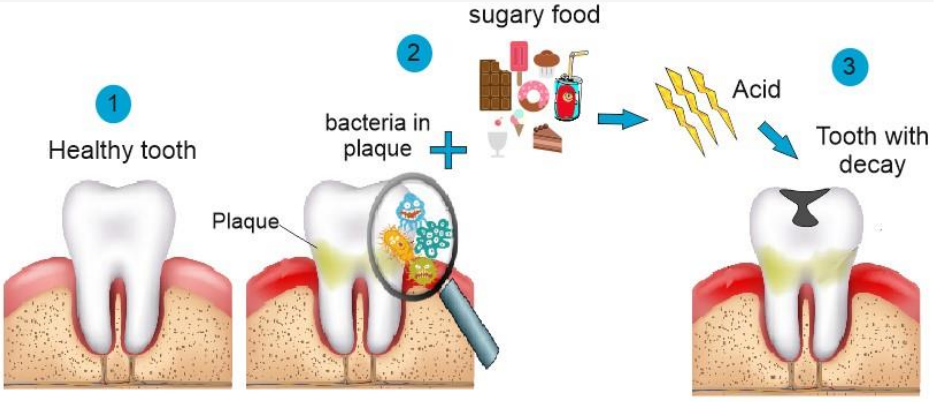
explain to them the tooth eruption sequence of the primary teeth and briefly about when the permanent molars start to erupt.

Have their child(ren) experienced any of the teething symptoms?

What did they do to deal with the teething symptoms?

Explain how they can make their child comfortable during teething

What happens if teeth are not cleaned?



3

What happens if teeth are not cleaned?

Purpose: To educate mothers about the tooth decay process as a result of not cleaning children's teeth

Inform:

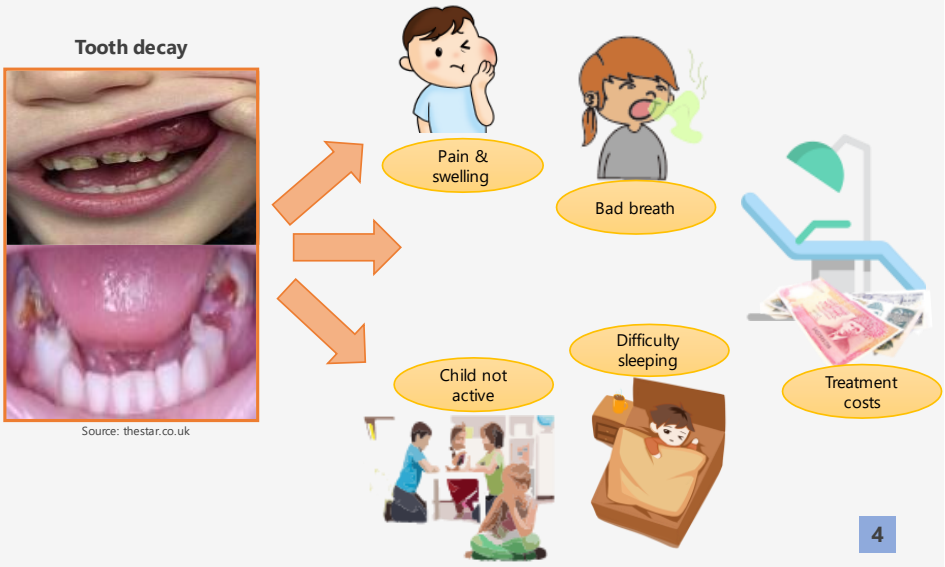
How plaque forms and what does it contain

How diet rich in sugars and carbohydrates is a source for bacteria to feed on and produce acids

How acids produced by bacteria feeding on sugars causes mineral loss from the tooth surface which results in tooth decay.

How toothbrushing cleans away the layer of plaque and food particles stuck in teeth so that there is not enough bacteria to feed on any residual food particles in the mouth to produce acids which can cause tooth decay.

What happens if teeth are not cleaned?



What happens if teeth are not cleaned?

Purpose: To educate mothers about the health, social and economic consequences of tooth decay as a result of not cleaning their children's teeth

Discuss :

How tooth decay progresses rapidly in milk teeth to reach the bundle of nerves within the tooth which causes sensitivity, pain and if left untreated can lead to swelling (infection) and even pus formation

Child can be irritable and may not wish to interact at school or with other children because of discomfort and/or pain.

Child may miss school because of pain and infection

Bad breath can be a source of embarrassment for children when they are shunned or made fun of by their peers.

Treatment costs can put financial burden on the family

How to take care of children's teeth

5

How to take care of children's teeth

Purpose: To educate mothers about how to take care of their children's teeth at different stages of their development.

Advise mothers:

How to clean children's gum even before their teeth erupt. Demonstrate how they can wrap a clean and moist soft cloth around their finger and gently wipe their gums pads after feeding them.

About the advantages of using a fluoride toothpaste and how it replaces minerals lost from the tooth surface due to acid attack, and makes teeth stronger.

Correct amount of toothpaste to be used according to child's age for example: a smear of toothpaste for children <3 years and a pea sized amount for children aged >3 years.

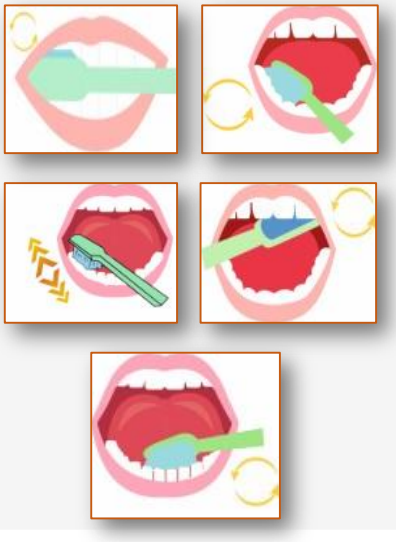
Importance of supervising their children's toothbrushing till the age of 7 years and brushing twice daily, once last thing at night before going to bed and once another time during the day (does not necessarily have to be early morning).

It is not necessary to buy a child toothpaste. The family toothpaste can be used by all but fluoride content should be 1350-1500ppm* and no less than 1000ppm.

Using a family toothpaste helps in avoiding transition difficulties for the child when switching to one as the child grows older.

*ppm= parts per million

How to brush children's teeth?



6

How to take care of children's teeth

Purpose: To demonstrate to mothers the toothbrushing posture and correct steps to ensure proper cleaning of teeth.

Advise mothers:

To choose any of the three positions that suits them and explain to them toothbrushing for very young children who cannot spit, does not necessarily have to be in the bathroom but can be done anywhere in the home.

To choose a soft children's toothbrush.

There is no particular order that they have to follow but whichever way they start, they must ensure that all the tooth surfaces are cleaned by following the correct movement as indicated by arrows .

How to manage difficult child behaviour?

Create a routine for habit formation

Lead by example and provide encouragement & praise

Stay calm and positive

7

What to do if a child does not cooperate?

Purpose: To inform mothers about the different ways which could help make toothbrushing fun and enjoyable routine.

Advise :

Form a habit of toothbrushing by including it as part of daily routine. Create a predictable routine in order to avoid stress and uncooperative child behaviour. For example brushing children's teeth before they are off to school or when they wash their hands after getting back from school (for day time routine) and after dinner for night time routine to avoid late nights when the child is too tired or sleepy.

Even if the child resists, the parent should persist even if only they are able to brush only two teeth. This is so as not to reinforce negative behaviour and to ensure that child understands that toothbrushing is a part of daily routine and has to be practised everyday

Provide encouragementto children and not to force them. For example: make funny faces to make them laugh when don't want to open their mouth, use play to encourage them and give lots of praise when they co-operate and/or reward them with a stickers for good behaviour

Lead by example by showing how you brush your teeth letting them follow you and taking over at the end. If a child wants to brush their teeth themselves then let them have a go whilst guiding them verbally and in the end finish it up for them. Ask for help from other family members(father, grandparents etc).

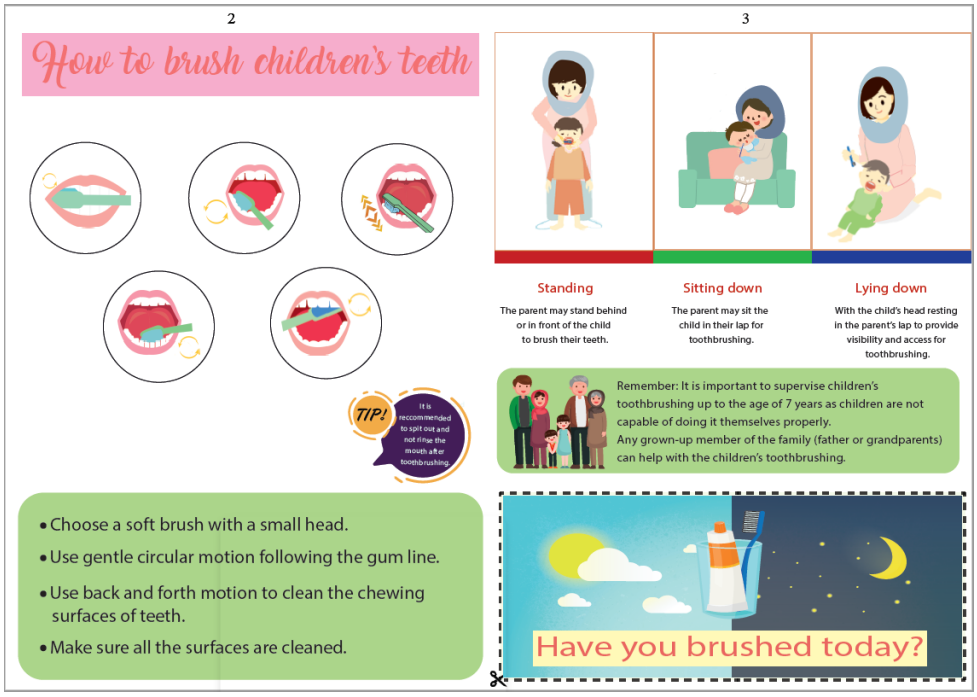
Stay calm and positive even when the child is being uncooperative as becoming forceful or raising one's voice can make children copy the behaviour by showing resistance and shouting. By building up toothbrushing routine in small steps can help make it less stressful for both the parent and child.


END

Leaflet

Front & back pages:

Centre pages:



Appendix 6.1: Feasibility study participant information sheets

Lady Health Workers for oral health promotion in children in Pakistan: Feasibility of developing and testing a behavioural intervention.

Information Sheet for Participants (Parents)

Please read this document carefully. We would like to invite you to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please ask us if there is anything that is not clear. If you decide you would like to take part then you shall be asked to sign a consent form and will be given a copy of this information sheet.

You are being asked to participate in a research study on promoting parental oral hygiene practices for their children. The purpose of this study is to understand how children's oral hygiene can be promoted by Lady Health Workers (LHWs) by giving oral health information to parent(s), during their routine home visits. Similar service has been found to be helpful in other countries and we want to assess its benefit for Pakistani population. Results of this study will help us in developing ways to support parents for routinising tooth brushing for their children.

You are asked to consider participating in the study because we have developed parental support material to help them engage in supervised tooth brushing of their children and we want to know how effective and acceptable it is to parent(s) who receive it and also to LHWs who deliver it. All the families that participate in the study will receive the parental support material and oral hygiene advice for their children's oral hygiene, once (on top of any services the family currently receives) from their visiting Lady Health Worker.

If you decide to take part, you would be given the parental support resource and advice for your children once by the Lady Health Worker. A short survey would be sent to you through text messages before and after the LHW visit. The survey will be based on questions related to your child's oral health and toothbrushing behaviours. You may be invited for a telephone interview, with the researcher, to understand your views about it. The interview will last for 30-60 minutes and will be audio taped.

You are free to choose whether or not to participate in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect you in any way. Should you wish to withdraw from the study, we may use data collected from you for the purpose of research, if you consent to it.

There is no known possible risk or discomfort that you can encounter connected to the activities in this study. We hope that we can demonstrate that receiving the parental support resource and oral hygiene advice from Lady Health Worker would be helpful to parents for making tooth brushing time easy and a routine for their children. If you need to travel for the purpose of this research, you shall be reimbursed your travel costs.

Your identity and location in this study will remain strictly confidential. The data obtained from audio recording shall be transferred securely to a software for the purpose of analysis and all identifying information of participants such as their names will be removed and given an ID instead. The results of the study, including data, may be published for scientific purposes but will not give your name or include any identifiable references to you.

If you have any questions or would like further information, please contact:

Research student Mehreen Faisal, E: mrf516@york.ac.uk

Department of Health Sciences, University of York

Thank you

Lady Health Workers for oral health promotion in children in Pakistan: Feasibility of developing and testing a behavioural intervention.

Information Sheet for Participants (LHWs)

Please read this document carefully. We would like to invite you to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please ask us if there is anything that is not clear. If you decide you would like to take part then you shall be asked to sign a consent form and will be given a copy of this information sheet.

You are being asked to participate in a research study on promoting parental oral hygiene practices for their children. The purpose of this study is to understand how children's oral hygiene can be promoted by Lady Health Workers (LHWs) by giving oral health information to parent(s), during their routine home visits. Similar service has been found to be helpful in other countries and we want to assess its benefit for Pakistani population. Results of this study will help us in developing ways to support parents for routinising tooth brushing for their children.

You are asked to consider participating in the study because we have developed parental support resource to help them engage in supervised tooth brushing of their children and we want to know how effective and acceptable it is to parent(s) who receive it and also to LHWs who deliver it. All the LHWs who consent to participate, and are working under the supervision of Lady Health Supervisors that are participating in the study, will receive training for oral hygiene advice and parental support resource delivery to parents for their children's oral hygiene, once (on top of any services the family currently receives) during routine home visits or not.

If you decide to take part, you would deliver the oral hygiene parental support resource and advice to parents/mothers for their children once during a routine home visit. After this you shall be invited for a telephone interview with the researcher to understand their views. The interview will last for 30-60 minutes and will be audio taped.

You are free to choose whether or not to participate in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect you in any way. Should you wish to withdraw from the study, we may use data collected from you for the purpose of research, if you consent to it.

There is no known possible risk or discomfort that you can encounter connected to the activities in this study. We hope that we can demonstrate that receiving the parental support resource and oral hygiene advice from Lady Health Worker would be helpful to parents for making tooth brushing time easy and a routine for their children. If you need to travel for the purpose of this research, you shall be reimbursed your travel costs.

Your identity and location in this study will remain strictly confidential. The data obtained from audio recording shall be transferred securely to a software for the purpose of analysis and all identifying information of participants such as their names will be removed and given an ID instead. The results of the study, including data, may be published for scientific purposes but will not give your name or include any identifiable references to you.

If you have any questions or would like further information, please contact:

Research student Mehreen Faisal, E: mrf516@york.ac.uk

Department of Health Sciences, University of York

Participant Consent Form

Title of Study: Lady Health Workers for oral health promotion in children in Pakistan: Feasibility of developing and testing a behavioural intervention

Please tick (√) the box to indicate agreement

1. I have read and understood the participant information sheet [date ....., version……] and have had the opportunity to ask questions and discuss this study. ☐

2. I understand my participation in the study is voluntary and that I am free to withdraw from the study: ☐

- At any time
- Without having to give a reason for withdrawing and without it affecting me in any way.
- With already collected data to be used for the purpose of research while maintaining participant confidentiality.

3. I understand that my interview or discussion sessions will be audio-recorded and notes taken. ☐

4. I understand that relevant sections of data collected during the study may be looked at by researchers. ☐

5. I understand that any information I provide, including personal data, will be kept confidential, stored securely and only accessed by those carrying out the study. ☐

6. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in any reports that result from the research. ☐

7. **I agree to take part in this study.** ☐

Participant Signature/thumb impression …… Date ……

Name of Participant:

Signature of person obtaining consent …… Date ……

Name of person obtaining consent:

Appendix 6.2: Text based survey

(Questions 4, 5, 6, 8, 9 and 10 were part of post-intervention survey)

1. Thinking of all the things you need to do to keep your child healthy, how important is brushing your child's teeth? *(indicate on scale)*

Not important				Very important
1	2	3	4	5

2. How often does your child usually brush their teeth (or have them brushed for them)?

(1) More than three times a day

(2) Three times a day

(3) Twice a day

(4) Once a day

(5) Less than once a day

(6) Never (skip question 3)

3. Who usually brushes your child's teeth nowadays?

(1) Your child

(2) An adult

(3) An adult and your child together (or child brushing with adult supervising)

4. Are you aware of the reocmmended tooth brushing behaviour for children?

(1) Yes

(2) To some extent

(3) No (Skip question 5 and 6)

5. When was the first time you became aware of the recommended toothbrushing behaviour for children?

(1) Before taking part in this study

(2) After being enrolled in this study and before delivery of support session by the Lady Health Worker

(3) After delivery of the support session by the Lady Health Worker

(4) Don't know

6. When did you start working towards achieving the recommended toothbrushing behaviour for your child?

(1) Before taking part in this study

(2) After being enrolled in this study and before delivery of support session by the Lady Health Worker

(3) After delivery of the support session by the Lady Health Worker

(4) Not yet

7. I am confident in my ability to brush my child's teeth (please choose an option which best describes how you feel)

(1) Strongly agree

(2) Agree

(3)Neither agree or disagree

(4) disagree

(5) Strongly disagree

8. The support session has been useful in supporting me to engage in my child's toothbrushing? (please choose an option which best describes how you feel).

(1) Strongly agree

(2) Agree

(3)Neither agree or disagree

(4) disagree

(5) Strongly disagree

9. How would you rate your child's dental health?

(1)Excellent

(2) Very good

(3) Good

(4) Fair

(5) Poor

10. How satisfied are you with your child's dental heath?

(1) Very satisfied

(2) Satisfied

(3) Neither satisfied nor unsatisfied

(4) Unsatisfied

(5) Very unsatisfied

Appendix 6.3: LHW training materials

LHW advice guide

Strong teeth, healthy kids

LHWs' Guide for delivery of children's toothbrushing advice to mothers

PROSPECT intervention
Version 1

Introduction

This guide has been developed to help you support mothers in developing healthy oral hygiene habits for their children early in their development. The focus of this guide is on initiation and continuation of toothbrushing of children's teeth. Toothbrushing with a fluoride toothpaste is the easiest and most effective way to prevent tooth decay in children and avoid pain, stress and financial costs associated with it. This training manual and training videos provided to you along with guide are for the purpose of providing you with evidence-based information regarding children's teeth, how to care for them, problems related to tooth decay and how to prevent them.

This guide will help you deliver advice to mothers related to toothbrushing in children as part of your routine home visits. According to research, just telling people to change their behaviour is not very effective in changing behaviour. However, providing people with motivation and reinforcing the message has proven to be effective in bringing a behaviour shift towards the desired behaviour. This guide presents tips to help you to use a set of materials – a flipbook, leaflet and a pack containing toothbrushes and a tube of toothpaste. Both these materials have been specially designed based on research evidence and with feedback from mothers and Lady Health Workers (LHWs) like you.

The materials

The children's toothbrushing advice shall be provided to mothers using two materials- the flipbook and the leaflet.

1. Flipbook

LHWs like yourself will deliver toothbrushing messages using a flipbook to guide the 10-minute behaviour support session with mothers. The flip book has 4 pages with messages about importance of teeth and what happens if they are not taken care of, and 3 pages about how to take clean children's teeth and how to manage the whole process.

2. Leaflet

The leaflet is to be provided to all the mothers during/after the support session. The leaflet contains all the important messages from the flipbook as a reminder to reinforce the advice delivered by you. It also contains a portion marked as a tear off part that has a adhesive at the back and can be used as sticker which can applied to bathroom mirror to remind about brushing children's teeth. This should be pointed out to the mothers so they can make use of the sticker provided.

3. Toothbrush and toothpaste

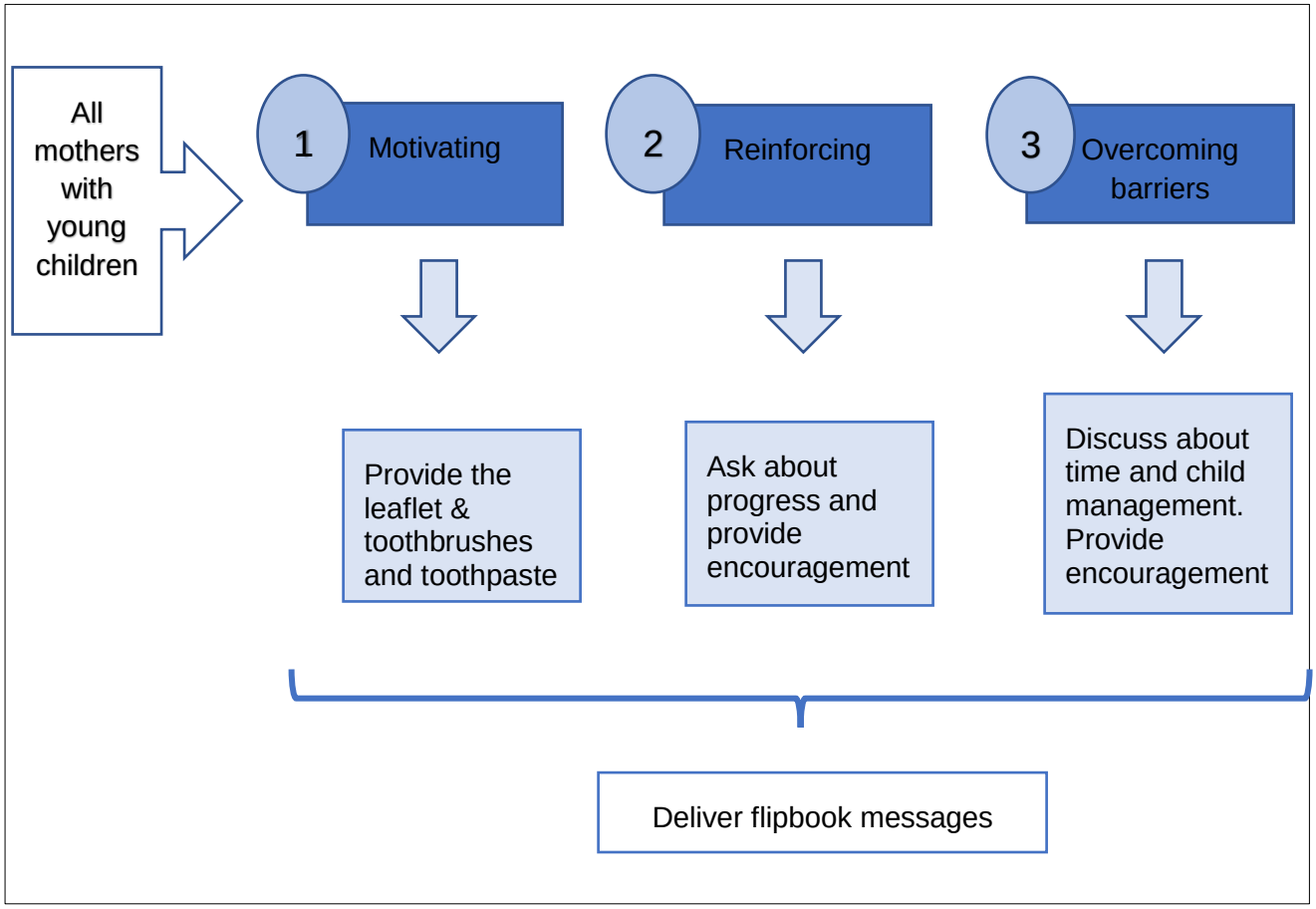
You shall also be provided with toothbrushes and toothpaste to be given out for the whole family, at the end of the support session.

When and how to use the behaviour support materials

We recommend that you provide the support session to all the mothers with children during your routine home visit during delivery of general health advice. If other family members are present, they should also sit in and hear the messages in order to provide

support to mothers in taking care of their children's teeth. The session should take about 10 minutes.

Each flipbook page has text on the back for LHW to use as prompts while the mother is looking at the picture shown. It is recommended that you cover all the points in the text, but you may want to tailor messages according to child's age or individual mother/child's needs. The materials are designed to cover all the important aspects of children's dental health that the mothers need to know and are in line with Department of Health England (DHE) guidance. The diagram below shows how to use the flipbook and leaflet in delivering behaviour support.



Delivering the flipbook messages

How to begin

It is recommended that you give the toothbrushing advice using the flipbook as part of the general health and hygiene advice that you regularly provide to women (more specifically mothers of young children in this case), during your routine home visits.

The established rapport that you share with families and your active listening skills are an asset and when provided with clear advice and encouragement, can help in initiation and routinisation of toothbrushing practice for young children. Thus, helping prevent tooth decay and improving oral health outcomes in children in the long run.

Flipbook page 1: Importance of teeth

What to cover

There will be prompts provided at the back of the slide for you to lead the conversation.

Purpose of the slide is:

- To explain the function of teeth

- Assess how important mothers consider their children's teeth to be.

Explain:

Milk teeth are as important as primary teeth.

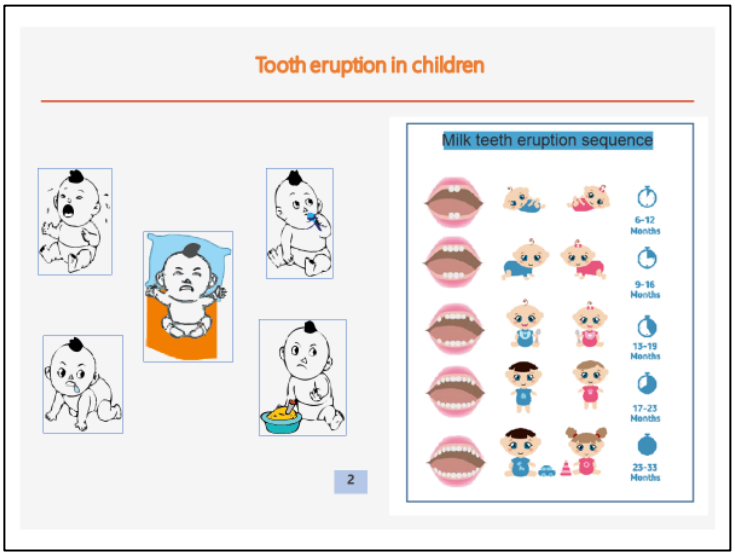
They act as place holders for permanent teeth

Tips:

If the mother does not agree then do not argue but instead respond by saying 'I used to think so too until I found out about the research results and what dentists say'

Some mothers may indicate that there are many dental problems in their family and/or bad teeth run in their family. You may respond to this by saying tooth decay is preventable if toothbrushing is initiated early in the life of a child which can avoid so many problems later on.

Flipbook page 2: Tooth eruption in children



What to cover

The main messages to convey on this slide are:

- Children's tooth eruption timeline

- Symptoms associated with tooth eruption and how to manage them.

Explain:

Children's milk teeth start erupting from 6 months onwards and they have a full set of 20 teeth around 2½ years of age.

It is normal for a child to feel irritable. Some of the symptoms include drooling, refusing food, biting/putting things in their mouth and difficulty sleeping.

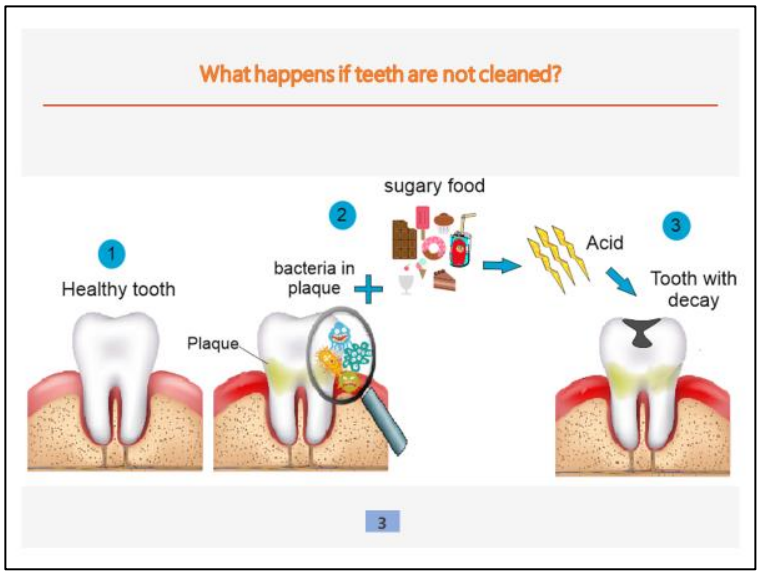
Provide them with tips on how to soothe a teething baby such as giving them teething rings to chew on, raw pieces of fruit or vegetable such as apple or carrots. Advise them never to leave the child unattended while they are eating in case they choke.

Tips:

Reassure mothers that these symptoms are normal during teething phase and will pass away soon and some children may experience no symptoms at all.

There is no evidence to support teething gels are effective but if they decide to use then it is advisable to use that is suitable for young children and better to avoid using homeopathic ones as they can have serious side effects.

Flip book page 3: What happens if teeth are not cleaned



What to cover

The main messages contained in this slide are:

- To explain the process of tooth decay.

Explain:

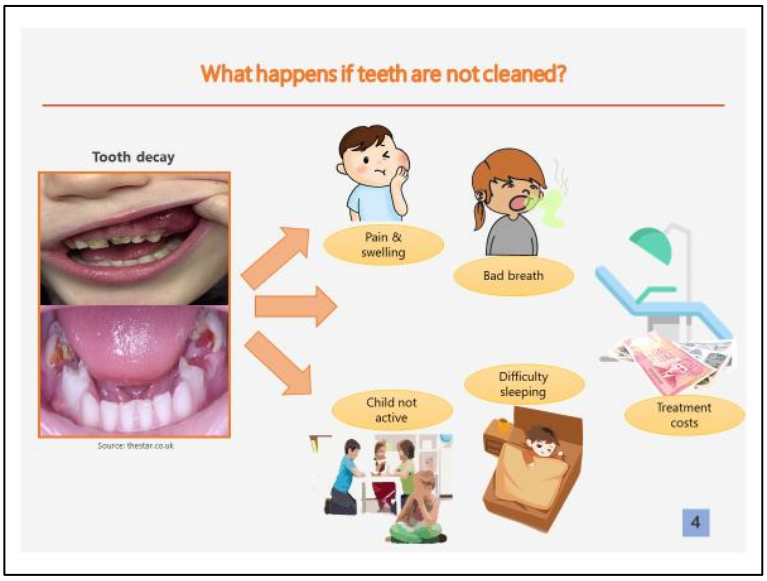
How not cleaning teeth results in formation of a film (plaque) containing germs (bacteria) which then feed on sugars and produce acids that attack the tooth surface causing loss of minerals such as calcium and phosphate, resulting in tooth decay.

Decay affects primary teeth much more rapidly than permanent hence it is essential children's teeth be cleaned as soon first tooth appears.

Tips:

Some mothers might argue that milk teeth appear clean and do not require cleaning. Advise them that plaque starts to form within 4-12 hours of brushing hence it is very important to clean teeth twice daily.

Flipbook page 4: What happens if teeth are not cleaned?



What to cover

The main messages in this slide are:

- To convey the message that tooth decay resulting from not cleaning teeth can have negative consequences for both child and the family.

Explain:

1. Health consequences

- Tooth decay in primary teeth progresses rapidly and can

result in pain and swelling. This can affect child's ability to chew and may even cause loss of appetite affecting child's physical development and growth.

- Toothache usually becomes more severe at night while sleeping because of position of the head which causes increased blood flow to the already swollen soft tissues within the tooth causing pressure which results in increased severity of pain. Lack of sleep also results in negative health impact.

2. Social consequences

- Bad breath resulting from unclean mouth can be a source of embarrassment for children and can result in low self-esteem.

- Pain, poor appetite/inability to chew and/or lack of sleep can result in children not being very active and even missing school days.

3. Financial consequences

- Time taken off from work by parents and cost of treatment can result in financial burden on the family.

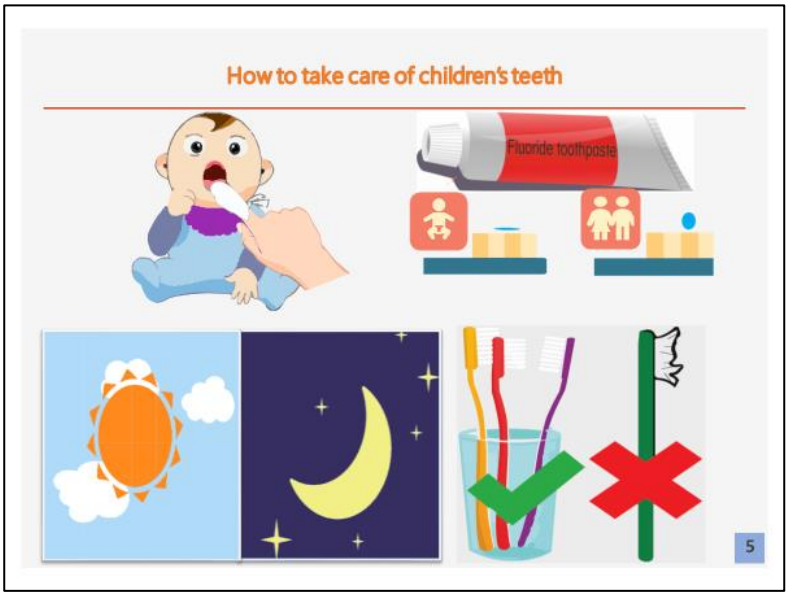
Tips:

- Some mothers may mention their child or someone in the family already has a toothache and may ask you for medicine to cure it. Advise them that medicines can only relieve the symptoms and to cure the problem- tooth decay, they need to visit the dentist otherwise the toothache will keep coming back.

- Waiting out the tooth decay as the primary teeth will eventually fall out. Advise <u>against</u> this course of action as untreated tooth decay can lead to infection which if spreads, has the potential to become life threatening.

- Someone might even express feeling of guilt for not being able to take care of their children's teeth. Aim to reduce their negative emotions and motivate them by saying it is never too late to start and the sooner that they start, the better oral health outcomes for their children.

Flipbook page 5: How to take clean children's teeth



What to cover

The messages to convey in this slide are:

- How to clean children's mouth before teeth erupt

- How to take care of children's teeth with regards to toothpaste and toothbrush use.

Explain:

Even before the teeth erupt, it is recommended that child's mouth be cleaned after feeding them. A clean, soft moist cloth can be wrapped around the finger and be used to wipe the gums pads. Doing this ensures baby's mouth is clean and helps lay the foundation for a routine of toothbrushing once teeth appear.

It is very important to explain about the choice of toothpaste and the amount to be used for children according to their age. Explain that using fluoride toothpaste makes teeth strong (by replacing any minerals lost due to bacterial acid attack). A family toothpaste containing 1350-1500 ppm fluoride can be used for everyone. Children under the age of 3 years should use a smear of toothpaste and between 3-6 years should use a pea sized amount. Keep the toothpaste out or reach of children and they should not be allowed to lick or eat toothpaste.

Everyone should have their own toothbrush in the family and toothbrushes should not be shared. Children's toothbrushes with smaller heads are best to use for cleaning children's teeth. Toothbrushes should be replaced after every 3-4 months or when their bristles become frayed.

Brushing twice daily is very important. Once last thing at night and one another time during the day.

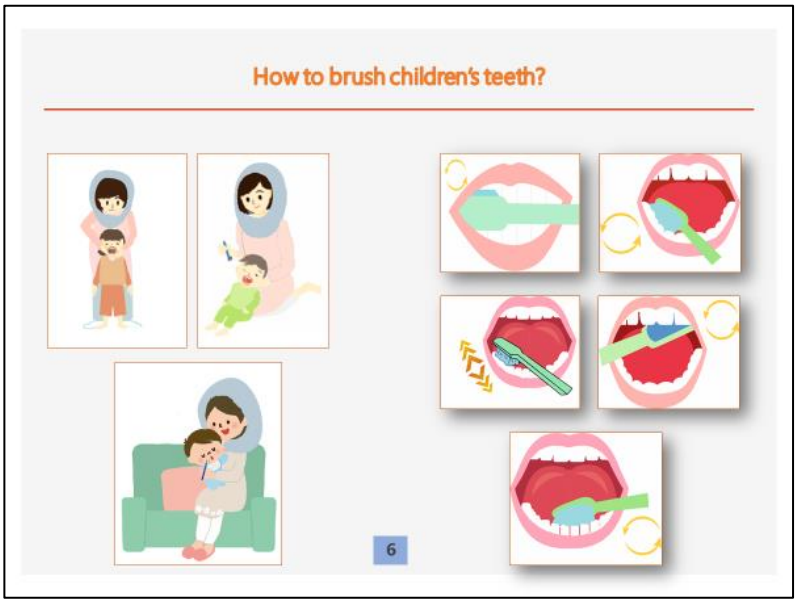
Tips:

Emphasise the amount of toothpaste to be used. TV commercials and newspaper ads often show toothpaste covering the whole brushing surface of the toothbrush. This much toothpaste is not needed. Using a smear of toothpaste ensures that small children who cannot spit, are not ingesting any excess fluoride.

Advise that spitting only after toothbrushing and not rinsing helps fluoride to stay in contact with the tooth surface and prevents its being washed away.

Reinforce the message about twice daily brushing and indicate brushing at night last thing before going to bed is very important otherwise bacteria feeds on food stuck in teeth and created producing acid leading to tooth decay.

Flipbook page 6: How to brush children's teeth



What to cover

The main messages in this slide are:

- Toothbrushing postures for brushing children's teeth

- Toothbrushing method and steps

Explain:

The importance of supervised brushing up to the age of 7 years.

The three different postures that be used for brushing infants and toddler's teeth are (1) while standing behind or in front of child (2) child lying down with their head in mother's lap (3) Child sitting in mother's lap.

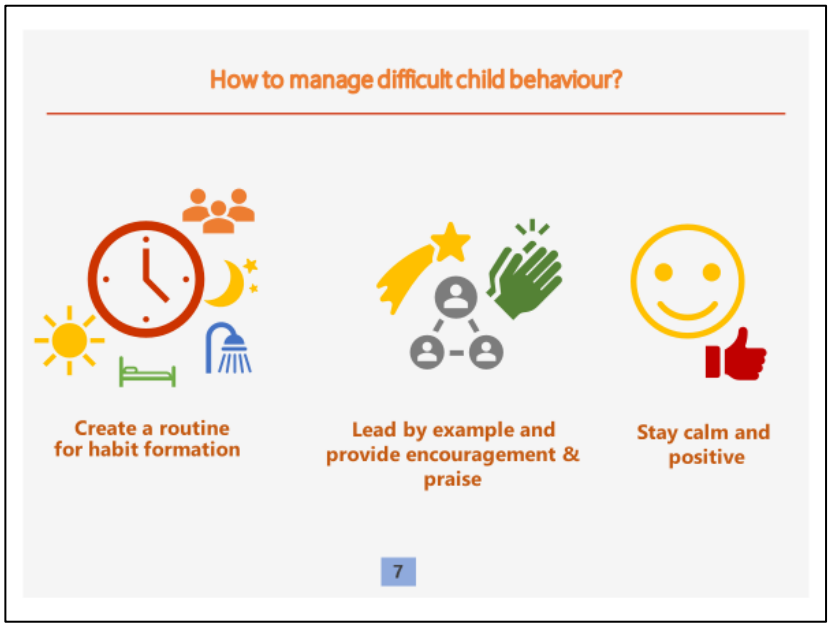
For toothbrushing method, round circular motion should be used roughly following the contours of the gumline, except while brushing the chewing surfaces of the back teeth when back and forth motion can be used. There is no particular order to be followed but it should be made sure that all surfaces are cleaned. As a general rule of thumb, toothbrushing should be carried out for approximately two minutes to ensure proper cleaning.

Tips:

Some mothers might argue that brushing very young children's teeth make them weak. Advise them that using a soft toothbrush and brushing gently would not hurt the teeth and gums but help in keeping keep clean and disease free.

Sticking to one order for example brushing left to right or vice versa helps in making sure all surfaces are cleaned and no part is inadvertently missed.

Flipbook page 7: How to manage difficult child behaviour?



What to cover?

The main messages in this slide are:

- How to create and manage a toothbrushing routine

- How to manage toothbrushing of an uncooperative child.

Explain:

How they can manage time and toothbrushing by associating with everyday routine things such as during child's shower/bath rime and right after dinner (not eating anything after that). Taking help of other family members such as fathers or child's grandmother can also help.

Parents should lead by example as most children follow the actions of their parents. Making toothbrushing a fun time and lots of praise and encouragement will help reinforce the behaviour.

It is important to stay calm and positive, using force or raising one's voice when the child is being cooperative can be counter-productive and child may resist further.

It is important to not to continue with the toothbrushing every day to create a habit even if the child cries in order not to reinforce negative behaviour.

Tips:

'Child wants to brush himself/herself'- Advise mothers that they can allow child to start with the brushing but to finish it up for them in the end to ensure all the tooth surfaces are cleaned.

'Child starts crying if I try to brush his teeth'- Recommend that mothers don't give up even if the child cries, as this would otherwise reinforce negative behaviour. With time child would understand that toothbrushing has to be done every day and is part of the routine.

'Child resists and does not sit still'- Advise that even getting to brush one or two teeth in the beginning is progress and continues twice daily every day. With time child would get in the habit and mother talking to child and staying calm during the process would help child in becoming cooperative gradually.

----------The End----------

Toothbrushing promotion in children

Lady Health worker Handbook

Overview

Why has this guide been developed?

This guide has been developed to provide an understanding of the importance of oral health as part of the general health and how dental diseases can be prevented in children.

Objectives

The objectives of this manual are to help develop knowledge and understanding of:

- Oral health and why is it important as part of general health and wellbeing
- Tooth eruption and causes of tooth decay in children
- Prevention of tooth decay in children
- Parental barriers to toothbrushing practices for their children and how they can be supported in this by provision of tailored advice.

How to use this guide?

The purpose of this guide is to provide guidance to Lady Health Workers (LHWs) who work in their communities as a link between the people and the healthcare and are responsible for providing basic health maternal and child health services.

As providing health advice and supporting mother's in adopting healthy child rearing practices to ensure optimal child growth and development is an integral part of LHWs work, incorporating toothbrushing advice for mothers of young children can help prevent tooth decay in them and form healthy habits early in the life course. This approach has been proven to be effective in reducing tooth decay in children in several other countries.

This guide will help you deliver appropriate toothbrushing advice to parents of children with the help materials that have been developed based on scientific evidence and input from mothers and LHWs.

The guide has been divided into 3 units:

Unit 1: Introduction to oral health

Unit 2: Prevention of tooth decay

Unit 3: Provision of behavioural support by you

Unit 1: Introduction to Oral Health

The focus of this unit is to provide an introduction to children's oral health.

> Oral health is defined as:
>
> 'multi-faceted and includes the ability to speak, smile, smell, taste, touch, chew, swallow and convey a range of emotions through facial expressions with confidence and without pain, discomfort and disease of the craniofacial complex.'

Why is it important to have a healthy mouth?

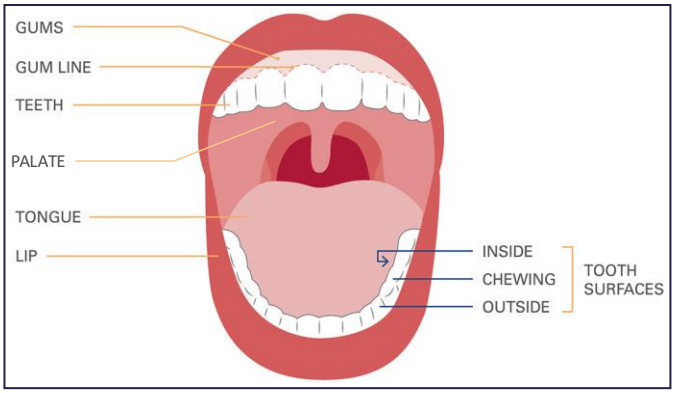
Oral health is very much a part of the general health. Our teeth help us speak clearly, chew and digest food and also give our face its shape. Keeping good oral and dental hygiene cam help prevent bad breath, tooth decay and gum disease which leads to tooth loss. Research has shown that dental disorders such as tooth decay and tooth loss can negatively impact a person's self-esteem and quality of life. Taking care of the teeth means all these problems can be avoided and can help one keep their teeth as they grow older.

A peek inside the mouth

Our mouth consists of three chief structures:

- **Teeth** help in chewing food
- **Tongue** help with taste and positioning of food
- **Palate** separates mouth from the nasal cavity.

Speech is produced with the help of all these structures and the lips.

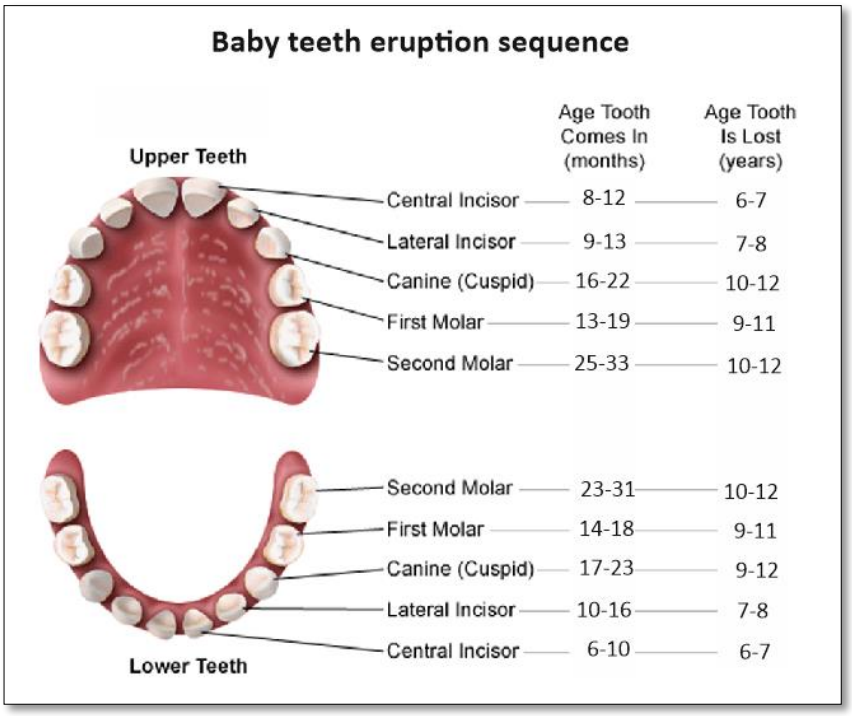


Why is keeping teeth clean so important?

Poor oral hygiene leads to bad breath, tooth decay and gum disease causing bleeding and swollen gums (gingivitis) which can advance to loss of tooth supporting structures (periodontitis) leading to tooth loss if left untreated.

Teething schedule in children

Children's first set of teeth are known as primary teeth or milk teeth or deciduous teeth. They start to develop while the baby is still in the womb. On birth, babies have 20 set of primary teeth (10 in the upper jaw and 10 in the lower jaw) hidden within gums. Although teething time in children may differ, the first tooth generally starts to appear at the age of 6 months and continues up to about 33 months of age.



Tooth decay

What is it?

Tooth decay is the damage to the tooth which is caused by bacteria by breaking down the food particles present on the tooth surfaces into acids.

Early Childhood Caries (ECC) is the term used to describe presence of decay in children younger than 6 years of age.

Baby bottle or Nursing caries: This is also a type of ECC but mostly seen in upper front teeth. This is caused by children sleeping with bottles, hence the name. When children go to bed with bottles containing milk or juice, basically anything except water, it provides a constant supply of food for bacteria to breakdown and form acids resulting in tooth decay. This type of decay usually affects children between the ages of 1-2 years.

On demand breast feeding and use of pacifiers dipped in honey or other sugary substance can also cause Nursing caries.

How does it happen?

Plaque is a sticky film that forms everyday around the teeth near the gum line and contains bacteria. These bacteria are responsible for causing tooth decay and gum disease. When diet rich in sugars such as carbohydrates or starch (such as milk, bread, sweets etc) is consumed, the bacteria in the plaque breakdown the sugars to get energy and produce acid which damages the tooth structure by causing loss of tooth minerals (calcium, phosphates etc) leading to tooth decay and eventually holes or cavities.

Regular toothbrushing helps remove the layer of plaque and prevents oral diseases such as tooth decay and gum disease.

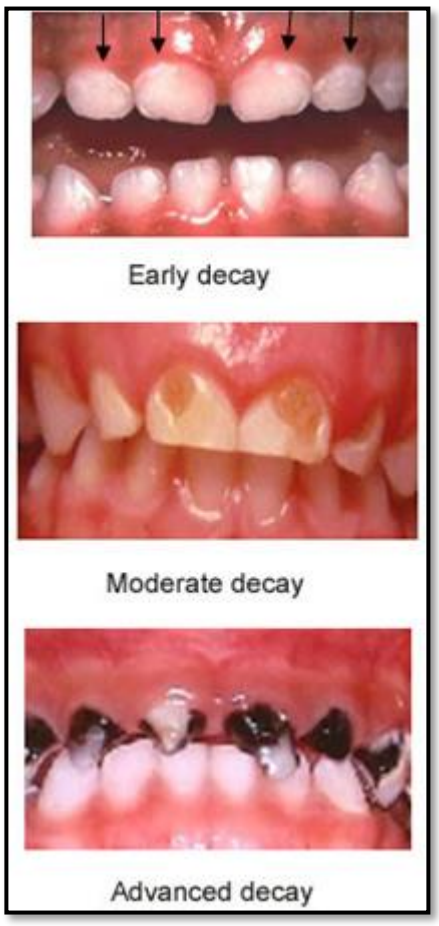
Early tooth decay appears as whitish discolouration or white spots on the surface of the tooth and is hard to spot. It may also appear as brownish spots and becomes dark brown or black as it progresses.

What are its consequences?

Tooth decay in primary teeth progresses very rapidly causing discomfort and pain. It left untreated it can even lead to infection and swelling or formation of pus. It can negatively impact a child's ability to eat, sleep, play and attend school. Treatment of tooth decay can also incur financial costs on the family and may result in dental treatment anxiety in children.

Is it possible to reverse the process of tooth decay?

Early tooth decay as indicated by presence of white spots which is the area of loss of minerals from the tooth surface, can be reversed at this stage and enamel can repair itself by using minerals from saliva, and fluoride from toothpaste and other sources. However, if process of tooth decay continues and as more minerals are lost from the tooth surface, the process cannot be reversed and requires treatment of the affected tooth by a dentist.



Unit 2: prevention

Fortunately, tooth decay is easily preventable!

Oral hygiene and healthy habits

Maintaining oral hygiene can help prevent against diseases such as tooth decay and gum diseases. It is important to advise mothers to follow oral hygiene measures for their children from a very young age to ensure formation of healthy habits.
Even before teeth appear, advise mothers to wipe their children's gum pads with a clean, soft cloth after feeding them and ask them not to let the child sleep with the baby bottle in his mouth.
Use of pacifiers dipped in sugar/honey should be strongly discouraged and consumption of juices or sweet drinks should be limited to mealtimes instead of child having it on demand through out the day.

Tooth brushing

Tooth brushing should be initiated in a child as soon as the first tooth appears. Twice daily tooth brushing with a fluoride toothpaste can help clear away the plaque and provide minerals thus preventing tooth decay and gum diseases.

<u>Child aged up to 3 years</u>

Parents or carers should brush or supervise toothbrushing of their children's teeth
Use a smear of fluoride tooth paste containing no less than 1000ppm of fluoride or a family tooth paste containing 1300 to 1500 ppm fluoride (the fluoride content in a toothpaste is provided on the pack).
As young children cannot spit, using a smear of toothpaste ensures they are not taking in too much toothpaste.
Brush twice daily for about 2 minutes: once last thing before going to bed and once at another time during the day.
Don't let the child lick or eat the toothpaste.

<u>Children aged 3 to 6 years</u>

Parents or carers should brush or supervise toothbrushing of their children's teeth
Apply a pea size amount of fluoride tooth paste containing no less than 1000ppm of fluoride or a family tooth paste containing 1300 to 1500 ppm fluoride (information about fluoride content is provided on the pack).
Brush twice daily for about 2 minutes: once last thing before going to bed and once at another time during the day.
Spitting after brushing, avoid rinsing to prevent fluoride from washing off.

<u>Children aged 7 and above</u>

Children aged 7 and over can brush their teeth themselves but it is a good idea to watch them to ensure they are brushing properly and for about 2 minutes.
Twice daily brushing, once last thing before going to bed and on one another occasion

Use of fluoride toothpaste containing 1300-1500 ppm fluoride (information about fluoride content is provided on the pack).
Spitting out after brushing, avoid rinsing to prevent fluoride from washing off.

Delivering advice & Reinforcement

Providing support to parents/carers (see LHW advice guide for details)

- Provide oral hygiene advice to mothers as part of the general health and hygiene advice
- Listen to their concerns and provide them with appropriate advice to overcome their problems
- Help mothers in setting targets for twice daily tooth brushing of their own and their children's teeth.
- Review their progress and provide guidance and encouragement for them to continue with their effort and motivate for further improvement where appropriate.

Positive reinforcement has been shown to be an effective method to make people change their behaviour and to continue with the desired behaviour for a longer time period.

Common myths regarding primary teeth

"Milk teeth appear clean, they don't need cleaning"
Wrong! Not cleaning teeth means risking tooth decay which can be easily prevented by twice daily tooth brushing. Plaque forms every day and has to be removed to ensure prevention of tooth decay and gum diseases.

"Toothbrushing of milk teeth causes them to become loose and they fall off quickly"
Not true! Gentle toothbrushing ensures teeth are cleaned properly and massages the gums improving blood circulation. Hard toothbrushing should be avoided so as not to cause damage to the teeth and gums.

"Milk teeth fall off eventually so it is okay not to get them treated if they have decay"
Tooth decay in milk teeth progresses rapidly to reach the nerves contained within the tooth. This can lead to discomfort, pain and even swelling, infection and pus discharge. Getting decay treated at the early stage can help avoid all these complications.

END

LHW training videos

Training video 1

Training video 2

Training video 3

Appendix 6.4: Fidelity checklist

Intervention content framework for developing fidelity checklist

Sr.No.	Topics	Key targets (behavioural determinants)	Ingredients of intevention	Behaviour Change Techniques
1.	Importance of teeth	Knowledge	• Assessing how important mothers consider children's teeth to be • Opportunity to start conversation about primary teeth	Social support (unspecified)
2.	Tooth eruption		• Detailing about tooth eruption in children (timing, symptoms and how to soothe a teething child)	Instructions on how to perform the behaviour
3.	Tooth decay process		• Explain to mothers the tooth decay process	-
4.	Consequences of not cleaning teeth	Knowledge & Beliefs about consequences Emotion	• Raise awareness about health consequences such as tooth decay, pain, inability to sleep, swelling, infection etc. • Talk about embarassment caused by bad breath, treatment costs and missed days from school and work. • Motivating mothers by stating it is never too late to start adopting health	Information about health consequences Information about social and environmental consequences Reduce negative emotions

			oral hygiene habits and incase of tooth decay already present in their children's primary teeth, advise them to get it treated as soon as possible	
5.	Toothbrushing in children	Skills	• Instruct on how to clean children's mouth and/or brush children's teeth including positions and technique.	Instructions on how to perform the behaviour Demonstration of behaviour
6.	Provision of toothpaste & toothbrushes and leaflet	Environmental context and resources Memory, attention and decision processes	• Provide Fluoride toothpaste and toothbrushes for the whole family. • Provide information leaflet to the mothers and indicate the sticker area to act as a reminder	Adding objects to the environment Instructions on how to perform the behaviour Demonstration of behaviour Prompts & cues
7.	Management: Plan Do	Beliefs about capabilities Reinforcement	• Advise on how to create a predictable routine • Advise on how to lead by example and provide praise and encouragement	Goal setting Action planning Behaviour substitution Identify self as role model

	Review	Goals & intentions Social influence Behaviour regulation	• Encourage to stay calm & positive, seek help from other family members • Provide encouragement	Non-specific reward Social support(practical) Problem solving Feedback on behaviour Review behaviour goals

Intervention Delivery Checklist

Mother's name:_____ Date:_____

Child's age:_____ Name of LHW:_____ Duration:_____

S.No.	Activity	Elements	Done	Notes
1	Initiated conversation with the mother about importance of teeth	• Provided information about importance of teeth • Assesed how important mother considers her children's teeth to be	☐ ☐	
2	Asked the mother about her child's teething and how she dealt with it	• Provided information about teething schedule in children • Informed about common teething symptoms and how to deal with them	☐ ☐	
3	Explained about the process of tooth decay	• Informed about plaque and its contents • Explained how bacteria causes tooth decay	☐ ☐	
4	Enquired about mother's thoughts regrading consequences of tooth decay in children	Explained about: • Health consequences • Social and environmental consequences • Advised to visit the dentist as soon as possible incase of decay already present • Provided reassurance (especially in case where decay is already present) that it is never too late to start with healthy oral hygiene	☐ ☐ ☐ ☐	

		habits for their children.		
5	Provided information about how and when to clean/brush children's mouth/teeth.	• Demonstrated how to use a piece of soft, moist cloth wrapped on finger to clean their child(ren)'s gums. • Highlighted the amount of toothpaste to be used according to child's age • Emphasised the importance of twice daily parental supervised toothbrushing of children	☐ ☐ ☐	
6	Provided information about toothbrushing positions and technique	• Demonstrated to the mother the three different positions for brushing child(ren)'s teeth and toothbrushing movements • Provided leaflet to the mother • Indicated the part on the leaflet which can be stuck to mirror/fridge to act as toothbrushing reminder • Provided toothpaste and toothbrushes for the whole family	☐ ☐ ☐ ☐	
7	Encouraged mothers to overcome barriers	• Helped mothers in goal setting and action planning • Advised to seek help from other close family members when needed • Prompted mothers to set example and offer praise and encouragement to children	☐ ☐ ☐	

		• Advised mothers to stay calm and keep going	☐	
8	Summarised & Encouraged	• Helped the mother to set goal for twice daily supervised toothbrushing for her child(ren). • Encouraged mothers to keep trying. • Provided tailored advice according to the mother-child needs	☐ ☐ ☐	

Appendix 6.5: Interview topic guides

Interview Topic guides for Lady Health Workers (LHWs)

Introduction

- Outline the purpose for the interview and thank the participant for agreeing to be interviewed
- Talk the participant through the interview methods:
    - Interview to be recorded
    - No right or wrong answers
    - Participation is voluntary
    - Assure about confidentiality
    - Written Informed consent (obtained previously)

1. Background Information/ Icebreaker

- How long have you been working in your role?

- How do you like your work (Prompts: what do you enjoy most, what are the challenges?)

- What are your main duties? (Prompts: related to health promotion? Where do you do it mostly?)

- In the absence of any standardised guideline related to oral health promotion as part of your work, how have you supported people in your community in this regard? (prompt: what do you do when people ask your advice on their or their children's dental problems?).

2. Recruitment process

- How did you find the process of recruiting mothers for this study? (Prompts: Was it easy/ difficult? what were the challenges, (probe: why is that?)).
- You were tasked to recruit 5 mothers, how many did you approach before the required number of 5 mothers expressed interest for participation in the research? (prompt: what could be the reason for declining (probe: why do you think so?)).

3. Training

- Now I would like to talk to you about the training provided to you to facilitate the delivery of the behavioural support session to the mothers.
- What do you think about the training that was delivered to you via training videos through the WhatsApp group? (prompts: was it helpful/less helpful?, probe: why is that so?).
- How did you find the training videos? (Prompts: were they well timed/too long/ too short, easy to understand, clarified concepts?).

- Under different/ normal circumstances, how would you like the training to be delivered? (prompts: venue, timings, duration etc).

4. Support materials/resources

Now moving on to the support materials that were provided to you:

- How did you find the written materials? (Prompts: were they easy to read, understand and navigate?).
- Was the flipbook easy use to and handle during the provision of the support session to the mothers? (probe: why is that so?).
- What do you think about the leaflet and the provision of toothbrushes and toothpaste for the family? (probe: why is that so?).
- How did you find the process of filling the support session checklist? (prompts: was it easy difficult, probe: why is that so?).
- How can they be improved? (prompt: messages, language, pictures etc).

5. Delivering the support session

Now that you have delivered the support session to the mothers, I would like to hear from you what you thought about it. There are no right or wrong answers, I am simply interested to know your views about it (Keeping the LHW filled intervention delivery checklist and flipbook at hand for reference)

- How many mothers have you delivered the support session to?
- How long did the sessions last on average? (prompts: did you have enough time? Were they too long/short?).
- How was your experience of delivering it? (Prompts: what went well, what did not go so well?).
- Was there need to/ did you provide tailored advice to the mothers?
- What did you most like about delivering the support session (prompts: do you think this could be easily incorporated into your routine home visits?).
- What were the challenges that you faced? (prompts: working during the Corona virus pandemic? were there any questions/aspects that mothers enquired, and you found difficult to clarify?).

Moving on to talk in detail about the structure of the session:

<u>Importance of teeth (page 1):</u>

This was the starting point to bring up the conversation with mothers about their children's oral care.

- How did you find discussing about children's oral health to mothers? (prompt: was it easy/ difficult?).
- Did the mothers look interested?
- How can this be improved? (pictures, message etc).

<u>Teething in children (page 2):</u>

- How did you find discussing teething in children with mothers?
  - what worked well/ less well?

- Was there any tailoring of the messages done?
- How could this be improved? (pictures/ message etc).

Tooth decay process and its consequences (pages 3 + 4)

- How did you find discussing about the tooth decay process? (prompts: was it easy/difficult?)
- How can this be improved? (pictures/messages?)
- How did you find discussing about the consequences of tooth decay? (prompts: easy/difficult? Why so?).
- Did mothers engage with you in this? (prompts: did it invoke any emotions in mothers?)
- How can this be improved? (pictures/ messages)?

Toothbrushing in children (pages 5+6)

- How did you find the process of explaining the toothbrushing positions and techniques to the mothers (prompts: easy/difficult, lengthy)?
- How did the mothers seem to receive the advice? (prompts: did they seem interested? Did they discuss any problems/beliefs about when should toothbrushing be initiated in children)?
- Were you able to provide the advice comfortably (with or without tailoring?).

Managing difficult child behaviour (page 7)

You may have discussed with the mothers about the different ways that can help them routinise toothbrushing for their children, including tips on how to manage difficult/uncooperative child behaviour.

- How did you find the process of advising about these matters? (Prompts: easy/difficult)?
- Were you able to engage mothers to set goal of twice daily toothbrushing of their children's teeth?
- Did you find it easy/difficult to motivate the mothers (why so?).
- Did mothers discuss with you their problems and were you able to provide tailored advice?
- How can this be improved? (Prompts: is there something more that can be added/removed?).

6. Impact and sustainability

- How much prior knowledge regarding children's oral health/ care and hygiene did you have?
- Has delivering the support session changed your knowledge? (how?)
- How confident would you rate yourself to be in supporting mothers for engaging in children's toothbrushing? (on a scale of 1-10 where 1 is least likely and 10 is extremely likely).
    - Why is that?

- How likely are you to continue using this resource in your routine work? (on a scale of 1-10 where 1 is least likely and 10 is extremely likely).
    - Why is that?
- What were the challenges faced due to the Corona virus pandemic (prompts: impacts on fieldwork, any concerns, any further support required).

7. **Final questions**

- Any final comments about the aspects of the resource that can be improved? (content, resources, length/timing etc).

8. **Closing remarks**

Thank the participant for their input & time.

Interview Topic guides for mothers

Introduction

- Outline the purpose for the interview and thank the participant for agreeing to be interviewed
- Talk the participant through the interview methods:
    - Interview to be recorded
    - No right or wrong answers
    - Participation is voluntary
    - Assure about confidentiality
    - Written Informed consent (obtained previously)

9. Experience of the intervention (acceptability)

I am going to talk to you about the behavioural support session that was delivered to you by your Lady Health Worker (LHW). There are no right or wrong answers, I simply want to know your views so please talk to me frankly about it.

Warm up question: How many children do you have?

a) Introductory questions

- Overall how did you find the session?
- How long was the session?
  Prompts: Do you think that the session was well timed?/ Did you get an opportunity to ask questions?
- What is it that you liked about it? Prompt: why is that?
- Was there something you did not like? Prompt: Why is that?

b) Detailed look at the different components of the session

(Keeping the LHW filled intervention delivery checklist and flipbook at hand for reference)

<u>i) Importance of oral health (page 1)</u>

- Can you tell me what you and your LHW discussed about the importance of health?

- What did you learn?

- How do you feel about taking care of your children's teeth?

- Was the information/discussion helpful?

<u>ii) Teething in children (page 2)</u>

The LHW may have discussed with you about teething in children.

- What did you learn?

- How do you feel about taking care of a teething child?
- Was it helpful/ less helpful?

iii) Tooth decay process and its consequences (page 3 + 4)

The LHW may have explained to you the tooth decay process and its consequences.

- What did you learn?
- How did you feel at this point? (Prompt: Was it a surprise for you?)
- Was it helpful? not helpful? (Probe: why?)
- Is there anything else that would have been helpful to talk about? (what is that?)

iv) Toothbrushing in children (page 5+6)

Your LHW may have clarified to you about how to clean your children's mouth/teeth

- What did you learn?
- Was anything a surprise for you? (Probe: what and why? Could be the amount of toothpaste to be used and age limit for supervised toothbrushing)
- Do you think this was helpful?
- Is there something else that might have been useful to add?

v) Managing difficult child behaviour (page 7)

Your LHW may have discussed with you about different ways that can be used to help initiate and routinise your child's toothbrushing.

- What did you learn? (Prompt: how do you manage difficult child behaviour).
- Was anything a surprise for you? (Probe: what, why?)
- Do you think this was helpful?
- Is there something else that might have been useful to add?

10. Perceived impact of the intervention (based on the Theoretical Domains Framework)

a) Readiness/Feeling equipped (pertaining to domains of knowledge, skills, beliefs about consequences and emotion).

- How do you feel about brushing your children's teeth (Prompts: how is it different from what you used to feel before?)
- What do you think will happen if you supervise your child's toothbrushing?
- Do you think you have the necessary knowledge and skills to brush/supervise brushing your children's teeth? (Prompts: Do you find it easy/difficult?)
- Do you feel that the support session has helped/ not helped (Probe: why is that?)

b) Self-efficacy (pertaining to domains of beliefs about capabilities, social support, environmental context and resources).

- How confident do you feel about brushing/supervising child's toothbrushing (Prompt: has the support session helped/not helped? (probe: why is that?)).
- To what extent do you feel it is your responsibility to brush your children's teeth? (Prompts: Do other family members offer to help? Do you seek their help?).
- How do you find managing your child's toothbrushing routine? (Prompts: early morning rushtime, around bedtimes? Other children/siblings (Probes: why is that?)).
- Has the provision of toothbrushes and toothpaste helped/not helped with brushing your child's teeth (Probe: Why is that?).

c) Planning (pertaining to domains of intentions and goals, behaviour regulation, memory attention & decision processes).

- Has the session helped you in intending/setting goals for your child's twice daily toothbrushing?
- How do think you are able to manage your child's uncooperative behaviour (Prompts: Are you making any progress (Probe: why is that?).
- Do you find remembering to brush your child's teeth easy/difficult? (Prompt: has the leaflet and the sticker been helpful in this regard?).

11. **Final questions**

Finally is there anything else that you would like us to change?

- Pictures (more or less?)
- Messages (language level etc)
- Materials (leaflets/sticker. Toothbrush and toothpaste etc).

12. **Closing remarks**

Thank the participant for their time.

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