A RANDOMISED CONTROLLED TRIAL TO TEST A PREVENTIVE DENTAL HEALTH PROGRAMME FOR MOTHERS OF INFANTS WITH CLEFT LIP AND/OR PALATE

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ABSTRACT

The University of Manchester

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Doctor of Philosophy

A randomised controlled trial to test a preventive dental health programme

for mothers of infants with cleft lip and/or palate

30th September 2010

Aim: To improve the dental behaviour and knowledge of mothers of infants with cleft lip and/or palate (CLP).

Design: A randomised controlled, single blind, prospective clinical trial of one year duration, measuring the effectiveness of a preventive dental health programme.

All mothers and their infants attending the regional cleft unit following primary surgery were invited to participate. All data collection took place within the same cleft unit.

Primary objectives examined dental attendance, use of a fluoride toothpaste and introduction of a feeder cup.

Mothers completed dental behaviour and dental health knowledge questionnaires followed by stratified random allocation concealed from the researcher, to test or control groups. Preventive dental advice was given according to group allocation. Data were collected at baseline, after 12 months and aged three years at a multidisciplinary clinic review. An independent researcher collected the 12 months data and a specialist in paediatric dentistry the data at aged three years, both were blinded to group allocation.

Results: 88 infants were recruited with 87 available at 12 months and 82 at three years, median age at baseline 10.5 months.

More infants in the test group had been examined by their dentist, 12 months (p = 0.063), 3 years (p = 0.054).

More infants in the test group were using a high fluoride toothpaste at 12 months (p = 0.001), no difference was found at three years (p = 0.105).

Fewer infants in the test group were consuming drinks considered detrimental between meals at 12 months (p = 0.022), no difference was detected at three years (p = 1.000).

A comparison of dental health knowledge over time revealed some differences.

The dental health status reported 60 (73%) children were caries free and 17 (21%) with dentinal caries requiring attention. Four children were in need of dental extractions under general anaesthesia. This study was not powered to detect important differences between groups. The mean caries experience, decayed, missing and filled teeth (dmft) for 82 children examined at three years was 0.51(SD 1.45) and for those 17 (21%) with caries into dentine, 2.47 (SD 2.35).

Conclusion: A dental health programme initially changes behaviour, however over time this is not maintained. Due to moderate caries levels the regional cleft Unit should ensure that all children with CLP receive preventive dental advice and dental care from either a hospital or community based specialist in paediatric dentistry. Further research is needed to improve the future care of this important group.

DECLARATION

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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Chapter 1

Introduction

The incidence of babies born with a cleft lip and/or palate (CLP) in the United Kingdom (UK) is approximately 1:700, (Derijcke et al., 1996). Multidisciplinary care is provided by a regional cleft team for at least the first 20 years of life.

The CLP anomaly can affect facial appearance, speech, dental arch relationships, hearing, craniofacial growth and in some cases may cause psychological impairment. The burden of care both to the child and family is immense. From birth through to adulthood, patients are expected to attend many appointments in order to manage, monitor and maintain their required care.

Traditionally, care for children with CLP in the UK was very fragmented, with many low volume operators providing subjective care without the guidance of agreed treatment protocols, audit or research evidence based practice.

Shaw et al. (1992a) conducted a six centre, international, comparative study of treatment outcome in unilateral cleft lip and palate (UCLP) patients. The two UK centres involved in the study were weakest in all areas of care. It was concluded that the UK centres offered minimal standardisation of care together with numerous low volume primary surgeons operating on too few patients. Conversely, the long term outcome was found to be good for patients under the care of treatment centres providing standardised treatment methods, centralised care and high volume operators (Shaw et al., 1992b).

Following the findings of Shaw et al. (1992b), it was recognised that a need existed to investigate more deeply CLP services in the UK. In 1996, Health Ministers commissioned a Clinical Standards Advisory Group (CSAG) to report on CLP care in the UK. The CSAG (1998) made recommendations suggesting that between 8-15 regional CLP centres within the UK be established. It also stated that all centres must provide multidisciplinary teams working to standardised treatment protocols offering opportunities for training, audit

and research for all team members. Any personnel involved in the care of a patient with CLP should be appropriately trained and accredited. The CSAG (1998) also recommended that a named member of the cleft team should commence dental health education during the infant's first year of life, and ensure that this is maintained throughout childhood and adolescence.

In order to address this guidance, the clinical service specification for the North West of England, the Isle of Man and North Wales, states that by the age of 18 years children with CLP will demonstrate a level of dental disease that is as good as or better than the average level in their local community.

All patients with CLP are advised to register with a local general dental practitioner (GDP) for regular recalls and routine care. Williams et al. (2001) highlighted that whilst 95 per cent of five year old children with UCLP in the UK were registered with a dentist, 40 per cent of the total sample were found to have dental caries and deemed in need of dental treatment.

The British Society of Paediatric Dentistry (BSPD) (2003) recommended that mothers should register their children with a dentist before their children's teeth erupt. A recent National Institute for Clinical Excellence (NICE) guideline (2004) stressed the need for regular dental recalls to reinforce preventive advice and raise awareness of the benefits of good dental health.

The General Dental Service (GDS) is considered to be the source of dental care for families. The Community Dental Service (CDS) has been developed to provide dental care for those unable to access the GDS due to the need for specialised care. Hence, community dental practitioners, many of whom are on the Paediatric Dental Specialist Register, are in a position to offer care for patients with CLP who may find access to the GDS difficult.

Tickle et al. (1999) emphasised that not all dentists encourage registration of young children, and of those who do, the treatment for pre-school children may be ineffective.

Epidemiological studies investigating the prevalence of dental caries in five year olds in the UK between 1983 and 2003 have indicated a worsening picture of dental health in some areas of the country (Todd and Dodd, 1985; O'Brien, 1994; Lader et al., 2005). Dental caries is more prevalent in the North of England and tends to be polarised to children from deprived areas, lower social classes and those receiving income support (Hinds and Gregory, 1995).

The literature regarding the dental health status of children with CLP is limited. Wong and King (1998) drew attention to the low number of robust studies relating to the oral health of this important group. The varying methodologies used together with the overall low study numbers make comparisons between CLP studies difficult and unreliable. Individually, a number of studies have highlighted the prevalence of dental caries within children with CLP to be higher than that of the general population (Johnsen and Dixon, 1984; Dahllöf et al., 1989; Bokhout et al., 1997 and Williams et al., 2001).

Shaw et al. (1996) and the CSAG (1998) stated that preventive dental health education must be provided by the cleft team. Poor dental health may compromise the long term results that are achievable on behalf of the patient with CLP. Williams et al. (2001) revealed that 40 per cent of five year old children with CLP and 20 per cent of 12 year old children with CLP demonstrated the presence of active dental caries. The BSPD (2001) stated that the dental needs of pre-school children were not being met, and suggested that intensive preventive advice together with restorations and/or extractions may address their needs. Furthermore, the Department of Health (2005) recommended attention be focused on preventive care for children in an attempt to reduce the prevalence of oral disease.

Many studies that have examined the oral health status of children with CLP call for preventive dental health programmes, provided by a specialist paediatric dentist, to be introduced from as early as possible and directed towards parents (Johnsen and Dixon, 1984; Dahllöf et al., 1989; Bokhout et al., 1997; Paul and Brandt, 1998; Gregg et al., 1999 and Chapple and Nunn, 2001). However, these studies have failed to test the effectiveness of such programmes and therefore the need exists to test this area.

Stephen and MacFadyen (1977) conducted a study to test a preventive dental health programme for infants with CLP. Whilst their findings promote the use of such a programme, the research methodology used may not be appropriate today.

A number of studies have examined the provision of dental health programmes in the general population with varying outcomes. Kay and Locker (1996) conducted a systematic review of the literature examining the effectiveness of these. Their review revealed that whilst knowledge and attitudes can be raised, chairside oral health education can reduce plaque levels only in the short term. More recently, Kowash et al. (2000) demonstrated the effectiveness of dental health education on caries incidence in children via home visits. Whilst this study and that of Kay and Locker (1996) did not specifically examine patients with CLP, the dental health status of this important group indicates a need to test the benefits of a specifically designed dental health education programme aimed at the mothers of infants with CLP.

The study to be reported was a randomised, controlled trial designed to test the effectiveness of a specific oral health education programme aimed at 1. increasing the uptake of regular dental attendance at an early age; 2. promoting the daily use of a fluoride toothpaste and 3. encouraging the use of a feeder cup from the age of six months for infants with CLP.

The next chapter will review the literature particularly in relation to the provision of cleft lip and palate services in the UK and the implementation of new guidelines for these services. The dental health status of children with CLP will be discussed and compared with the UK general population. The provision of preventive dental care will be reviewed, looking at national guidelines, the work carried out within CLP units and within other special needs groups. Access to general dental care will be investigated together with UK guidelines relating to routine dental care.

The research methodology will be presented including the random allocation to groups, the preventive advice given, baseline and follow-up data collection together with a cost assessment of providing this programme. The proposed statistical tests will be described together with the results following collection of the data. Following statistical analysis, a discussion of the project and its findings will be provided and compared to that of the current literature. Conclusions will be offered in the light of findings made.

If this study proves effective, and following national dissemination of the results, there may be an opportunity to carry out a multi-centre study including the UK regional cleft units. In the shorter term, positive data may allow the provision of intensive preventive advice to the mothers of all infants with CLP born in the North West region. Postal deliveries of a high fluoride toothpaste would be ideal although the cost implications of providing this may prove to be a barrier. In the longer term, a successful project will allow the introduction of a preventive dental health programme to mothers of infants with CLP that can then be followed up when the infants attend for their 18 month, three year and five year reviews. Collection of audit data will allow long term follow-up regarding dental health and behaviour so providing evidence for practice.

Chapter 2

Literature Review

2.0   **Cleft Lip and Palate Care in the United Kingdom**

The management of children with cleft lip and/or palate (CLP) requires a multi-disciplinary approach from birth through to adult life. However, the long term outcome of care can vary between treatment centres. Shaw et al. (1992a) reported on a six centre international study of the outcome of treatment in patients with a complete unilateral cleft lip and palate (UCLP). The study assessed facial growth, dental arch relationship together with facial and nasolabial appearance of 151, 8-10 year old patients. Results revealed that treatment outcomes for children living in the United Kingdom (UK) failed to compare well with those in Europe. In particular, this study identified that in centres where there was standardisation of treatment methods, centralised care and high volume operators, results were good. However, in centres with no treatment standardisation and low volume operators, the outcome was poor (Shaw et al., 1992b).

In 1991, the Royal College of Surgeons established a steering group to examine the care of patients with CLP, which aimed, amongst other tasks to produce a "Recommendation for Minimum Standards of Care" for patients with CLP (Shaw et al., 1996). The steering group recommended the establishment of a comprehensive service to include dental care with an emphasis on team work across all specialities involved in the long term outcome. Furthermore, they suggested that a named member of the cleft team should commence dental health education whilst also ensuring that this, alongside fluoride supplementation and dental attendance, is maintained throughout childhood.

Health Ministers in 1996 commissioned a Clinical Standards Advisory Group (CSAG) to advise on the provision and standards of CLP care in the UK. Quality of care for patients and the training of professionals involved in providing care was assessed. Children aged five years, born between April 1st 1989 and March 31st 1991, and aged 12 years, born between April 1st 1982 and March 31st 1984 were included. Those with developmental delay and/or associated syndromes were omitted. Fifty centres provided a total of 457

children, (52.3% five year olds and 47.7% 12 year olds), allowing a retrospective study of results of treatment (Sandy et al., 2001). In conclusion, the CSAG made recommendations including opportunities for training, audit and research for all members of the multidisciplinary CLP team. In relation to paediatric dentistry, the CSAG highlighted that poor dental health may compromise the achievable results, and focusing particularly on orthodontic treatment, stated that this should be contra-indicated in the presence of uncontrolled dental caries and poor oral hygiene. The CSAG suggested that cleft teams were neglecting their duty to improve the dental health of these patients. Their report underpins the recommendations of Shaw et al. (1996) by stating that dental health education should be given to the parents of newly born cleft children within their first year of life and paediatric dental services should be provided throughout childhood and adolescence (CSAG, 1998).

2.1   Dental Caries Prevalence in the United Kingdom and North West Region

There has been a considerable decline in the prevalence of dental caries in children during the past 30 years in the UK. In 1973 the mean decayed, missing and filled teeth (dmft) score in the primary dentition of five year old children was 4.0 and this had more than halved in 1983 to 1.8. However, this reduction appears to have levelled off by 1993, the dmft still being 1.8. In 2003 the mean dmft recorded for five year olds was 1.5, but more importantly, for those children found to have dental disease the mean number of teeth affected was 3.7 (Todd, 1975; Todd and Dodd, 1985; O'Brien, 1994 and Lader et al., 2005). Other epidemiological studies have also highlighted the problem of dental caries experience across Great Britain. Hinds and Gregory (1995) found 17 per cent of 1.5 - 4.5 year olds in Great Britain to have dental caries, with 83 per cent of the dmft being composed of unrestored dental caries. More recently, Pitts et al. (2005) have demonstrated the dmft experience of five year old children in England and Wales (2003/4) is 1.55.

Whilst generally the dental health of five year olds does not appear to be improving, it is evident that there are also marked geographic and social variations in dental caries experience. In the North West Region children experience particularly high levels of dental caries with the dmft for five year olds ranging from 0.5 in Crewe to 3.43 in Preston, with an overall dmft of 1.85 in Cheshire and Merseyside, 2.27 in Cumbria and Lancashire and 2.42 in Greater Manchester (Pitts et al., 2005). This underpins the results of Pitts et al. (2003) who drew attention to national surveys indicating that five year old children within the north west of England demonstrated the highest levels of dental caries in England.

Whilst many children have good oral health, the provision of operative care for five year olds with dentinal caries has decreased revealing a care index of only 12 per cent in the year 2003/4 in England and Wales compared with 14.3 per cent in 1999/2000 (Pitts et al., 2005).

2.2   **Dental Health Status of Cleft Lip and/or Palate Children**

Few studies have been conducted in the UK relating to the dental caries experience of children born with CLP. Those that have, and others carried out throughout the world, have small samples due to the particular group being studied. This fact, together with the differing methodologies used, causes difficulties in comparing caries prevalences (Wong and King, 1998). However, it must be recognised that maintaining good oral health is of vital importance for children with CLP as both surgical and orthodontic treatment may be compromised by dental caries and periodontal disease (CSAG, 1998).

Lauterstein and Mendelsohn (1964) conducted the first study to examine the prevalence of dental caries in children with CLP compared to a non-cleft group of children. This American study, examined 285 cleft children with a mean age of 8.5 years, and compared collected data to that of a 300 non-cleft control group where the mean age was nine years. No marked differences in caries experience were found between the groups. The cleft

group recorded a mean decayed, missing and filled teeth (DMFT) score in the permanent dentition of 8.01 and the non-cleft group a DMFT of 7.45. No difference was detected when comparing the presence of maxillary and mandibular caries in the cleft group alone. Whilst the numbers studied are large, the control group was taken from one practice and therefore not a fair match. No insight into the DMFT figures were given, rendering it difficult to make assumptions on the dental health status of these children.

Johnsen and Dixon (1984) examined 64 children attending a Craniofacial Defects Clinic in Cleveland, America aged between 18 months and four years, 42 of whom were diagnosed as having a CLP. The presence of carious incisors only was recorded. Anterior caries was detected in 14 (33%) of the children with CLP. The children with a bilateral CLP (BCLP) demonstrated the highest prevalence of caries with six affected incisors (43%), while children with cleft palate (CP) had four (29%) and those with UCLP three (21%). One child with anterior caries had a submucous cleft. Carious incisors were more commonly found in the cleft site. In children with both UCLP and BCLP, caries progressed slowly and in children with UCLP with a missing incisor, dental caries was less frequently detected. However, in children with CP, when diagnosed, incisor caries was extensive and progressed rapidly, following the pattern of nursing caries (Ripa, 1988).

Dahllöf et al. (1989) studied the caries prevalence and gingival health in 49, 5-6 year old children residing in Stockholm between 1980-1981. Within the study group two children were diagnosed with Pierre Robin Sequence and one child with Larsen Syndrome. A control group of 49 children matched for age and gender was selected from patients attending the paediatric department within the same hospital. There is no history given regarding the reason why these children attended the hospital, so we are unaware if it was an unbiased or fair match. When examined for caries the number of decayed surfaces in the primary dentition (ds) differed greatly between the two groups, a mean of 3.9 ds being detected within the cleft group compared to a mean of 1.5 ds in the controls (p < 0.01).

However, no significant differences in caries experience between cleft types were detected. All parents were interviewed to ascertain fluoride use and dietary habits. Whilst no significant differences could be found that related to the higher caries levels detected within the group with CLP, it must be noted that this was reported and not actual behaviour. Neither is it clear if early infant feeding practices were investigated, as almost certainly these would have been influential in the establishment of caries within the age group of children examined. Gingival health was markedly poorer when comparing the upper anterior regions including the cleft site, with 13 per cent showing evidence of gingival bleeding in the test group compared to four per cent in the controls ($p < 0.001$). Poor gingival health may be related to difficult access, scar tissue and incompetent lips, yet in a later study, Lucas et al. (2000) reported no differences in gingival health in children with CLP.

Bokhout et al. (1997) investigated the incidence of dental caries in the primary dentition in children with CLP. The research was conducted between two University hospitals based in Amsterdam and Rotterdam. The study investigated 158 children, 81 with CLP and 77 without. Children with congenital disorders were not included. All children were examined at three monthly intervals during their first year of life, then every six months until reaching four years. The presence of dental caries, gingival inflammation and dental plaque were recorded at each examination. The examiner also completed a questionnaire with parents at each examination relating to dietary habits and use of fluoride. The socio-economic status of the parents was also recorded. Children with CLP had significantly poorer oral hygiene, more gingival inflammation and were more likely to have parents from a lower social class than the non-cleft children ($p < 0.05$). Results demonstrated that 69 per cent of children with CLP were caries free, compared to 93 per cent of non-cleft children. Only 30 (19%) children of the total group developed caries during the study. However, 25 (83%) were children with CLP, accounting for 101 (91%) of the carious teeth detected with almost 50 per cent of the caries being located in the maxillary incisors.

These findings support those of others who have investigated this area (Johnsen and Dixon, 1984; Dahllöf et al., 1989). Whilst poor oral hygiene was evident around the cleft area, reported dietary habits between the two groups did not differ significantly. Accepting that dietary control is important, it would appear that lack of brushing (due to limited access) and as a consequence lack of fluoride may correlate both to the poor oral hygiene and presence of dental caries.

In an attempt to address the lack of data surrounding the oral and dental health status of children with CLP, Paul and Brandt (1998) carried out research examining 114 children aged 3-18 years attending two cleft units in the UK. Children with syndromes were excluded. In order to allow for the wide age range studied, the sample was sub-divided into three age groups, 3-5 year olds (36%), 6-12 year olds (43%) and 13-18 year olds (21%). Similarly, the clefts were also divided into three groups, cleft lip (CL) (9.6%), CLP (51.8%) and CP (38.6%). Dental caries, gingival health and the presence of calculus were recorded for all participants. Just over half (53.5%) of the study group reported no past dental caries experience. However 46.5 per cent demonstrated evidence of caries, with 20 per cent of the children examined presenting with active dental caries, with a mean decayed, missing and filled teeth (dmft) score of 2.3 in the primary dentition and 0.9 DMFT in the permanent dentition. Within the 3-5 year old age group the mean dmft was 1.9 with the group with CLP (54.2%) showing a significantly higher prevalence of dental caries. No differences in caries prevalence for the permanent dentition were found. These results support those of Johnsen and Dixon (1984) who reported a higher prevalence of caries in the primary dentition in children with BCLP. However, it must be recognised that Johnsen and Dixon (1984) recorded anterior caries alone and therefore it is unfair to make a direct comparison.

Paul and Brandt (1998) when examining by cleft type recorded a mean dmft of 3.6 for the group with CP. This was significantly higher ($p = 0.05$) than the CL mean dmft of 1.7 and the CLP mean dmft of 1.4. Johnsen and Dixon (1984) commented on the appearance of nursing caries within their group with CP, whereas Paul and Brandt (1998) reported this higher dmft level being due to the inclusion of children from the Indian subcontinent who have a higher prevalence of dental caries. Dahllöf et al. (1989) found no statistically significant differences in caries levels between their groups with CLP which contradicts the results reported by Paul and Brandt (1998). Yet, as the populations studied differed, comparisons between the study groups are not viable.

When examining oral hygiene, Paul and Brandt (1998) found significantly higher levels of debris ($p = 0.05$) and gingival bleeding ($p = 0.002$) in the combined groups with CL/CLP when compared to the group with CP alone. Interestingly, more children with CL (73%) and CLP (64%) reported having their teeth brushed twice a day than the children with CP (59%). This supports the work of Dahllöf et al. (1989) who also found poor oral hygiene within the cleft area, suggesting it may be related to scar tissue, incompetent lips and poor access to gingival tissues. Whilst Paul and Brandt (1998) offered evidence relating to the oral health status of children with CLP in the UK, the age range studied was wide and hence age groups within the sample were small. Within the 3-5 year old group with CLP, caries was detected in nine (22%) children with a dmft of 1.9 which is higher than the target of 1.0 set for five year olds by the Oral Health Strategy for England (DoH, 1994).

Turner et al. (1998) evaluated the oral and dental health of 89 Russian children with a repaired UCLP, with an age range of 5-9 years. Twenty-six of the study group were noted to have a palatal fistula. The oral hygiene, defined by the presence of plaque, was significantly better ($p < 0.01$) in those patients without a palatal fistula. However, manual dexterity and tooth brushing technique will vary greatly within the age range examined. More importantly, via parental interviews conducted during the study, it became apparent

that the availability of toothbrushes and toothpaste was limited. Therefore it is unfair to suggest an association between the presence of a palatal fistula and poor oral hygiene. The data collected on the presence of dental caries were limited. Missing teeth were not counted. The mean number of decayed and filled teeth (dft) was 7.31 suggesting many of the children examined were in need of both restorative and preventive dental care.

Gregg et al. (1999) assessed the efficacy of a specialist paediatric dentist involved on the cleft palate team based in a paediatric hospital in Northern Ireland. The study examined 133 children attending the joint cleft palate clinics. Dental caries, restorative care and fluoride uptake were recorded. There was no matched control group, data being compared with National Survey Population figures for 1993 for five and 12 year old children in Northern Ireland. The authors failed to discuss duplication of examination methods, or the inclusion or not of any children with CLP diagnosed with additional syndromes or anomalies. However, the results revealed 42 per cent of five year old children attending the CLP clinic had untreated caries. In the longer term it would appear that 12 year old children with CLP had better oral health than that of the general population, yet 28 per cent were found to have active, untreated caries. This would have consequences when aiming to move forward with proposed orthodontic treatment which should not be offered according to the CSAG (1998).

Rivkin et al. (1999) investigated the dental attendance and dental caries experience of all patients attending a cleft audit/assessment clinic in the UK over a two year period. The sample examined consisted of 85 patients ranging from 5-20 years old. The majority regularly attended a dentist for routine care (92%) and of these 76 per cent were registered within the General Dental Service (GDS). The sample included 23 (27%) five year olds and of these, 43 per cent had evidence of dentinal caries experience with 30 per cent showing the presence of active dental caries. This compares to work conducted by Williams et al. (2001) where 40 per cent of five year old children with UCLP displayed

active dental caries requiring care. However, as Rivkin et al. (1999) examined all cleft types a direct comparison cannot be made.

Lin and Tsai (1999) investigated caries prevalence and bottle feeding practices in infants with CLP in Taiwan. This study raises issues around the use of feeding bottles that may be relevant to the prevalence of nursing caries and should therefore be discussed. Prolonged, on demand bottle feeding, especially during the night is known to cause rampant caries in the primary dentition (Ripa, 1988). Lin and Tsai (1999) studied 123, two year olds attending a hospital based paediatric and orthodontic clinic. There was no control group. Parents completed a questionnaire related to parental awareness and attitudes to bottle feeding and dental care. Results revealed that 48 (39%) respondents reported bottle feeding their children whilst in bed. Maxillary anterior dental caries, associated with night time bottle feeding, was recorded in 19 (15.4%) children, with bottle feeding at night being significantly related to this type of caries (p = 0.019). However, Johnsen and Dixon (1984) associated its presence with enamel deficiencies and only children with CP were believed to have dental caries linked to bottle feeding. Lin and Tsai (1999) divided their study group by cleft type, but made no further reference to this when discussing their findings.

Bian et al. (2001) also investigated caries prevalence, together with parental attitudes towards feeding habits and oral health care for children. The researchers examined 104 Chinese 3-6 year olds with CLP, all of whom had been referred to a Smile Train charity initiative offering care for families unable to afford cleft treatment. Only non-syndromic children were included in this cross-sectional study. Results showed that 75 per cent had dental caries. Within the group with CL 25 (68%) children had caries together with 79 (77%) with CLP/CP. Twelve per cent of the group with CL and 30 per cent of the group with CLP/CP demonstrated rampant caries. The mean dmft for the group with CL was 2.7, which was significantly different from the mean of 4.1 for the group with CLP/CP (p < 0.05). When examining the association between rampant caries and feeding method,

rampant caries was significantly associated with bottle feeding ($p < 0.01$). These results underpin those of Lin and Tsai (1999).

Lucas et al. (2000) investigated the dental health and caries related microflora of children with UCLP. Sixty children attending a multi-disciplinary cleft clinic were matched to 60 attending the trauma clinic at the same UK hospital. Their ages ranged from 3-15 years. The study failed to find any differences in the prevalences of dental caries between the study and control groups. However, the mean scores of 2.35 dmft and 1.18 DMFT indicated a relatively high caries level particularly in the primary dentition, which ultimately may compromise care for this group of children. Interestingly there were fewer restored carious surfaces in the group with UCLP compared to the control group. The authors suggested that this difference might be associated with the parents of the children with UCLP giving priority to other areas of care, for example speech therapy. Yet Tickle et al. (2003a) when discussing care within general dental practice, offered the suggestion that preventive dental health advice may be given rather than a restoration, which may be more acceptable to the patient/parent if care is also needed within other disciplines. Additionally, the children in the study group attended a multidisciplinary cleft centre for care and had received preventive dental health advice from an early age. Therefore, despite repeated preventive advice, this study group had failed to control their caries development, or alternatively the preventive advice had not been acceptable.

Hewson et al. (2001) conducted a cross-sectional study investigating the caries experience and initial access to dental services in a group of children with CLP in the West of Ireland. The study group, consisted of 90 children with CLP (14 of whom had also been diagnosed with an associated syndrome), ranging in age from 18 months to 16 years 11 months. They were matched to a control group of 100 non-cleft children, ranging from 3-16 years drawn from schools within the same region. Results revealed a significantly higher prevalence of dental caries in the group with CLP ($p < 0.05$), with a highly significant difference being

associated with the primary dentition (p < 0.0001) thus supporting the findings of Bokhout et al. (1997).

This study fails to differentiate between cleft type and disease level; neither does it offer any data relating to the caries status of the 14 children with syndromes. Therefore it is difficult to make any comparisons with other recent work in this area such as that of Paul and Brandt (1998) who also examined the caries status of 3-18 year old patients with CLP.

Chapple and Nunn (2001) carried out a cross-sectional study to assess the prevalence of dental caries and other related factors in children with CLP in the North East of England. The study group consisted of four, eight and 12 year old children with CLP attending an audit clinic within their cleft care centre. A total of 91 children were examined, 19 aged four years, 28 aged eight years and 44 aged 12 years. The prevalence of dental caries increased with age, 63 per cent of four year olds being caries free, while only 34 per cent of 12 year olds had healthy mouths. A mean dmft of 1.3 in four year olds and a mean DMFT of 1.8 in 12 year olds were recorded.

The researchers also recorded exposure to fluoridated water or fluoride supplements. Full-time exposure was recorded for 50 children, with 25 reporting no exposure. The remaining 16 reported part exposure, due to home relocation, or the use of fluoride supplements for a period of time. The mean age of the total group with full time fluoride exposure was 9.1 years (n = 50) with a mean dmft of 1.04 and a DMFT of 0.84. The no fluoride exposure group (n = 25) had a similar mean age (9.1 years) with a mean dmft of 1.88 and a DMFT of 0.96. The researchers suggested that the lower caries levels demonstrated in the full time fluoride exposure group may have been related to fluoride, however due to the small study numbers, more robust work is needed with a larger group.

Ahluwalia et al. (2004) investigated the possible association between increased oral clearance time and higher caries levels in children with CLP. Their study group consisted of 81 children with CLP ranging from 6-16 years, attending a craniofacial multi-disciplinary clinic in the UK. The control group consisted of 61 non-cleft children attending a trauma clinic within the same hospital. The children with CLP were analysed as a single group rather than being divided into the varying cleft types. Results revealed the group with CLP to have significantly greater mean caries scores (2.0 dmft/1.0 DMFT) when compared with the control group (0.62 dmft/0.48 DMFT) (p < 0.01). The study group also demonstrated significantly poorer oral hygiene and higher levels of mutans streptococci, lactobacilli and yeasts. The researchers also recorded a significantly longer oral clearance time for a starch-containing biscuit. In view of the fact that there was no difference in the mean number of snacks consumed by each group on a daily basis (2.01 study group and 2.18 control group) the longer oral clearance time may be associated with the higher caries levels detected in the study group.

Lages et al. (2004) conducted a study in Brazil to investigate the oral health of 77 patients with CLP aged 1-32 years. Two were diagnosed with severe cardiac problems and were excluded from the periodontal data collection. In the 1-5 year old group, (11 children), an average 2.91 dmft was recorded, rising to 13.62 DMFT for the 19-32 year old group. Due to the wide age range within the study group, it is not possible to compare these results with other studies. Gingivitis was detected overall in 65 (86.7%) of the 75 patients examined. In the 1-5 year old group, gingivitis was observed in six (60%) of the patients. Dahllöf et al. (1989) found a significantly higher number of 5-6 year old children displaying gingivitis when compared to a matched control group, however, due to the age difference between these two studies it is unfair to compare the results. Lages et al. (2004) stated that their results were similar to those of the general population within the region studied, arriving at this statement following comparison of their data with local population data.

Whilst data relating to caries experience within children diagnosed with CLP are sparse, primarily due to the low sample numbers studied, general conclusions can be drawn from the national epidemiological studies. The North West region demonstrates a high caries level amongst five year olds. The high levels of dental caries detected in the general population should act as a baseline for individual cleft teams to work on until more robust data relating to dental caries experience within the population diagnosed with CLP become available.

2.3   Preventive Dental Care

The review of the literature shows that the prevalence of dental caries in children in some regions of the UK remains unacceptably high particularly in the north of England, areas of multiple deprivation and some regions deficient in water fluoridation. The BSPD (2001) believes that within the UK, dental services fail to meet the needs of many pre-school children and efforts should be made to improve their dental health. They recommend that preventive dental care for children must include advice on the use of fluoride, relevant dietary counselling and oral hygiene instruction. The repair or extraction of carious teeth is also recommended. However, from recent surveys, evidence suggests few primary teeth are currently being restored (Hinds and Gregory, 1995; Pitts et al., 2005; Lader et al., 2005).

Several studies report that children with CLP have poorer dental health than children within the general population (Johnsen and Dixon, 1984; Dahllöf et al., 1989; Bokhout et al., 1997; Hewson et al., 2001). Achieving a satisfactory standard of oral health to allow for example, orthodontic treatment, may be difficult due to access around the cleft area, a malaligned permanent dentition and poorly formed, hypoplastic teeth (McDonagh et al., 2000). Whilst study numbers tend to be small, evidence suggests that a higher caries incidence may be detected in children with BCLP (Johnsen and Dixon, 1984) and research

carried out by Paul and Brandt (1998) showed poorer dental health to be apparent in children with CLP than in those diagnosed with clefts of the lip or palate alone.

Stephen and MacFadyen (1977) recognised the need to research a preventive dental health programme from birth for their patients with CLP following observations of the high caries rate of children already attending their CLP clinic in Scotland. Their target population consisted of all children attending the CLP Unit with an unerupted or erupting primary dentition. Mothers of infants with CLP were interviewed by the dental surgeon within two weeks of birth. Information relating to the importance of maintaining healthy dentitions was offered and reinforced with a booklet. Fluoride tablets, 0.25mg were also prescribed. Parents were seen on a monthly basis when information was reinforced with additional dietary advice relating to the restriction of sugar intake. Tooth brushing instruction was given when the primary dentition erupted. The fluoride prescription increased with age so that by two years each infant was taking a 1mg fluoride tablet daily, with encouragement to suck the tablet when cooperation was sufficient. Following full eruption of the primary dentition fluoride gel was applied weekly for six weeks then on a monthly basis. Primary molars and first permanent molars were fissure sealed when cooperation allowed. The authors did not state if any children were excluded from the study. To allow comparison, retrospective caries data from patients attending the CLP Unit prior to the commencement of the study were used. A cost assessment was also made. Results were confined to data from children aged 3-5 years and only included primary canines and molars due to a number of the cleft children having missing incisors (Stephen and MacFadyen, 1977). This is a constraint of the study as the presence or absence of dental caries in the anterior teeth may have altered the results, and certainly later studies have shown that caries is a concern in the anterior teeth in children with CLP (Johnsen and Dixon, 1984; Bokhout et al., 1997). Similarly, Dahllöf et al. (1989) demonstrated a marked difference in gingival health in the upper anterior region when comparing children with a cleft with non-cleft pre-school children; the children with a cleft having significantly poorer gingival health ($p < 0.001$).

The study by Stephen and MacFadyen (1977) consisted of a test group containing 57 children and a control group of 34 children. On examination, the mean age of each group was 5.08 years and 4.7 years respectively. The test group showed a mean decayed/filled score in the primary dentition (dfs) of 0.75, compared to 4.95 in the control, which was highly significant (p < 0.001). Whilst this result is encouraging it should be welcomed cautiously. The two groups differed greatly and whilst the history of preventive advice to the test group including acclimatisation and preventive measures is given, no such information is made available for the control group. It is reasonable to assume that the controls received no such care and advice as they were attending the CLP Unit prior to the implementation of the study.

The research by Stephen and MacFadyen (1977) failed to describe the various cleft types within the groups and therefore it is not possible to say whether the caries was associated with a particular type. Johnsen and Dixon (1984) and Dahllöf et al. (1989) reported higher caries levels in children with CLP, however Paul and Brandt (1998) found higher caries levels in 3-5 year olds with CP only. The presence of any syndromes or genetic disorders within either group is not discussed. Inclusion of either may have skewed the collected data.

Stephen and MacFadyen's study (1977) was designed at a time when children with CLP attended the CLP Unit very frequently. Today's service is much different and recommendations are such that visits to the main unit are minimal, with care being carried out locally where possible (CSAG, 1998). So, for example, routine dental care may easily be carried out locally. Hence the centralised provision of regular fluoride application, repeated preventive dental health advice and fissure sealants may not be feasible, particularly if care is offered by general dental practitioners (GDP). This was highlighted by Tickle et al. (2003a) who found preventive dental care within general dental practice to

be offered following the development and detection of dental disease rather than in an attempt to prevent its occurrence.

Stephen and MacFadyen (1977) strongly recommended and prescribed fluoride supplements from two weeks of age. Daily administration of fluoride supplements is a difficult regime to follow and is a recognised problem of this preventive method (Levine and Stillman-Lowe, 2004). However, Davies et al. (2002) found significant oral health benefits by postal distribution of a high fluoride toothpaste to high risk children living in non-fluoridated districts. Stephen and MacFadyen (1977) demonstrated the cost of their intervention to be highly beneficial when compared to the cost of the treatment needed by the control group.

The need to improve the dental health of all children is paramount (DoH, 1994; DoH, 2005). In an attempt to monitor improvements in oral health, the Government set dental health targets to be achieved by 2003 (DoH, 1994). The target set for England stated that 70 per cent of five year olds should have no decay experience, and within this group, the average dmft should be no more than 1.0. The Children's Dental Health Survey in the UK, 2003 (Lader et al., 2005) recorded only 59 per cent of five year old children to be caries free, with a mean dmft of 1.5. These results together with those previously discussed reinforce the continuing need for more effective preventive and treatment services if the dental health of this age group is to improve significantly. To this end, the Department of Health (2005) launched, "Choosing Better Oral Health, An Oral Health Plan for England". A key aim of the action plan is to reduce the prevalence of oral disease with particular emphasis on reducing the inequalities across all age groups. No specific dmft targets have been set, but general goals are to be achieved by providing those already involved in general and dental health care with specific information needed to improve oral health. The strategy underpins those set in NHS Dentistry - Options for Change (DoH, 2002), where the need to focus on preventive care particularly in children has been underlined.

Dental caries is primarily preventable when the consumption of refined carbohydrates is controlled and effective, and twice daily tooth brushing with a fluoride toothpaste is carried out (Levine and Stillman-Lowe, 2004). Children who brush their own teeth are more likely to develop dental caries when compared to children who sometimes or always have their teeth brushed by an adult (Hinds and Gregory, 1995).

The success of integrated, preventive dental care is apparent when examining the services for haemophilia and cardiology patients where caries rates for children who receive regular dental care and advice are lower than controls. Boyd and Kinirons (1997) conducted a study to determine the dental caries prevalence of children diagnosed with haemophilia in Northern Ireland. Data were compared to national data relating to children of the same age range in the general population. This method, rather than a control group, was used due to the small numbers of age groups within the study group. The values for age intervals from Northern Ireland dental health data were weighted in accordance with the age range of the study group. The study group consisted of 38 children. Within the 2-10 years age range (29 children), 25 (86%) showed no active caries which was significantly higher than the Northern Ireland weighted population data, 16 (55%) ($p < 0.01$). A similar result for the 7-15 years group (22 children) revealed 22 (100%) showed no active caries compared to 15 (68%) nationally ($p < 0.05$). There are two small areas of Northern Ireland benefitting from water fluoridation schemes. Thirty six of the 38 children did not receive fluoridated water, although 28 (77%) reported that they always used fluoride supplements. The researchers highlighted the centralisation of dental care within the haematology department. They suggested that the provision of dental care as an integral part of the haematology care, together with fluoride use allowed for an effective dental care programme for this group of children.

Sonbol et al. (2001) investigated the prevalence of dental caries, gingival health and enamel defects in children with severe haemophilia. The study group consisted of 38 children attending a London paediatric hospital, aged 4-13 years with a mean age of 8.8 years. The control group of 30 children, matched for age, gender and ethnicity were healthy children attending a London dental hospital, aged 4-15 years, with a mean age of 9.8 years. The results matched 30 children from each group, the unmatched children being excluded. Results showed no significant difference in the mean dmft between the two groups but the mean DMFT was significantly greater for the control group (2.4), compared to that of the study group (0.7), ($p = 0.04$). No differences were detected in gingival health or enamel defects between the two groups. The researchers underpin the work of Boyd and Kinirons (1997) by also suggesting that a greater proportion of children in the haemophilia group were caries free due to the multidisciplinary service offered together with the provision of dental health advice from an early age. However, neither of these studies specifically tested this theory and therefore definitive conclusions cannot be made.

Saunders and Roberts (1997) investigated dental knowledge, attitudes and dental health practices of families of children with congenital heart disease. The study group, drawn from a London paediatric hospital, consisted of 60 children aged 2-16 years with severe cardiac disease, whilst the matched control group, comprised of 60 children, were healthy siblings of the study group or attended a dental trauma clinic at a London dental hospital. All children received a dental examination and their parents completed a questionnaire to assess parental knowledge. The study group parents had significantly less knowledge regarding diet, ($p < 0.001$), tooth brushing ($p < 0.005$) and the use of fluoride tablets in relation to preventing dental disease ($p < 0.01$). Within the study group, 18 per cent were not registered with a dentist and as a consequence had not received any preventive dental health messages. The researchers questioned the cardiologist's responsibility for ensuring dental care for such an important group of vulnerable children. Shaw et al. (1996) and the

CSAG (1998) appear to have addressed this potential pitfall by recommending a team member be responsible for ensuring dental advice and care for all patients with CLP.

The Department of Health (1994 and 2005) called on GDPs to carry out more preventive dental health care on patients attending their practices. Tickle et al. (2003a) reported on a retrospective study of 677 case notes relating to children regularly attending 50 GDPs within the North West of England. Only children with approximal caries were included in the study. Whilst they discovered that a significant amount of preventive dental care was being offered, it was more likely to be given after the disease had become apparent and therefore not particularly effective in preventing the initial disease. The researchers also found the mean age of the children first attending the GDP to be 3.4 years, suggesting that despite preventive care being given the dental caries had probably developed prior to the first dental visit. The preventive care offered by the GDPs included dietary advice, prescription of fluoride tablets, application of fluoride varnish and oral hygiene instruction. Few prescriptions were given for fluoride tablets (13.9%), and according to the written record only one per cent of the sample were recommended to use a fluoride toothpaste. However, as the researchers noted, this may be due to a failure in recording the specific advice given.

The National Institute for Clinical Excellence (NICE) (2004) dental recall guideline suggested a preventive dental health programme must include regular dental recalls, monitored oral hygiene instruction supervised by parents where appropriate, use of fluoride and tailored dietary counselling. When considering a child with CLP, Kirchberg et al. (2004) stressed the need for GDPs to be better informed about the special needs of these patients in order to offer intensive preventive dental care and where necessary relevant clinical treatment.

Research investigating GDPs' potential to influence mothers of pre-school children revealed that dental health education should be very specific. Blinkhorn (1978) investigated dentists' assumptions concerning the tooth brushing behaviour of pre-school children. A random sample of 342 mothers with children aged between two and four years were interviewed. Questionnaires were sent to 56 GDPs and ten community dental officers all working within the same area health authority. A total of 51 questionnaires were returned. When comparing data provided by mothers and dentists, tooth brushing began at a much earlier age than assumed by the dentists. In conclusion the researcher suggested that dentists should build on the work already achieved by mothers by teaching them the specific mechanics of tooth brushing.

Kowash et al. (2000) studied the effect of dental health education on caries incidence in infants. A random sample of 228 mothers with a child born between January 1st and September 30th 1995 living in a low socio-economic/high caries suburb of Leeds (UK) was selected. Each mother/child pair were then randomly assigned to one of four active dental health programme groups. The mean age of the children at baseline was 11.4 months, and of mothers, 29 years. The majority of children (80%) at baseline were bottle fed and 40 per cent of mothers reported that their children fell asleep with a bottle in their mouths. Comparing final data collection at three years between the study groups and a control group drawn from those children not originally randomly assigned to the study groups, statistically significant differences were recorded for frequency of dental visits ($p < 0.01$), frequency of drinking, sweet consumption and tooth brushing ($p < 0.001$). Interestingly, there was no difference in effect between the group receiving three monthly dental health visits compared to the group receiving 12 monthly visits. However, as the control group was not part of the randomised study, comparisons between the study groups and the control are open to bias. Equally, the study numbers for the final data collection were small and therefore may not be sufficient to detect clinically important differences.

Blinkhorn et al. (2001) examined the dental health knowledge of regularly attending mothers of high risk, pre-school children. Results demonstrated that whilst mothers may be very aware of the need to brush their child's teeth, this often may not occur. Equally, mothers require specific information relating to the use of toothpaste and dietary control in relation to their children's oral health. When testing the value of a dental health educator in general practice over a two year period, the overall benefit in reducing dental caries was not significant. Yet an improvement was detected in dental health knowledge, attitudes and tooth brushing skills among the mothers within the study group (Blinkhorn et al., 2003). Arguably, it may have been that the test group targeted were in fact not at risk, whereas perhaps a specific programme geared towards children with CLP may prove more effective. However, Davies et al. (2005) demonstrated that parents of children aged 8-32 months who received dental health advice, a feeder cup and postal deliveries of a high fluoride toothpaste adopted positive dental health behaviours. These included use of a free-flow feeder cup from the age of one year, brushing twice daily with a high fluoride toothpaste and use of drinks safe for teeth.

Kay and Locker (1996) carried out a systematic review of current evidence relating to dental health education interventions published between 1982 and 1994. The researchers examined 143 papers, 72 of which were excluded. The remaining 71 papers were assessed following set criteria and 37 papers were retained. All 37 papers included the use of a control or comparison group, and the majority assessed the effects of educational interventions on knowledge and attitudes or oral hygiene. Analysis revealed that 14 studies focused on improving knowledge and attitudes and all of these were successful in demonstrating a positive effect. Oral hygiene focused in 15 papers. A meta-analysis of three of these that used a plaque index as an outcome measure showed a small reduction in plaque accumulation. The researchers concluded that whilst plaque accumulation can be reduced, this occurred only in the short term, and to date dental health interventions had no effect on caries increment. Kay and Locker (1996) called for more rigorous, well designed,

randomised controlled trials to be conducted in order to further test the effects of dental health education programmes.

Rivkin et al. (2000) emphasised that parents of children with CLP must realise the importance of achieving good oral health from as early as possible, so forming preferred dental habits for life, allowing the most achievable dental outcome.

2.4   **The Use of a Fluoride Toothpaste**

The use of toothpaste containing fluoride has been shown by systematic review to be an effective method of topical, caries prevention (Marinho et al., 2003). A small, pea sized amount of a fluoride toothpaste should be used twice daily by young children, with brushing being supervised by the child's parent/carer. When teeth initially erupt, a smear of toothpaste is sufficient, with the emphasis being placed on effective parental brushing (BSPD, 1996). The level of fluoride concentration within the toothpaste may vary, however, there is a lack of evidence suggesting that toothpastes containing less than 1000 parts per million fluoride (ppmF) are effective (Levine and Stillman-Lowe, 2004). The BSPD (1996) stated that 1000ppmF toothpaste should be recommended for children at higher risk, and for children over six years considered at risk of developing caries the use of a 1450ppmF toothpaste should be strongly recommended.

Many pre-school children in the North West of England are from socially deprived backgrounds and research has shown that they are more likely to begin tooth brushing later in life and brush less frequently when compared to children from affluent backgrounds (Hinds and Gregory, 1995). Davies et al. (2002) found that a 1450ppmF toothpaste was significantly more effective in reducing caries in their study of children aged 12 months to 5.5 years. Their study carried out in the North West of England included nine districts reporting high caries levels. Children were randomly allocated to either the control or one of two test groups. The two test groups received postal deliveries of either a 1450ppmF or

a 440ppmF toothpaste. Children in the control group continued to brush without any intervention, therefore the fluoride content of their paste is unknown. Results revealed that the children using the 1450ppmF toothpaste demonstrated a statistically significantly lower mean dmft increment than either those receiving 440ppmF toothpaste or those in the control group ($p < 0.05$). Despite recommendations regarding the beneficial use of higher fluoride toothpastes, Blinkhorn et al. (2003) revealed that only three per cent of mothers were able to recall the ideal concentration of fluoride in toothpaste during their North West dental health education study. The review of the literature surrounding the oral health of children with CLP, despite its limitations, indicates a need for preventive dental health measures from as early as possible, and the use of a high fluoride toothpaste must be paramount in the care of these patients.

2.5 **Bottle Feeding Cessation and the Introduction of a Feeder Cup**

Prolonged, on demand, use of a feeding bottle containing a sugary drink or milk has been shown to be directly related to the formation of nursing caries (Ripa, 1988). Early caries development can ultimately result in young children undergoing general anaesthesia for the extraction of a number of carious teeth. This traumatic experience can lead to the child developing a fear of dental visits (Bridgman et al., 1999).

The Department of Health (1994b) advised that children should be encouraged to drink from a cup from the age of six months together with being discouraged from using a feeding bottle from the age of one year. The BSPD (2003) have endorsed these recommendations. However, Hinds and Gregory (1995) reported that 49 per cent of children aged 1.5-2.5 years still used a feeding bottle to drink from during the night.

When examining feeding practices in babies with CLP in Brazil, da Silva Dalben et al. (2003) found bottle feeding to be the prime feeding method for this study group. The caretakers of 200 babies with CLP ranging from 7-18 months of age were interviewed.

Results revealed the mean number of daily contacts with sugar via a feeding bottle in the 7-12 month old age group to be 5.92, and 5.19 in the 13-18 month old group. No reference was made to the introduction of a feeding cup, and although cultural differences may be present, the results do offer evidence regarding prolonged use of a feeding bottle containing a sugary drink. This evidence contributes to the high risk of caries development amongst children with CLP. In conclusion, the authors call for the development of a specific oral health programme for babies with CLP with particular emphasis on parental education and plaque control.

Lin and Tsai (1999) studied caries prevalence in children with CLP under the age of two in Taiwan. They also recorded parental attitudes towards the use of a night time feeding bottle. Whilst bottle feeding was significantly found to be related to nursing caries ($p = 0.019$), the study also revealed that the parents of the non-bottle fed children received better oral care (brushing frequency and brushing before bed) than the parents of the bottle-fed children ($p < 0.001$). This study underlines the call for early oral health promotion programmes directed towards the parents of children with a cleft.

2.6   **Periodontal Disease**

Periodontal disease primarily consists of gingivitis and periodontitis. Gingivitis is an inflammatory response of the gingival tissues to dental plaque. It is present in the majority of mouths and is characterised by redness, swelling and bleeding on brushing. Although gingivitis is readily reversible with effective plaque control, it may be a precursor of chronic periodontitis, which is the irreversible progression of infection and inflammation of the gingivae, periodontal ligament and bone (Williams et al., 1992). Parents are advised to brush their children's teeth twice a day using a small headed toothbrush together with a toothpaste containing fluoride (Levine and Stillman-Lowe, 2004). Parental brushing is necessary, particularly for pre-school children who do not have the manual skills to brush effectively themselves (BSPD, 2003).

Wong and King (1998) noted in their review of the literature, the lack of data available relating to the oral hygiene of children with CLP. Brägger et al. (1985) examined 80 patients with CLP aged 18-20 years, who had been under the care of a cleft team for 18 years in Switzerland. They reported that the percentage of tooth surface covered in plaque was high in all cleft types, ranging from 65 per cent in patients with isolated CL to 77 per cent in those with isolated CP. Patients were found to have poor oral hygiene, together with poor gingival and periodontal health. A further study by Brägger et al. (1992) re-examined 52 of the original 80 patients, their ages ranging from 26-28 years. On a positive note, the rate of progression of periodontal disease over the eight year period was not found to be significantly greater at the cleft site compared to control sites. The periodontal destruction at the cleft site in part may be due to the sub-gingival placement of prosthodontic reconstructions. Despite being under the care of various professionals linked to the cleft team, there was concern about the lack of an effective preventive dental health programme. Hence, Brägger et al. (1992) called for close supervision and motivation of oral health for the life time of all patients with CLP. Dahllöf et al. (1989), when comparing the oral health of 49 five and six year olds with CLP with matched controls, demonstrated a significantly higher number of sites with gingivitis within the group with CLP. Research conducted by Paul and Brandt (1998) showed that children with CP had cleaner teeth compared to children with CLP, and the authors suggested this may be related to oral hygiene maintenance being difficult in areas of anterior surgical repair. However, Lucas et al. (2000) reported no statistically significant differences in plaque levels or gingivitis between children with UCLP and matched controls. Whilst periodontal health per se may not be a prime issue in young children with a cleft, the literature emphasises the need for good long term dental health in order to achieve the maximum outcome.

2.7   Provision of General Dental Care for Children with Cleft Lip and/or Palate

The BSPD policy document (2003) examining oral health care in pre-school children stresses the importance of early dental registration. This should occur before or as soon as the primary teeth erupt, so providing the best opportunity to offer preventive dental health education. Equally the policy supports the use of health visitors as they are well placed to offer advice and to identify families in greatest need. Pre-school children who do develop dental caries should be referred to a specialist for care if the primary dental carer feels unable to offer restorative treatment.

Parents of children with CLP are advised and encouraged to register their children for routine dental care with their family GDP (CSAG, 1998). Not only does this reduce visits to the regional cleft centre, it also allows continuity of care, ensuring regular dental examinations for the child with CLP alongside his/her family. The community dental service (CDS) is also available to parents if their child has an associated syndrome and/or a management problem, or the family have experienced difficulties in accessing local NHS care through the GDS. Many of the dentists employed within the CDS are on the Paediatric Dentistry Specialist Register held by the General Dental Council, and are able to offer a more in-depth knowledge of the treatment relating to a patient with CLP. If clinicians are not able to provide dental care, the BSPD (2003) recommend that they should refer the child to a specialist clinician to allow provision of dental treatment accordingly. Whilst both Shaw et al. (1996) and the CSAG (1998) stress the need for regular, routine dental care for all children with CLP from their first year of life, accessing care locally for some families may prove difficult.

Williams et al. (2001) reported that whilst 95 per cent of five year old children with a UCLP in the UK were registered with a dentist, 40 per cent of the total sample was described as being in need of dental treatment due to the presence of unrestored dental caries. When comparing these data with a UK survey of five year olds conducted at a

similar time, Pitts and Evans (1997) reported 44 per cent of five year olds to be in need of restorative care, this figure rising to 54 per cent for the North West region.

The research has identified that whilst caries prevalence has reduced over time, this has not continued for young children, and much of the dental disease detected in pre-school children remains untreated. Hinds and Gregory (1995) found 83 per cent of the average dmft to be active caries. One factor relating to this may be lack of routine dental attendance. However, Tickle et al. (1999) revealed that dental registration may not automatically lead on to regular dental attendance. Hinds and Gregory (1995) have shown that dental attendance within the 1.5-4.5 year old group is very dependent upon the age, social class, educational qualifications and dental attendance habits of the mother. Pre-school children rely upon being taken to the dentist by their parent or carer. Amongst five year old children research demonstrates a positive association between regular dental attendance and reduced caries levels when compared to irregular attenders (Tickle et al., 1999). Kowash et al. (2000) reported regular home visits by dental health education promoters providing preventive dental advice to mothers of young children to be effective in improving dental attendance. However this is an expensive service possibly best targeted to children with identified special needs.

Hewson et al. (2001) recorded the age at the first dental visit for 90 children with CLP. Data were recorded for 67 (72%) of the study group. It is not clear if the remaining 28 per cent were not registered or merely that the information could not be recalled by the parent. Of the 67 (72%) registered 37 (55%) were initially examined within the school community dental service, 23 (34%) had initially been offered care via the orthodontic service and seven (11%) were seen by a private dental practitioner. The researchers offered no information as to where the children with CLP currently received their routine dental care. The point is made that children with CLP born in the 1990's (n = 23) had a mean age for a first dental visit of 21 months, ranging from five months to 4.5 years, whereas those born

in the 1980's received their first dental check up at a mean age of 5.7 years, ranging from 1.5 to eight years. The reason for this difference may be explained by a policy change made in 1993, where the local protocol deemed that all children with CLP during their first year of life should be referred to a paediatric dentist for care and preventive advice. This supports the CSAG (1998) recommendations but does not appear to allow parental choices regarding location of care which Shaw et al. (1996) and McDonagh et al. (2000) highlighted as being important.

Dabed and Cauvi (1998) conducted a study to ascertain the experience of dentists treating children with CLP in Chile. Questionnaires were sent to 203 paediatric and general dentists treating children in private and public health centres. Replies were received from 118 (58%) dentists. More than half (59%) reported experience of treating children with CLP, with 40 per cent working within the public health centres. Children treated were aged 7-15 years, as it was suggested this age range allowed better cooperation. This study failed to examine the provision of preventive dental care and therefore it is not clear if the children with CLP were under the care of the dentist prior to requiring dental treatment. Attention was also drawn to the lack of experience many dentists have in treating children with CLP, thus underpinning Shaw et al. (1996) and the CSAG (1998) who call for a named member of the central cleft team to coordinate and ensure effective preventive and restorative care for all children with CLP under their care.

McDonagh et al. (2000) designed a postal questionnaire to evaluate the attitudes of parents of 4-8 year old children with CLP, relating to the provision of paediatric dental care and to assess their experience of treatment within the GDS. Data were requested from 142 parents of children registered on the Birmingham CLP data base. A response rate of 77 per cent (109) was achieved. Results revealed that 99 (91%) children were registered with a GDP. Consideration must be given to the possibility that the 33 non-responders may not have been registered, giving a possible 30 per cent of the total sample not registered with a

dentist. Children under the age of four years were not included in the study as it was felt that many would not be registered with a dentist. This goes against recommendations made by BSPD (2003), Shaw et al. (1996) and the CSAG (1998) and is unacceptable in the long term provision of care for children with CLP. The data showed that the children had a varying degree of experience of dental care, 32 (29%) receiving restorative care, 10 (9%) dental extractions, 75 (69%) dietary advice and 63 (58%) oral hygiene instruction. The history of treatment was not offered, therefore it is not known if the care centred around the primary or permanent dentitions. Equally, they failed to discuss how long the children had been under the care of GDPs, or perhaps more importantly what, if any, preventive advice had been offered.

McDonagh et al. (2000) make no association between those children receiving preventive advice and those having active treatment. Therefore no comment can be made relating to the effectiveness of the preventive care offered. When asked whilst attending the cleft centre would parents welcome dietary advice from a paediatric dentist, 42 (39%) responded positively, this rising to 70 (64%) when being offered a dental examination by a paediatric dentist. However, if treatment was found to be needed 46 per cent indicated that they would prefer this to be carried out locally, thus underpinning the recommendations of Shaw et al. (1996). Yet Tickle et al. (2003a) have demonstrated that GDPs are restoring fewer primary teeth and therefore treatment may not ultimately be offered. However, they do report that preventive advice may be offered, together with fluoride varnish in more affluent families. McDonagh et al. (2000) highlighted almost one third of respondents reported never receiving dental health education from their GDP, which potentially rises to 43 per cent if the non-responders are included.

Rivkin et al. (2000) stressed the need for early dental registration for all children with CLP, but suggested that this is often delayed, especially if the family GDP discourages early

registration before two years of age. Unfortunately, studies have shown that dental caries may be evident by this age (Johnsen and Dixon, 1984; Bokhout et al., 1997).

Morrison et al. (2000) investigated the attitudes of parents of young children to early dental registration with GDPs in Scotland. Many parents believed some dentists may lack the appropriate skills to treat children. This possibly may also be an issue for parents of children with CLP. Tickle et al. (2003b) investigated parents' attitudes to the dental care of their children. Interestingly, response via a postal questionnaire revealed only six per cent of parents would wish their GDP to restore a carious, asymptomatic tooth and 21.6 per cent wanted intervention for a tooth causing pain, whereas McDonagh et al. (2000) demonstrated that 46 per cent of parents would want treatment to be provided by their GDP should dental caries be detected by the CLP multidisciplinary team. Encouragingly, the most recent Children's Dental Health Survey in the UK, 2003 (Lader et al., 2005) reported more children to be visiting a dentist than at an earlier period. In 1983, only seven per cent of parents of five year old children reported that their children had visited a dentist before the age of two. By 1983, this figure had more than doubled to 15 per cent and by 2003 the reported figure for this age group was 31 per cent. Importantly, in 2003, 22 per cent of parents of five year olds reported problems in accessing dental care from NHS dentists for their children (Pitts et al., 2005). Rivkin et al. (2000) suggested that parents value the opportunity to gain dental advice, often before their infant's teeth have erupted. Regular dental visits allow a relationship to develop between the parent and the dentist, providing the ideal situation for continued preventive dental health advice. However this may not be possible for some families who find accessing local dental care difficult.

Rodd et al. (2007) investigated the number of scheduled and failed dental appointments for 45 cleft patients attending the Sheffield Dental Hospital. The children ranged from 3-14 years of age, with a mean age of 8.8 years. They were compared to 45 non-cleft children but the authors did not state why these children attended the Dental Hospital. Results

revealed that the cleft group had significantly more dental appointments ($p < 0.05$) and more importantly, the cleft children failed more appointments than the non-cleft children (24.6% versus 11.1%). The largest number of failed appointments across the specialities was in the paediatric dentistry department. This perhaps underpins the views of McDonagh et al. (2000) who found that should a child with CLP require dental treatment, its parents would prefer this to be carried out locally rather than in a hospital based cleft unit. It also adds weight to Shaw et al. (1996) who recommended that where possible dental treatment should be provided locally.

In an attempt to address the availability of local dental care, the Department of Health (2002) proposed a service enabling the dental profession to offer high quality care centred around the individual needs of each patient. Preventive measures in order to tackle the dental disease particularly experienced by children are emphasised. Following implementation of new standards the following will be available to all children:

- Children at high risk of dental disease would have access to appropriate prevention and treatment.
- Parents/carers will find it easier to locate local NHS dental services.
- Primary Care Trusts will be introducing targeted initiatives to reduce DMF levels which may involve prevention, registration and tooth brushing schemes.
- Children and parents/carers who require it will be given more help and encouragement to prevent dental disease.
- Dental services for children with special needs will be locally available and easy to access.
- There will be comprehensive emergency dental care for children.
- Children's experience of dental services, including the communication skills of the dental team, the environment and the care provided, will improve.

    (NHS Dentistry: Options for Change, DoH, 2002).

Similarly, a recent NICE guideline (2004) recommends the importance of regular dental recalls in order to provide an opportunity to offer preventive dental advice whilst simultaneously increasing the parents' awareness of the benefits of good oral health. The introduction of these proposals will address the recommendations of Shaw et al. (1996) and the CSAG (1998) regarding regular preventive advice and dental care being provided locally. This reinforces the need for a member of the cleft team being able to ensure patients are receiving targeted preventive care and advice as needed.

2.8   **Conclusion**

The review of the literature relating to the dental health status of children with CLP highlights the poor oral health experienced by some children.

Johnsen and Dixon (1984), Dahllöf et al. (1989), Bokhout et al. (1997) and Lin and Tsui (1999) all recommended a dental health programme for parents of children with CLP from as early as possible with particular emphasis being placed on the oral hygiene surrounding the cleft area. However, their research did not test the effectiveness of this and therefore the need to investigate this area exists. Paul and Brandt (1998) called for improved communication between the patient, parent and dental operator in order to improve oral hygiene and reduce caries levels in children with CLP. Yet there is no clear evidence to suggest this method is effective and therefore it should be tested. Gregg et al. (1999) recommended a specialist in paediatric dentistry form part of the CLP multi-disciplinary team in an attempt to improve the oral health of children with CLP. Whilst this agrees with the CSAG (1998) this has not been tested and there is no evidence to suggest that this role could not be carried out by other dental team members.

Overall, this literature review demonstrates the lack of randomised controlled trials available to examine this important group in an attempt to discover an evidence based way forward in the dental health care of these children.

A study to measure the effectiveness of a preventive dental health programme aimed at modifying the dental behaviour and knowledge of mothers of infants with CLP is relevant.

In order to test this, the following aim and objectives have been formulated.

2.9   **Aim**

2.9.1   To monitor and test the effectiveness of a specific Preventive Dental Care Programme for infants with CLP.

2.10   **Objectives**

In order to achieve this aim, the following primary objectives were set. To record and compare:

2.10.1 dental registration and attendance at local dentists of the infants in the Programme with those in a control group.

2.10.2 the use of 1100ppmF toothpaste by parents in the Programme to brush their infant's teeth with those in a control group.

2.10.3 the use of a feeder cup by infants in the Programme with those in a control group.

Further, secondary objectives were also set:

2.10.4 To record and compare the age of cessation of a feeding bottle used by infants in the Programme compared with those in a control group.

2.10.5 To measure and compare parental dental health knowledge of mothers in the Programme with mothers in a control group.

2.10.6 To record the cost of providing the Programme to mothers of infants.

The null hypotheses and methodology will be discussed in detail in Chapter 3.

Chapter 3

Methodology

3.0   Introduction

This chapter will focus on the formulation of the aim, objectives, hypotheses and sample size for this randomised controlled trial of one year's duration. Information presented will follow the CONSORT 2010 Statement, (Schulz et al., 2010) in conjunction with recommended guidance, (Moher et al., 2010). The Preventive Dental Health Programme (the Programme) devised for the study will be discussed together with detailed information relating to the provision of the programme. The method of cost assessment and selected statistical tests together with confidence levels will also be included.

3.1   Aim

Following a review of the literature it was concluded that a randomised controlled trial to measure the effectiveness of a preventive dental health programme aimed at modifying the dental behaviour and knowledge of mothers of infants with cleft lip and/or palate (CLP) was relevant. The aim therefore was:-

To monitor and test the effectiveness of a specific Preventive Dental Care Programme for infants with CLP.

3.2   Objectives

In order to achieve this aim, the following primary objectives were set. To record and compare:

3.2.1   dental registration and attendance at local dentists of the infants in the Programme with those in a control group.

3.2.2   the use of 1100 parts per million fluoride (ppmF) toothpaste by parents in the Programme to brush their infant's teeth with those in a control group.

3.2.3   the use of a feeder cup by infants in the Programme with those in a control group.

Further, secondary objectives were also set:

3.2.4   To record and compare the age of cessation of a feeding bottle used by infants in the Programme compared with those in a control group.

3.2.5   To measure and compare parental dental health knowledge of mothers in the Programme with mothers in a control group.

3.2.6   To record the cost of providing the Programme to mothers of infants.

In order to test these objectives they were stated as null hypotheses.

3.3   **Development and Conduct of the Study**

It was planned to test the hypotheses using a two group randomised, controlled, single blind prospective clinical trial of a year's duration (CONSORT 3a, Schulz et al., 2010). Infants with CLP who were referred to the Greater Manchester Cleft Lip and Palate Unit (the Unit) were included following their primary surgery after their mothers had read an approved information document and signed an informed consent form (CONSORT 4a, Schulz et al., 2010). They then verbally answered piloted dental health knowledge and behaviour questionnaires. Following this they were randomly allocated to test and control groups (3.5). Data were collected pre-randomisation within a dental surgery in the Unit and post intervention via a telephone interview in an independent setting, (CONSORT 4b, Schulz et al., 2010).

Each mother in the test group then received the Programme. This consisted of advice to seek dental care locally and assistance, if requested, in obtaining regular dental care for her child from a local community dental service (CDS) clinic near her home. In addition, she received an infant toothbrush and a tube of 1100ppmF toothpaste for her child with instruction in its use. She was also given advice on diet control, specifically introducing and using a free-flow feeder cup instead of a baby's bottle. The mother was then given a free-flow feeder cup for her infant to use and a specifically designed leaflet reinforcing the information given. This was followed up periodically over the next year by communicating with the infant's dentist encouraging regular attendance and reinforcement of preventive dental health behaviour. A new tube of 1100ppmF toothpaste together with the leaflet was also sent to the infant every three months over the 12 month study period, (CONSORT 5, Schulz et al., 2010).

Each mother in the control group received at the first visit a traditional preventive dental health programme. This consisted of a tube of 1100ppmF toothpaste, advice on regular attendance with a referral to a local CDS clinic if required and the use of a free-flow feeder cup. No further contact was made with the mothers in the control group until the year's end, (CONSORT 5, Schulz et al., 2010)

At the end of the year all mothers in both control and test groups were telephoned by an independent investigator who was unaware of the group allocation and asked to respond to similar knowledge and behaviour questionnaires as at baseline, (CONSORT 5, Schulz et al., 2010).

The primary outcomes were the proportion of infants registered and attending, using fluoride toothpaste and using a feeder cup measured at one year post intervention, reported via a behavior questionnaire. The secondary outcomes examined the cessation of a feeding bottle, dental health knowledge between groups and provision costs of the programme. The success of the Programme was measured by comparing the responses between both groups and between baseline and final responses within groups. There were no important changes made to the methods or trial outcomes following commencement of the trial, (CONSORT 3b, 6b, Schulz et al., 2010). In addition, the dental health status was recorded of those children in both groups who attended their multidisciplinary team review clinic appointment aged three years. They were examined by a specialist in paediatric dentistry who was unaware of the group allocation. The dentition and presence of dental caries were recorded, (CONSORT 6a, Schulz et al., 2010).

The following section will describe the details of this general description and Figure 3.1 provides an overview of the conduct of the study.

Figure 3.1   **Process of the study**

```
                    ┌─────────────────────────────┐
                    │ Primary surgery post op visit│
                    └─────────────────────────────┘
                                  │
                                  ▼
                    ┌─────────────────────────────┐      ┌──────────────┐
                    │ Mother given information sheet│─────▶│   Negative   │
                    └─────────────────────────────┘      │   consent    │
                                  │                        └──────────────┘
                                  ▼                               │
                    ┌─────────────────────────────┐               ▼
                    │ Positive consent from mother │      ┌──────────────────┐
                    └─────────────────────────────┘      │ Dental health    │
                                  │                        │ education as that│
                                  ▼                        │ of control group │
                    ┌─────────────────────────────┐      │ but not allocated│
                    │ 2 questionnaires with researcher│   │ to the control   │
                    └─────────────────────────────┘      │ group            │
                                  │                        └──────────────────┘
                                  ▼
                    ┌─────────────────────────────┐
                    │        Randomisation         │
                    └─────────────────────────────┘
```

Test group	Control group
Preventive advice: Dental attendance Tooth brushing 1100ppm fluoride paste Cessation of baby bottle Use of a feeder cup Diet advice **Mothers will receive** Free flow feeder cup 1100ppm fluoride paste Small headed toothbrush Dental health leaflet 3 monthly supply of tooth paste and leaflet Referral to local CDS if needed Liaison with dentist Liaise with mother if fails to attend dentist	**Preventive advice:** Dental attendance Tooth brushing 1100ppm fluoride paste Use of a feeder cup **Mothers will receive** 1100ppm fluoride paste Ref to local CDS if needed

12 mth telephone review by independent researcher, questionnaires x 2 (Test group)

12 mth telephone review by independent researcher, questionnaires x 2 (Control group)

Dental exam aged 3 years

Results analysis

Discussion

3.4   **Sample Size Calculation**

In order to determine the number of infants required for the study, data relating to infants referred to the Unit during 2002 were collected and used within the sample size calculations. The Unit catchment area covers Manchester and its surrounding boroughs. These are Bolton, Oldham, Stockport, Wigan, Salford, Rochdale, Tameside, Trafford and Blackburn. It also extends out to Lancashire, South Cumbria (from Grange over Sands to Barrow in Furness), West Derbyshire (to include Buxton and Glossop) and parts of Cheshire to incorporate Macclesfield.

Tables 3.1 and 3.2 describe the cleft type, gender and home area for the infants referred from which the sample size for the study was calculated. This was carried out controlling for three factors, dental registration, use of 1100ppmF toothpaste and use of a feeder cup. The data in Table 3.1 and verbal estimates from the three clinical nurse specialists (CNS) on the Unit's team were used for this and the largest sample size required was selected, (CONSORT 7a, Schulz et al., 2010). Loss to follow-up of these infants is small due to the close contact with the families by the Unit's CNS and Unit coordinator.

3.4.1   Dental registration

A two group continuity corrected chi-squared test with a 0.05 two-sided significance level will have 90% power to detect the differences in dental registration between a control group proportion of 0.150 and a test group proportion of 0.500 (odds ratio of 5.667) when the sample size in each group is 42.

3.4.2   Use of 1100 parts per million fluoride toothpaste

A two group continuity corrected chi-squared test with a 0.05 two-sided significance level will have 90% power to detect the difference in the use of a fluoride toothpaste between a

Table 3.1

Cleft type and gender of infants under the care of the Greater Manchester

Cleft Lip and Palate Unit born during 2002

Cleft Type	Male n (%)	Female n (%)	Total n (%)
CP	11 (31)	27 (56)	38 (45)
UCLP	10 (28)	8 (17)	18 (21)
CL	9 (25)	12 (25)	21 (25)
BCLP	6 (17)	1 (2)	7 (8)
Total	36 (101)	48 (100)	84 (99)

(Irregularities due to rounding)

Key:

CP = Cleft palate

UCLP = Unilateral cleft lip and palate

CL = Cleft lip

BCLP = Bilateral cleft lip and palate

Table 3.2

Residential area of infants under the care of the Greater Manchester

Cleft Lip and Palate Unit born during 2002

Area	Total
Manchester	13
Bolton	12
Oldham	7
Stockport	7
Wigan	6
Salford	6
Rochdale	6
Tameside	6
Fylde	5
Lancaster	4
Blackburn	4
Trafford	3
Derbyshire	3
Cheshire	1
Preston	1
Total	84

control group proportion of 0.100 and a test group proportion of 0.500 (odds ratio of 9.000) when the sample size in each group is 31.

3.4.3   Use of a feeder cup

A two group continuity corrected chi-square test with a 0.05 two-sided significance level will have 90% power to detect the difference in the use of a feeder cup between a control group proportion of 0.200 and a test group proportion of 0.600 (odds ratio of 6.000) when the sample size in each group is 35.

Following these calculations it was decided to include 86 infants in the study.

3.5   **Random Allocation to Group**

Allocation to either test or control group by stratified, random allocation controlling for variation in cleft type was prepared by an independent statistician and a Unit administrator and concealed from the researcher, (CONSORT 8b, Schulz et al., 2010).

Ninety cards were prepared, 45 of which read "test" whilst the remaining 45 read "control". Ninety opaque, plain envelopes were used, sixty of which were labelled "Cleft Palate" and numbered 1-60, whilst the remaining 30 were labelled "Cleft Lip" and numbered 1-30. Random allocation of cards to envelopes via a computer generated random numbers programme, was then carried out by the statistician and a Unit administrator not involved in the trial. The sealed envelopes were then kept in a locked cupboard by the administrator. A further ten cards were allocated randomly by the statistician to the Cleft Palate group. This allowed further recruitment to this group whilst waiting for Cleft Lip only infants to join the trial. The envelopes were opened in numerical order within the two cleft groupings, (CONSORT 8a, 9, 10, Schulz et al., 2010).

3.6   **Development of the Preventive Dental Health Programme**

The Programme was designed and developed to impart dental health knowledge to the mothers of infants attending the Unit. The Unit's care plans dictate that infants with CLP receive primary surgery to close the lip at the age of 3-4 months followed by the hard palate at 9-10 months. Therefore infants attending for primary surgery, post-operative review appointments range from 5-11 months of age. It was decided that prior to surgery, parents may have too many other concerns to be receptive to dental health education. Therefore the decision was made to introduce the Programme at the post-operative review appointment of the primary surgery. The Programme and questionnaires were developed to ascertain baseline and final knowledge and reported behaviour of the parents to address the null hypotheses set. The development of these will now be discussed followed by an explanation of how the Programme was carried out.

3.6.1   Parent information letter and consent form

These were written following ethical approval guidelines issued by the Ethics Committees of the University of Manchester and the Central Manchester Hospitals (Appendices 1 and 2).

3.6.2   Questionnaires to mothers regarding their children's oral health

Two questionnaires were developed; one to record reported behaviour and the other to determine their dental health knowledge in respect of their infants.

The questionnaires were piloted among parents attending the Unit. The researcher verbally carried out the pilot test, recording parents' answers on the questionnaires themselves. Care was taken not to involve parents who may have been included in the planned research project. Alterations to the questionnaires were made accordingly. The format of the questionnaires was also changed to incorporate answer coding allowing the smoother transfer of collected data to the selected statistical package. The final questionnaires incorporated relevant changes and included a data sheet for collecting information relevant to each infant (Appendices 3 and 4).

In order to prepare the questionnaire on reported behaviour, guidance was requested from the Unit's clinical nurse specialists in order to discover all possible feeding methods for these babies.

The final behaviour questionnaire after 12 months mirrored the baseline reported behaviour questionnaire in order to allow comparisons between the two. However, the non-relevant questions were omitted, for example if the infant was registered with a dentist the mother was not asked if she would like help with registering her infant with a local dentist (Appendix 5).

The baseline and final dental knowledge questionnaires were identical in order to allow comparisons between the two.

3.7 Dental Health Leaflet

A specifically designed leaflet was produced in order to reinforce the dental health advice given to mothers in the test group. Information contained in the leaflet related to the subject areas questioned in the null hypothesis.

3.7.1 Leaflet content

Information was presented encouraging early dental registration, emphasising the fact that dentists are able to accept children from birth. The benefits of early and regular dental attendance were stated.

Specific advice was also given relating to the size of toothbrush, amount and fluoride content of toothpaste to be used. The appearance and access to teeth in the cleft area were explained together with the benefits of using a fluoride toothpaste.

The relationship between frequency of sugar intakes and development of dental caries was also explained. Information encouraged readers to use a feeder cup, and guidance was given regarding acceptable drinks in relation to dental health.

A check list of information followed to reinforce this advice.

Finally, information regarding contacting a local general dental practitioner (GDP) or CDS was given, together with contact details of the Unit.

3.7.2 Leaflet production

In order to produce a leaflet relevant to parents of children with CLP the researcher organised a clinical photographer to take photographs of infants with CLP and their mothers in the dental setting. Consent was gained from all mothers who participated (Appendix 6). The first draft of the leaflet was produced using the help of the Staff Teaching Workshop, University of Manchester. This was then piloted with parents attending the Unit and also sent for comments to a number of local experts in dental health promotion. Critical comments were incorporated into the second draft of the leaflet. This was then returned to the advisors for further comments. Alterations were made and the final leaflet was compiled (Appendix 7). Two hundred and fifty copies of the leaflet were ordered for use during the research project. The leaflets were produced by the Staff Teaching Workshop, University of Manchester.

3.7.3 Leaflet distribution

The final leaflet was given to every mother allocated to the test group during their primary surgery, post-operative review clinic appointment. The leaflet reinforced the dental health information given to the mother by the researcher. The leaflet was also posted to the dental practices where the infants in the test group were registered. The dentist was asked to reinforce the advice given in the leaflet to the mother when they attended for an inspection. Toothpaste was posted out to the infants every three months during the test period, and the same leaflet was included with each posting.

3.8 **Provision of Toothpaste**

The literature review underpinned the need to recommend a toothpaste containing 1100ppmF or more, for this high risk group. In order to address this it was decided to use Colgate Looney

Tunes 1100ppmF toothpaste throughout the study. During the baseline data collection, infants in both groups were given a tube of the chosen toothpaste. Infants within the test group then received a further three tubes, posted out at three monthly intervals to the infant's home address. The toothpaste tubes were placed in a jiffy bag together with a copy of the dental health leaflet and a compliment slip stating from where the toothpaste and leaflet had been sent. In order to test the feasibility and cost of this process, the researcher posted a tube of toothpaste to herself. The package arrived at the researcher's home address intact. The package was small enough to be posted through the letterbox, and the transit did not cause any damage to the contents of the package. Hence, all toothpaste was posted out similarly. The packages were addressed to the infants involved in the study group, so as to avoid any confusion as to who the toothpaste was for.

3.9   Provision of a Toothbrush

All infants allocated to the test group were provided with a Colgate small headed, baby toothbrush.

3.10   Provision of a Feeder Cup

The guidance regarding dental health and feeder cups clearly recommends the use of a free-flow feeder/trainer cup introduced as weaning begins. The researcher discussed the most suitable type with the Unit's clinical nurse specialists and agreement was reached favouring the purchase of Product Technology (UK) Ltd, 1st Trainer Cup. This is free-flow and has a twist and seal lid allowing a drink to be carried whilst travelling without leaking (Appendix 8).

3.11   Referral Letter to Community Dental Services

Parents in the test and control groups who requested help in finding a local GDP were offered a referral to their local CDS. This was done using an appropriate letter (Appendix 9).

3.12 Letter to General Dental Practitioner/Community Dental Services

During the baseline interview details of the dental practice where the infant was registered were recorded. The dentists of those infants within the test group who were registered were sent a letter one month after the initial interview asking them to ensure frequent recalls and to reinforce preventive dental advice (Appendix 10). A copy of the study leaflet was included with the letter, with the request that information within the leaflet be reinforced by the dentist.

3.13 Letter to Parents who Fail to Register/Attend for Local Dental Recall

Parents who failed to register their infants at a local practice/community dental clinic were sent a letter asking if they required help in finding local care (Appendix 11). A stamped addressed envelope was included to encourage continued communication.

3.14 Ethical Approval

The draft protocol together with the parents' information document, consent form, questionnaires and letters to dentists and parents were sent to the Ethics Committees of the University of Manchester and the Central Manchester Hospitals Trust for approval. All their suggestions were incorporated in the final protocol. Concern was expressed about the possible hazard of an infant swallowing the contents of a tube of fluoride toothpaste. On being acquainted with a Colgate policy document on this issue they were satisfied and the final protocol was approved.

3.15 Conduct of the Project

A Unit administrator informed the researcher when infants would be attending for post-operative primary surgery appointments. The researcher attended these clinics and approached mothers of infants requesting their inclusion in the project. The Patient Information Sheet (Appendix 1) was given to every mother and the researcher was on hand to answer any queries raised by the mothers. Mothers agreeing to be included in the project then completed the Consent Form (Appendix 2) which was also signed by a witness and the

researcher. All consent forms were retained by the researcher who enrolled these infants into the trial, (CONSORT 10, Schulz et al., 2010).

3.15.1 Completion of infant data and baseline questionnaires

Following the provision of positive consent, using the baseline data collection sheet and questionnaires (Appendices 3 & 4), the researcher proceeded to ask the mother the set questions. The mothers' responses were duly recorded. Contact details were also entered onto the record sheet.

3.15.2 Allocation to group

Upon collection of the baseline data, the researcher informed the Unit administrator of the cleft type of each infant whose mother had signed a consent form. Dependant on whether the child had a cleft lip only, or cleft lip and palate an appropriate envelope was opened by the administrator to reveal the allocation to either the test or control group. This information was then recorded by the administrator, (CONSORT 10, Schulz et al., 2010). Allocation to group was not recorded on the infant data collection record, as the recorded contact details would be required by a separate independent person who would perform the final telephone data collection of all infants included in the study. This was to maintain the single blind component of the study for the collection of the 12 month outcome data. Obviously the parents of the infants knew which group their infant had been allocated to, (CONSORT 11a, Schulz et al., 2010).

3.16 **Procedure for the Test Group**

Mothers of infants allocated to the test group were then given specific advice relating to their infant's dental health, (CONSORT 5, Schulz et al., 2010).

3.16.1 Dental registration

The need for regular dental inspections with a local GDP or CDS was discussed. If the infant was not registered with a dentist, help was given to find local care for the infant. If a parent

chose to contact her family dentist, the researcher contacted her one month later for the contact details of the dentist. A number of mothers requested a referral to their local CDS clinic. A referral letter (Appendix 9) was sent to the requested clinic by the researcher.

3.16.2 Tooth brushing

The importance of good oral hygiene was stressed in relation to both personal hygiene and long term gingival health should an alveolar bone graft and/or orthodontic appliances be required. Each mother was then shown how to brush her infant's teeth by laying her child flat and gently lifting the upper lip to gain access to the cleft area. Smearing the toothpaste onto malaligned teeth in the cleft area was recommended (with the explanation that the topical effect of the fluoride offered protection to these teeth). The possibility of hypoplastic teeth erupting in the line of the cleft was discussed. The researcher also described the appearance of these teeth and reinforced their care. Each mother was given a small-headed baby toothbrush and a tube of 1100ppmF toothpaste. Postal delivery of further toothpaste at three monthly intervals for one year was explained.

3.16.3 Diet advice

The researcher described the association between frequent in-between meal sugar intakes and dental caries, as an introduction to a controlled diet. However, as many of the infants were still in the process of being weaned, the advice focused more specifically on the introduction of a feeder cup and its contents. The need to stop all bottle feeding by the age of 12 months was discussed, with information focusing on prolonged on-demand bottle feeding and its association with dental caries. A free-flowing feeder cup was given with the recommendation to use this instead of a bottle, aiming to stop the use of a feeding bottle by 12 months of age. The researcher suggested that the feeder cup should contain either cooled boiled water or milk. Mothers were encouraged to use feeder cups instead of feeding bottles putting small amounts into the cups to minimise spills and wet clothing. Perseverance was encouraged with the long term aim of stopping the use of the feeding bottle.

3.16.4 Reinforcement of advice

Every mother was given a copy of the Programme's dental health leaflet (Appendix 7) which reinforced all the information given by the researcher. The researcher also pointed out contact telephone numbers contained in the leaflet. The opportunity to ask questions and clarify information was given throughout the interview.

3.16.5 Continuation of the research

Mothers were informed of the three monthly postal deliveries of toothpaste, and asked that they continue to use this toothpaste for their infant during the study. The researcher explained she would contact the infant's local dentist in order that he/she reinforced the given dental health advice at recall (Appendix 10). If the infant was not registered with a local dentist, the researcher offered a referral to a local CDS (Appendix 9). One month later, the researcher contacted the mother by telephone to check registration and record the dentist's contact details. Failure to register with a local dentist resulted in a letter being sent to the mother offering help with local dental registration (Appendix 11). All dentists were contacted to inform them of their patient's inclusion in the study, to provide them with a copy of the Programme's dental health leaflet and to request that they reinforce the preventive dental health messages at each dental recall.

3.17   **Procedure for the Control Group**

Mothers of infants allocated to the control group were given general dental advice relating to their infant. They were advised to use a toothpaste containing 1100ppmF or more and given a tube of Colgate Looney Tunes 1100ppmF toothpaste to take home. If requested a referral to their local CDS clinic was arranged.

3.18   **Final Data Collection following the Twelve Month Intervention**

All the mothers in both groups were informed that they would be contacted by telephone in a year's time by an independent person who would ask them to verbally complete the questionnaires again (Appendix 5).

3.19   **Final Data Collection at the Multidisciplinary Review Clinic, Aged Three Years**

Children involved in the trial were followed up whilst attending their three year multidisciplinary team (MDT) review at aged three years. All mothers were asked to complete the questionnaires again, (Appendix 5) and the dental health status of all infants was recorded during a dental examination.

3.19.1   Dental examination

A dental examination was conducted by a specialist in paediatric dentistry who had not been involved with the study and was unaware of group allocation. The examination was conducted in a dental surgery on a dental chair or with the child on its mother's lap if the child declined to sit on the dental chair. A dental mirror and dental examination light were used and the teeth were air dried during the examination. Radiographs were not taken unless deemed clinically necessary. The examination data were recorded in writing by a trained dental nurse not involved in the study and unaware of group allocation, (CONSORT 11a, Schulz et al., 2010).

3.20   **Procedure for the Cost Assessment**

Throughout the study period records were kept relating to the cost of postal charges incurred in sending toothpaste and letters relevant to the study. Time spent on telephone calls both to parents and dental practices was recorded and costed accordingly. A continual record of time spent on the administration of the test group was kept and costed to that of a relevant pay scale.

3.21   **Statistical Analysis**

3.21.1   Reported dental behaviour and dental knowledge

Following the 12 month study period, collection of the questionnaire data and three year review clinic data, the process was evaluated. Statistical tests were not conducted on the baseline data alone as randomisation will have ensured equal groups (Roberts and Torgerson, 1999). The primary outcomes, (3.2.1 – 3.2.4) were analysed using descriptive statistics

together with a discussion of the project process . Additionally, a statistical analysis of the quantitative data was conducted using the Chi square test or Fishers' Exact Test for 2x2 tables when expected numbers were small (less than 10). Confidence intervals were also calculated to further examine and explain data relating to primary objective 3.2.1 (dental registration and attendance). The secondary objectives, 3.2.4 - 3.2.6 were assessed by descriptive statistics, Chi square test or Fishers' Exact Test for 2x2 tables when expected numbers were small (less than 10) whilst the McNemar test was used to examine changes in dental health knowledge over time between baseline and 12 months or three years, (CONSORT 12a, Schulz et al., 2010). No additional statistical methods were used for subgroup analyses, (CONSORT 12b, Schulz et al., 2010).

3.21.2   Dental caries

The distribution of dental caries in comparison to gender and cleft type are shown. The means and standard deviations are presented for the decayed, missing and filled teeth (dmft) and decayed, missing and filled surfaces (dmfs) in enamel and dentine for the combined groups.

Chapter 4

Results

4.0   **Introduction**

Recruitment and data collection commenced in April 2004, and this phase lasted 22 months. Figure 4.1 describes the flow of participants through the analysis process. At baseline 88 participants were recruited to the study, 45 in the test group and 43 in the control. Following the 12 month study period 87 participants were contacted, 45 in the test group and 42 in the control. One participant in the control group was lost to follow up. The third and final data set was collected when the infants attended their three year multidisciplinary cleft team review (MDT) appointment. A total of 82 participants were available, 42 in the test group and 40 in the control. The six missing participants, three in each group had moved out of the area and hence were lost to follow up. The results are presented in five sections (4.1 – 4.5) followed by an overall summary (4.6).

4.1   Description of the Study Population

4.2   Baseline Characteristics of the Whole Sample

4.3   Results of the Intervention

4.4   Description of the Study Population Dentition Aged Three Years Recorded at the Multidisciplinary Review Clinic

4.5   Cost of the Programme

4.6   Summary of Results

Figure 4.1   Flow of participants through stages of the results analysis
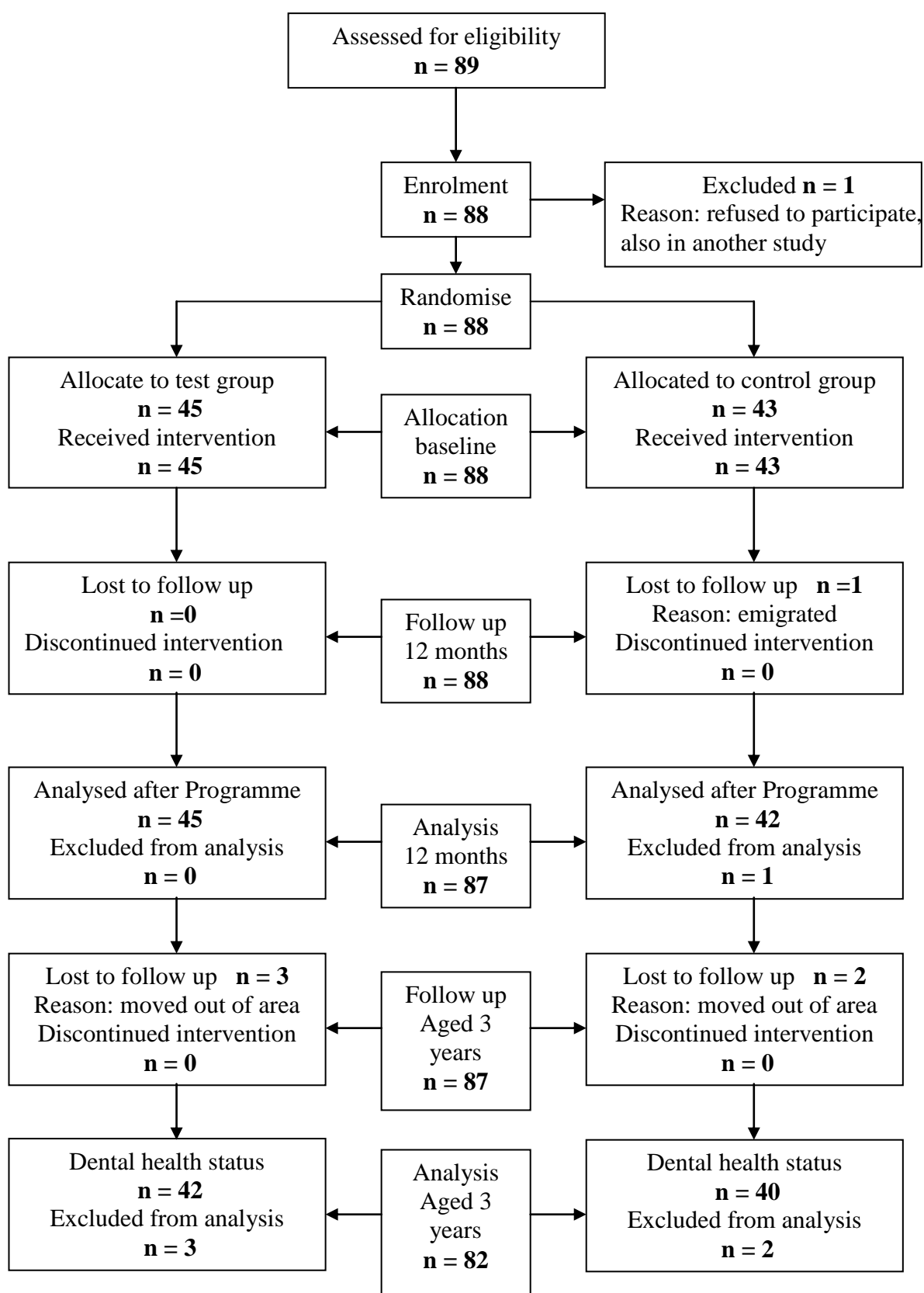
4.1 Description of the Study Population

4.1.1 Age, cleft types and area of residence

A total of 88 mothers of infants with cleft lip and/or palate (CLP) were recruited to the trial, 55 (63%) males and 33 (38%) females. Only one mother refused to participate in the study as she was involved in another project.

At baseline the age of the infants ranged from four to 31 months. As there was one outlier aged 31 months it was more appropriate to examine the median age of the infants, which was 10.5 months, with four months at the 5th percentile and 17.1 months at the 95th percentile. Further exploration demonstrated that the median age for males was eight months, with four months at the 5th percentile and 15 months at the 95th percentile. The median age for females was 11 months, with 4.7 months at the 5th percentile and 24.7 months at the 95th percentile.

At baseline the type of cleft for each infant was recorded. The distribution of cleft type according to gender is described in Table 4.1. A third of males (36%; 20) and over half of the females (55%; 18) were diagnosed with a cleft palate (CP). Fourteen (25%) males and six (18%) females were diagnosed with a cleft lip (CL), 14 (25%) males and seven (21%) females with a unilateral cleft lip and palate (UCLP) and seven (13%) males and two (6%) females with a bilateral cleft lip and palate (BCLP). Data regarding infants with CL and UCLP were further explored to ascertain the position of the cleft. Eleven (13%) were located on the right side of the mouth and 26 (32%) on the left.

The majority resided in the Manchester (26%), Fylde (14%), Stockport (11%) and Blackburn (11%) areas of the region (Table 4.2.).

Table 4.1

Distribution of cleft type compared with gender at baseline

Type of Cleft	Male n (%)	Female n (%)	Total n (%)
CP	20 (36)	18 (55)	38 (43)
CL	14 (25)	6 (18)	20 (23)
UCLP	14 (25)	7 (21)	21 (24)
BCLP	7 (13)	2 (6)	9 (10)
Total	**55 (99)**	**33 (100)**	**88 (100)**

(Irregularities due to rounding)

Key:

CP: Cleft palate

CL: Cleft lip

UCLP: Unilateral cleft lip and palate

BCLP: Bilateral cleft lip and palate

Table 4.2

Residential area of infants involved in the trial under the care of the Greater Manchester Cleft Lip and Palate Unit

Area	n (%)
Manchester	23 (26)
Bolton	5 (6)
Oldham	4 (5)
Stockport	10 (11)
Wigan	6 (7)
Salford	2 (2)
Rochdale	2 (2)
Tameside	1 (1)
Fylde	12 (14)
Lancaster	1 (1)
Blackburn	10 (11)
Trafford	2 (2)
Derbyshire	1 (1)
Cheshire	4 (5)
Preston	2 (2)
Bury	3 (3)
Total	**88 (99)**

(Irregularities due to rounding)

4.1.2 Medical history

At baseline the medical history was recorded and this was updated at the three year MDT appointment. Over a fifth, (23%; 20) of the infants had been diagnosed with further medical conditions. Examination of the data in relation to cleft type demonstrated that the greatest proportion of infants with medical history problems were those with CP, (34%; 13), with the remaining seven spread across the cleft types; three (15%) with CL, three (14%) with UCLP and one with BCLP, (Table 4.3).

4.2 **Baseline Characteristics of the Whole Sample**

Mothers completed both dental health behaviour and dental health knowledge questionnaires, (Appendices 3 and 4). The main baseline results are presented in Tables 4.4 and 4.5.

4.2.1 Reported dental behaviour

4.2.1.1 Dental registration and care

At baseline 33 (38%) mothers reported that their infants were registered for local dental care and of these 13 (39%) had attended their local general dental practitioners (GDP) for an inspection, (Table 4.4). The data were explored to discover why 75 (85%) infants had not been examined by a local GDP. Over half (55%; 41) were not registered, 14 (19%) felt registration was unnecessary at the time of questioning, and 20 (27%) reported that they had not received an appointment to commence care following registration.

Table 4.3

Reported medical history of infants included in the trial compared to cleft type

Medical history	CL n (%) n = 20	CP n (%) n = 38	UCLP n (%) n = 21	BCLP n (%) n = 9	Total group n (%) n = 88
22q11 deletion		1			1
Sticklers syndrome		2			2
Heart defect	1	1	1		3
Chromosome defects		3	1		4
Hearing loss				1	1
Pierre Robin syndrome		3			3
Congenital hydrocele	1	1	1		3
CHARGE syndrome	1				1
Skeletal dysplasia		1			1
Delayed educational development		1			1
Total	**3 (15)**	**13 (34)**	**3 (14)**	**1 (11)**	**20 (23)**

Key:

CL: Cleft lip

CP: Cleft palate

UCLP: Unilateral cleft lip and palate

BCLP: Bilateral cleft lip and palate

Table 4.4

Summary of baseline reported behaviour of mothers

Reported behaviour of mothers	n (%)
Infant registered with a dentist	33 (38)
Infant attended dentist for dental examination	13 (39) (n = 33)
Mother is brushing infant's teeth	41 (47)
Mother is using a toothpaste containing ≥1100ppm fluoride	12 (29) (n = 41)
Infant is fed solely by bottle, spoon or breast	37 (42)
Infant solely uses feeder cup	12 (14)
Infant uses a combination of bottle or cup	39 (44)

n = 88   median age at baseline = 10.5 months

Table 4.5

Summary of baseline reported knowledge of mothers

Knowledge of mothers	n (%)
My child should be registered with a dentist as soon as possible	45 (51)
My child's teeth should be brushed twice daily	80 (91)
A smear of toothpaste should be used	39 (44)
Level of fluoride in toothpaste should be $\geq$ 1100ppm	2 (2)
Sugar between meals will cause dental decay	86 (98)
Use of a feeding bottle should cease by aged 12 months	48 (55)
A feeder cup should be introduced between aged 4 – 6 months	68 (77)
Prolonged use of milk in a feeding bottle during the night will cause decay	52 (59)

n = 88   median age at baseline = 10.5 months

4.2.1.2 Tooth brushing

At baseline 41 (47%) mothers reported that they brushed their infant's teeth whilst 38 (43%) mothers reported brushing had not commenced as no teeth had erupted to date. Twelve (29%) reported using toothpaste containing 1100 parts per million fluoride (ppmF) or higher (Table 4.4).

4.2.1.3 Feeding method

Baseline data showed that 76 (86%) infants were using a feeding bottle and 51 (58%) had also been introduced to a feeder cup. Thirty seven (42%) infants were fed solely via a bottle, spoon or breast, 12 (14%) were only using a cup whilst the remaining 39 (44 %) were using a combination of a bottle, lidded feeder cup or normal cup (Table 4.4).

4.2.2 Reported dental health knowledge

Mothers were asked to complete a dental health knowledge questionnaire regarding their infant's dental care. (Appendix 4). Each question was asked verbally by the researcher and the mothers' responses were recorded in writing on the interview schedule. A summary of the collected data is presented in Table 4.5.

4.2.2.1 Dental visiting

Mothers were asked how old their children should be before visiting a dentist. Half (51%; 45) correctly stated that this should occur as soon as possible (Table 4.5).

4.2.2.2 Tooth brushing

Most mothers 80 (91%) correctly reported their infants' teeth should be brushed twice daily. Almost half of the mothers (44%; 39) correctly reported a smear of toothpaste to be the ideal amount for this age group. Mothers were questioned regarding the ideal fluoride content of their infants' toothpaste. Only two mothers were able to provide the correct answer of 1100ppmF or higher to this question (Table 4.5).

4.2.2.3 Diet and dental health

Whilst most mothers agreed that sugar intake between meals may cause dental decay, (86; 98%) (Table 4.5), many thought that sugar eaten as part of a meal could also cause this disease to develop, (52; 59%). In response to a question asking whether milk in a bottle taken on demand during the night would affect teeth 52 (59%) correctly reported that this habit would lead to the development of decay, (Table 4.5). Mothers were asked the ideal age to stop giving their infants a feeding bottle. Slightly more than half (55%; 48) were able to offer the correct answer of 12 months. When asked the ideal age to introduce a feeder cup the majority (77%; 68) correctly thought that this should be between four to six months (Table 4.5).

4.2.3 A comparison of the test and control groups at baseline

On completion of the questionnaires all 88 mothers together with their infants were randomly allocated to either the test (45 infants) or control (43 infants) group, (Figure 4.1).

The distribution of cleft type according to group allocation appeared well balanced for all cleft types apart from BCLP where a slightly larger number were seen in the control group.

Data collected via the questionnaires were investigated regarding dental registration, tooth brushing habits, feeding methods and provision of dental health information and current dental health knowledge. Results indicated there was a good balance between groups at baseline.

4.3   Results of the Intervention

After randomisation to group the intervention was conducted, (Figure 4.2).

Following the 12 month study period 87 mothers, 45 in the test group and 42 in the control were contacted and a telephone interview was carried out. One mother was lost to follow up (Figure 4.1). A total of 82 infants, 42 in the test group and 40 in the control attended a MDT clinic when aged three years where a dental examination was completed. The modified baseline behaviour and knowledge questionnaires were repeated, (Appendix 5).

Following the 12 month study period the ages of the 87 remaining infants ranged from 16 to 34 months. The median age for the 55 males was 23 months and for the 32 females 24 months. The ages of the 82 infants available at the three year review ranged from two years eight months (32 months) to four years six months (54 months). The median age for the 53 males was three years seven months (43 months) and for the 29 females three years and ten months (46 months). At this review 36 (44%) infants with CP, 17 (21%) with CL, 20 (24%) with UCLP and nine (11%) with BCLP provided data on their dental health status.

Figure 4.2   **Process of the intervention**

```
        ┌──────────┐                        ┌──────────┐
        │   Test   │                        │ Control  │
        └────┬─────┘                        └────┬─────┘
             ▼                                   ▼
```

Test

Preventive advice:
Dental registration and regular attendance
Twice daily tooth brushing with small headed tooth brush
Smear of 1100ppm fluoride paste
Cessation of baby bottle by 12 months
Use of a free flow feeder cup
Diet advice
Mothers received:
Free flow feeder cup
1100ppm fluoride paste
Small headed toothbrush
Specifically designed dental health leaflet
3 monthly supply of 1100ppm toothpaste and designed leaflet
Referral to local CDS if requested
Liaison with GDP/CDS to confirm attendance
Liaise with mother if fails to attend GDP and ref to CDS if requested

Control

Preventive advice:
Twice daily tooth brushing with small toothbrush
Smear of 1100ppm fluoride toothpaste
Use free flow cup
Mothers received:
One tube 1100ppm fluoride paste
Ref to CDS if requested

Review after 12 months via telephone by independent researcher. Completion of questionnaires x 2

Review after 12 mths via telephone by independent researcher. Completion of questionnaires x 2

Dental exam of all infants aged 3-4 years. Completion of questionnaires x 2

4.3.1 Reported dental behaviour

4.3.1.1 Dental registration

Following the 12 month study period the majority of mothers (94%; 82) reported that their children were registered locally for dental care and after three years this level remained similarly high (91%; 75). Table 4.6 shows that the majority were registered with a GDP at 12 months (80%; 66) and three years (76%; 57). Examination of the three year data showed more children in the test, (33; 85%) were registered with a GDP than in the control (24; 67%). No statistically significant differences were found between the groups, (12 months Fisher's Exact, $p = 0.79$, three years Fisher's Exact, $p = 0.10$), (Table 4.6).

4.3.1.2 Problems registering for local dental care

At the 12 month data collection period, 12 (14%) of the total group reported problems when accessing local dental care for their child. Ten of these were unable to find a local GDP offering care within the National Health Service (NHS) and two were refused registration because these dentists were unwilling to provide care for a child with a cleft. Four mothers had contacted the CLP Unit to request a referral to a local CDS clinic. Three of these were successfully registered and one, arriving late for their appointment, was still not registered at this time. Two mothers contacted NHS Direct and successfully registered with local NHS care while three arranged for private dental care for their children. At this time no significant differences were found according to cleft type in the ability to access local registration.

Table 4.6

Reported type of dental registration

Type of dental practice	Test 12 mths n (%)	Control 12 mths n (%)	Test 3 yrs n (%)	Control 3 yrs n (%)
GDP/Private	36 (82)	30 (79)	33 (85)	24 (67)
Children's services	8 (18)	8 (21)	6 (15)	12 (33)
Total	**44 (100)**	**38 (100)**	**39 (100)**	**36 (100)**

12 month data: Fisher's Exact, $p = 0.79$

3 year data: Fisher's Exact, $p = 0.10$

Key:

GDP/Private: General dental practitioner offering care within the National Health Service/Private dental practitioner

Children's services: Dental care provided within a hospital paediatric dental service or the Community Dental Service

4.3.1.3   Contact with dental care provider following six months of intervention

Following recruitment to the trial, the dental care provider for each infant allocated to the test group was contacted six months into the intervention. The researcher telephoned the practice to verify continued registration and attendance. The majority of infants (76%; 34) had been examined by their dentist and the onus was on the mothers to contact the surgery for further reviews. At the time of data collection, although registered, almost a quarter (24%; 11) of infants had not received a dental examination.

4.3.1.4   Dental attendance following 12 and 36 months

Following the 12 month study period the majority of infants in the test (93%; 42) and control (79%; 33) groups had been examined by their dentists, (Table 4.7). However, 12 had not been examined, nine in the control group and three in the test, this difference being of borderline significance, (Fisher's Exact; $p = 0.063$). The 95% confidence interval for the difference in proportion at 12 months was 0.004-0.29, which suggests a statistically significant difference. The reasons for their non-attendance were that five had not yet been registered and seven reported that they had not received an appointment following registration. The median age of these 12 non-attenders was 23.5 months which mirrored that of the whole group.

When aged three years the mothers reported that the majority of infants (98%; 41) in the test group had been examined by their GDP with fewer in the control (85%; 34). This difference was statistically significant, (Fisher's Exact; $p = 0.054$), (Table 4.7).

Table 4.7

Reported local dental attendance of all infants recorded

at the twelve month and aged three year data collection points

Dental attendance	Test 12 mth n (%)	Control 12 mth n (%)	Test 3 yr n (%)	Control 3 yr n (%)
Yes	42 (93)	33 (79)	41(98)	34 (85)
No	3 (7)	9 (21)	1 (2)	6 (15)
Total	**45 (100)**	**42 (100)**	**42 (100)**	**40 (100)**

12 month data: Fisher's Exact, $p = 0.063$
Mean difference in proportion attending = 0.148
(95% CI; 0.004-0.29)

3 year data: Fisher's Exact, $p = 0.054$
Mean difference in proportion attending = 0.126
(95% CI; 0.006-0.246)

The 95% confidence interval for the difference in proportion at three years was 0.006-0.246, which suggests a statistically significant difference.

4.3.1.5   Tooth brushing

At 12 months the majority of mothers (82%; 71) reported that brushing was carried out twice or more daily and this was similar after three years (89%; 73). At 12 months all the mothers in the test group, 45 (100%) were using toothpaste containing 1100ppmF or higher, whereas in the control only 31 (74%) reported this. This difference was highly statistically significant, (Fisher's Exact; $p < 0.001$), (Table 4.8). After three years 41 (98%) in the test and 35 (88%) in the control were using a toothpaste containing the recommended level. This difference was not statistically significant, (Fisher's Exact; $p = 0.105$), (Table 4.8).

4.3.1.6   Dental health information

Mothers were asked if they had received any dental health information about caring for their infant's teeth. Most at both 12 months (91%; 79), (test: 43 and control: 36) and three years (91%; 75), (test: 40 and control: 35) said that they had. At 12 months the majority of mothers within the test (73%; 33) and control (67%; 28) groups had received advice from either the CLP Unit via the study or their clinical nurse specialist (CNS). Although after 12 months as many as 42 (93%) of the infants in the test and 33 (79%) in the control group had been examined by their dentist, of these only 10 (24%) in the test and six (18%) in the control reported receiving dental health advice from this source. A similar pattern was also evident in the three year data. The majority of infants in the test (98%; 41) and control (85%; 34) groups had been examined by their dentists (Table 4.7), however of

Table 4.8

Reported level of fluoride toothpaste used by mothers to brush

their infant's teeth at twelve month and aged three year follow up

Toothpaste	Test 12 mth n (%)	Control 12 mth n (%)	Test 3 yr n (%)	Control 3 yr n (%)
≥1100ppm fluoride	45(100)	31(74)	41(98)	35(88)
<1100ppm fluoride	0(0)	11(26)	1(2)	5(13)
Total	**45 (100)**	**42 (100)**	**42 (100)**	**40 (101)**

12 month data   Fisher's Exact, p = 0.001

3 year data   Fisher's Exact, p = 0.105

Key:

1100ppm fluoride – toothpaste contains 1100 parts per million fluoride

these, only 11 (27%) in the test and 10 (29%) in the control reported the receipt of dental health advice from this source.

At the three year data collection the majority of mothers (96%; 78) felt they had received sufficient dental health information to date.

4.3.1.7 Tooth brushing advice

At 12 months all 79 (91%) mothers (test: 43 and control: 36) in receipt of dental health advice were asked what information had been given. Most in both the test (93%; 40) and control (92%; 33) groups had received verbal advice on tooth brushing. Within the control group, of the 36 (86%) mothers who had received advice, three had not received brushing instruction. This figure, combined with the six mothers in the control group who had not received any dental health advice, equates to over a fifth (21%; 9) of mothers in the control group reportedly receiving no brushing instruction. These data were further investigated to discover if receipt of tooth brushing instruction was related to cleft type. Table 4.9 demonstrates that when examined by CL, UCLP and BCLP separately fewer mothers reported receiving advice specifically related to the cleft area; CL (25%; 12), UCLP (25%; 12) and BCLP (12%; 6). No statistically significant difference was demonstrated, (p = 0.87).

 At three years all 75 (91%) mothers (test: 40 and control: 35) who reported receiving dental health advice had received tooth brushing advice. However some mothers still reported receiving no brushing advice in relation to the cleft area; CL 5 (11%) and UCLP 5 (11%). Analysis failed to demonstrate a statistically

Table 4.9

Reported tooth brushing instruction in relation to cleft area received by mothers compared to infant cleft type during the study period

Cleft type	Brushing advice cleft area 12 mths n (%)	No brushing advice 12 mths n (%)	Total 12 mths n (%)	Brushing advice cleft area 3 yrs n (%)	No brushing advice 3 yrs n (%)	Total 3 yrs n (%)
CL	7 (14)	12 (25)	**19 (39)**	12 (26)	5 (11)	**17 (37)**
UCLP	9 (18)	12 (25)	**21 (43)**	15 (33)	5 (11)	**20 (44)**
BCLP	3 (6)	6 (12)	**9 (18)**	9 (19)	0 (0)	**9 (19)**
Total	**19 (38)**	**30 (62)**	**49 (100)**	**36 (78)**	**10 (22)**	**46 (100)**

12 months data   Chi square value = 0.290, 2 df, p = 0.87

3 year data   Chi square value = 3.213, 2 df, p = 0.20

Key:

CL: Cleft lip

UCLP: Unilateral cleft lip and palate

BCLP: Bilateral cleft lip and palate

significant difference when comparing cleft type with receipt of advice, (p = 0.20), (Table 4.9).

4.3.1.8   Dietary advice

At 12 months the 79 mothers, (test: 43 and control: 36) who had received information were asked if they had received any specific advice relating to the problems caused by an uncontrolled sugar intake. Twelve month data revealed that the majority in both the test (91%; 39) and control (81%; 29) groups had received such information.

At three years, of the 75 (91%) mothers (test: 40 and control: 35) who reported receiving dental health advice, the majority in both the test (93%; 37) and control (89%; 31) groups reported receiving dietary advice.

4.3.1.9   Feeding method

After 12 months mothers were asked if their infant was still using a feeding bottle. The majority in both the test (71%; 32) and control (57%; 24) groups had ceased this practise. At three years, five (12%) infants in the test and five (13%) in the control were still using a feeding bottle.

4.3.1.10   Night time feeding practices

Prolonged night time feeding practises were investigated in more detail. At 12 months five (11%) children in the test group reported this behaviour, however this was almost double, nine (21%) in the control group. This difference did not prove to be statistically significant, (Fisher's Exact, p = 0.25). The contents of the bottles

in the four children in the test group and all in the control were considered to be detrimental to dental health either because they contained sugar or because they were acidic or both. Of the seven infants, (five in the test group and two in the control) who were night time feeding at baseline, two had continued the practise, both of these being in the test group. The median age for infants still using a night time bottle was 22 months, ranging from 17 to 34 months.

Three year data revealed that four infants in the test and four in the control took a drink to bed. Three of these, one in the test group and two in the control, had reported this behaviour at 12 months. The contents of the bottles of those in the test group were considered to be detrimental to dental health whereas only one infant in the control group was consuming this type of drink. The median age of the eight children reporting a prolonged night time feeding habit after three years was 42 months, ranging from 34 to 48 months.

4.3.1.11   Day time feeding practices

The 12 month data reported similar results for both groups with 44 (98%) mothers in the test group and 42 (100%) in the control stating they gave their infants a drink between meals during the day. Most infants in the test (87%; 39) and in the control (98%; 41) were regularly using some form of cup. A small number of children in both groups, three in the test and five in the control, were using a non spill cup.

At three years the majority of infants in both groups, 76% (32) in the test and 75% (30) in the control, were using a normal cup. Nine (21%) in the test group and eight (20%) in the control reported using a free flow lidded cup whilst two infants

in the control group were using a non spill lidded cup. One infant in the test group was not using any form of cup, as she was taking all fluids from a spoon.

Exploration of the 12 month data examining the type of drink given between meals revealed over half (58%; 26) of the test group were consuming drinks considered to be detrimental to dental health between meals and this habit was practised by over three quarters (81%; 34) of the control. This difference proved to be statistically significant, (Fisher's Exact; p = 0.02), (Table 4.10).

At the three year data collection over a quarter in both the test (29%; 12) and control (30%; 12) groups reported consuming drinks considered to be non cariogenic (water and/or milk) between meals, (Table 4.10).

4.3.2   Reported dental health knowledge

After 12 months and again at three years those mothers remaining were requested to answer a modified dental health knowledge questionnaire that they completed at baseline, (Appendix 5). The 12 month data reported the knowledge of 87 mothers, 45 in the test and 42 in the control while the three year data reported the knowledge of 81 mothers, 41 in the test group and 40 in the control. At three years one infant in the test group had been placed in the care of another family member and therefore it was not possible to compare their knowledge over the study period.

Table 4.10

Drinks considered to be detrimental to dental health

reportedly given to infants between meals

Is reported drink detrimental to teeth?	Test 12 mths n (%)	Control 12 mths n (%)	Test 3 yrs n (%)	Control 3 yrs n (%)
Yes	26 (58)	34 (81)	30 (71)	28 (70)
No	19 (42)	8 (19)	12 (29)	12 (30)
Total	**45 (100)**	**42 (100)**	**42 (100)**	**40 (100)**

12 month data   Fisher's Exact, p = 0.02

3 year data   Fisher's Exact, p = 1.00

4.3.2.1   Dental attendance

Mothers were asked to consider how old their child should be before visiting a local dentist. At baseline half (51%; 23) in the test group and a similar proportion in the control (51%; 22) stated that this should occur as soon as possible. At the 12 month follow up this view was held by a majority (64%; 29) in the test and (71%; 30) in the control groups. This data was not collected at three years as it was anticipated that most would be under the care of a dentist. No statistically significant differences were found when comparing baseline with 12 month data in either the test (McNemar; $p = 0.24$) or control group (McNemar; $p = 0.12$).

4.3.2.2   Tooth brushing

After 12 months the majority of mothers, in both the test (93%; 42) and control (88%; 37) groups stated their infants' teeth should be brushed twice daily and this knowledge did not differ from that recorded at baseline. The three year data reported similar results with the majority in the test (100%; 41) and control (98%; 39) groups stating their infant's teeth should be brushed twice a day.

4.3.2.3   Ideal amount of toothpaste to use when brushing infant's teeth

At baseline 22 (49%) mothers in the test group and 17 (39%) in the control correctly answered that a smear was a suitable amount of toothpaste for their infant. At 12 months nine (20%) in the test and six (14%) in the control said this but the majority in both groups 34 (76%) in the test and 34 (81%) in the control, reported a pea sized amount was ideal. For both groups there was a statistically significant change with fewer mothers at 12 months stating that a smear of toothpaste should

be used than at baseline, (McNemar tests: test group p=0.004, control group p = 0.021).

The three year data demonstrated the same proportion in both groups, 86% (36) in the test and 88% (35) in the control thinking that a pea sized amount of toothpaste was sufficient.

4.3.2.4   Ideal fluoride content of toothpaste

When mothers were asked at baseline the ideal fluoride level of their infants toothpaste only one in each group was able to offer the correct answer of 1100 ppmF or higher. After 12 months 19 (42%) mothers in the test group and 17 (40%) in the control gave the ideal answer. A comparison of the baseline with 12 month knowledge data demonstrated a statistically significant difference, with more mothers in each group stating the correct level of fluoride toothpaste to use, (McNemar tests: test group p = <0.001, control group p = <0.001).

After three years 27 (66%) mothers in the test group and 18 (45%) in the control thought the level of fluoride should be at least 1100ppmF. A comparison of the 12 month and three year data demonstrated a statistically significant difference in the test group only, with more mothers stating the correct level, (McNemar tests; test group p = 0.03, control group p = 0.61).

The three year data sets were examined to compare reported behaviour of mothers using a toothpaste containing 1100ppmF or higher to brush their child's teeth with knowledge on this matter. The data demonstrated 26 (63%) mothers in the test and

18 (45%) in the control reported the correct behaviour and knowledge. Further analysis demonstrated no statistically significant difference in the test group, (Fisher's Exact; p = 1.000) but in the control a borderline significant difference was found, (Fisher's Exact; p = 0.053) indicating fewer in the control group reported the correct knowledge and behaviour.

Further examination of the three year data compared the presence of dental caries with mothers' knowledge regarding the ideal level of fluoride in toothpaste. This revealed that more mothers of children diagnosed with dental caries (14; 17%) were unaware of the ideal level of fluoride than in those of children diagnosed caries free, (59; 73%). This difference was statistically significant, (Fisher's Exact; p = 0.04). No statistically significant difference was found when comparing the use of a toothpaste containing 1100ppmF or higher with the presence of dental caries, (Fisher's Exact; p = 1.00).

4.3.2.5 Diet and dental health

Most mothers at 12 months (99%; 86) and at three years (99%; 80) agreed that sugar intake between meals may cause dental decay; this did not differ from their baseline knowledge.

At baseline over half in both groups, 58% (26) in the test and 60% (26) in the control, stated that sugar eaten as part of a meal may also lead to the development of dental decay. At 12 months this had changed with only 17 (38%) in the test and 16 (38%) in the control holding this belief. However after three years this had regressed with over half of the mothers in both the test (54%; 22) and control (60%;

24) groups believing that sugars consumed with a meal would cause dental caries. Analysis of knowledge over the study period failed to show any statistically significant differences.

Information was also sought concerning the ideal time of day to give their infant juice. At baseline almost three quarters of mothers in both groups, 73% (33) in the test and 72% (31) in the control correctly reported that the ideal time was with a meal. This knowledge had continued to the 12 month follow up, with the majority, (84%; 38) in the test and (79%; 33) in the control giving the correct response. No statistically significant difference was found between knowledge and behaviour. At three years mothers were asked the ideal time to offer juice to their child and 40 (95%) mothers in the test and 35 (88%) in the control said that this was with a meal. A comparison of the behaviour and knowledge data across the study period failed to demonstrate any differences between groups. Similarly an analysis of knowledge over the study period failed to show any statistically significant differences.

4.3.2.6   Use of a feeding bottle

Knowledge relating to whether milk in a bottle taken on demand during the night would detrimentally affect teeth was sought. At baseline responses were similar in both groups with 28 (62%) in the test group and 24 (56%) in the control reporting that this habit would lead to the development of dental decay. At the 12 month follow up 29 (64%) in the test group and 34 (81%) in the control believed prolonged use of a night bottle would be detrimental to their child's dental health. The three year data showed a reduction in positive responses with 22 (52%)

mothers in the test group and 15 (38%) in the control holding this belief. Comparison of all the behaviour and knowledge data sets regarding use of a night time bottle failed to demonstrate a statistically significant difference between groups. A comparison of baseline knowledge with that held after 12 months revealed a statistically significant change in the control group, with more mothers after 12 months stating that prolonged use of a night bottle would potentially be detrimental to their infant's dental health, (McNemar test: test p = 1.00, control p = 0.02).

4.3.2.7   Cessation of a feeding bottle

Mothers were asked to state the ideal age to stop their infant using a feeding bottle. At baseline 19 (42%) in the test group and 22 (51%) in the control were unable to offer the correct answer of 12 months. At the 12 month follow up knowledge had improved with almost two thirds in both the test (60%; 27) and control (67%; 28) groups giving the correct answer. Despite this, at this time 13 (29%) mothers in the test and 18 (43%) in the control reported they were still giving their infant a feeding bottle, (Fisher's Exact; p = 0.19). The knowledge data collected at 12 months from mothers in the test group reported five (38%) giving the right answer, but eight (62%) saying they did not know the ideal age. The answers from the mothers in the control group revealed nine (50%) who thought a bottle should cease by the age of 12 months and nine (50%) did not. Statistical analysis to compare knowledge with behaviour failed to show a statistically significant difference either in the test (Fisher's Exact; p = 0.09) or control group, (Fisher's Exact; p = 0.96). A comparison of baseline and 12 month knowledge data failed to demonstrate any significant differences within each group, (McNemar tests: test group p = 1.00,

control group p = 0.24). Similarly, no statistically significant differences were found in the three year behaviour and knowledge data sets.

4.3.2.8 Introduction of a feeder cup

At baseline the majority of mothers, 80% (36) in the test group and 74% (32) in the control, correctly thought a cup should be introduced between four to six months of age. Following the 12 month study period their reported knowledge had changed with 15 (33%) in the test group and 21 (50%) in the control giving the right answer. A comparison of reported behaviour with knowledge failed to demonstrate any statistically significant differences. However, there were statistically significant differences from baseline to 12 month knowledge within each group, (McNemar tests: test group p = 0.01, control group p = 0.02).

4.4 Description of the Study Population Dentition Aged Three Years Recorded at the Multidisciplinary Review Clinic

As previously explained 82 children, 53 (65%) male and 29 (35%) female were examined at their MDT clinic appointment aged three years. At this review thirty six (44%) infants with CP, 17 (21%) with CL, 20 (24%) with UCLP and nine (11%) with BCLP provided data on their dental health status.

The prevalence of dental caries is the key information to be considered.

4.4.1 Dental caries experience in both enamel and dentine

The majority (73%; 60) of children were caries free at the time of examination. Seventeen (21%) children were diagnosed with dentinal caries and of these two also demonstrated

carious lesions in enamel only. A further five (6%) children were diagnosed with enamel caries only, (Table 4.11). None of the children had any restored (f) surfaces or extracted (m) teeth due to caries.

Fifteen (28%) males and seven (24%) females were affected. No statistically significant differences were found when comparing the presence of dental caries with gender, (Fisher's Exact; p = 0.80).

Examination of the data demonstrated the presence of dental caries across all cleft types; eight (22%) with CP, five (29%) with CL, three (33%) with BCLP and six (30%) with UCLP.

The mean caries experience, decayed, missing and filled teeth (dmft), for all the children was 0.51 (SD 1.45) with values ranging from 0-9, (Table 4.12) Further exploration of the data demonstrated the mean dmft for the 17 (21%) children with caries into dentine was 2.47 (SD 2.35) with values ranging from 1-9, (Table 4.12).

When examined by cleft type the data demonstrated six children with CP, four children with CL, six children with UCLP and one child with BCLP with dentinal caries. Eleven (13%) children had lesions confined to the non-cleft area. Three children, one with CL and two with UCLP, had one dentinal carious lesion in the cleft area alone.

Table 4.11

Number of children with and without dental caries in the primary dentition at the three year dental examination for both groups combined

Presence of dental caries	Total group n (%)
Caries free	60 (73)
Enamel only	5 (6)
Enamel and dentine	17 (21)
Total	82 (100)

Table 4.12

Distribution of dental caries in the primary dentition

at the three year dental examination

Distribution of dental caries	Total n Mean (SD)
dmft **all children**	82 0.51 (1.45)
dmft **children with** **dentinal caries**	17 2.47 (2.35)
ds$_e$ **all children**	82 0.12 (0.46)
ds$_d$ **all children**	82 0.87 (2.57)
ds$_d$ **children with** **dentinal caries**	17 4.18 (4.32)

Key:

dmft: mean number of decayed, missing and filled teeth

ds$_e$: mean number of decayed surfaces in enamel

ds$_d$: mean number of decayed in dentine

4.4.1.1   Dental caries experience detected in enamel surfaces

Five children were diagnosed with caries affecting enamel only plus a further two who were also diagnosed with separate lesions in dentine; hence seven children in total reported carious lesions in enamel only involving ten surfaces (Table 4.13). The mean decayed surfaces in enamel (ds_e) was 0.12 (SD 0.46) values ranging from 0-3, (Table 4.12). The seven children included three with CP, one with CL and three with BCLP with lesions primarily involving the lower molars and lower canines. One child with BCLP demonstrated enamel caries in the location of the cleft area, affecting the upper left canine.

4.4.1.2   Dental caries experience detected in dentine surfaces

The mean decayed surfaces in dentine (ds_d) for the whole study group was 0.87 (SD 2.57) with values ranging from 0-16, (Table 4.12). The mean ds_d for the 17 children with dentinal caries was 4.18 (SD 4.32), (Table 4.12) involving 71 surfaces, (Table 4.13). Dentinal caries was evident across all cleft types, six children with CP, four with CL, six with UCLP and one with BCLP. Statistical analysis failed to demonstrate a statistically significant difference when comparing cleft type with dentinal caries, ($p = 0.57$). At the time of examination no restorations or missing teeth due to extractions were recorded and all 17 children with active dentinal caries were considered in need of dental treatment.

Table 4.13

Number of children in both groups with

decayed surfaces in enamel or dentine

Decayed surfaces (per child) n	Decay in enamel only (per child) n	Decay in dentine (per child) n
0	75	65
1	5	7
2	1	2
3	1	0
4	-	3
5	-	1
7	-	1
9	-	1
11	-	1
16	-	1
Total surfaces	**10**	**71**
Total children	**82**	**82**

4.4.1.3   Dental registration compared to presence of dental disease

At the three year examination, 22 children were diagnosed with dental caries in enamel and/or dentine, (Table 4.11) and of these 14 (64%) mothers reported that their children were registered with a local GDP, five (23%) were registered with their local CDS and three were not registered, (Table 4.14). There was no statistically significant difference when comparing dental attendance with the presence of dental caries, (p = 1.00).

Four children required dental extractions under general anaesthesia (GA). A total of 16 teeth were extracted. Three of the children requiring dental extractions under GA were under regular care with their local GDP and all had been examined within a week of their three year MDT examination. All parents were unaware of the severity of their child's dental disease.

Further exploration demonstrated one child reporting skeletal dysplasia required nine extractions, all primary molars and one upper central incisor, another the extraction of the upper central incisor and a non vital supplemental incisor and the third, four hypoplastic and carious second molars. One child, not registered for local dental care required the extraction of one carious, pulpally involved, lower first primary molar.

4.4.1.4   Comparison of feeding habits with presence of dental caries

Twenty two (27%) children were diagnosed with dental caries and of these the majority (77%; 17) were consuming drinks between meals considered to be detrimental to dental health. Further analysis of these data to compare the presence

Table 4.14

Local dental care provider compared with outcome of three year

dental examination for children diagnosed with dental caries

Local provider of dental care	Letter to dentist to report findings	Referral to CDS for care	Referred for treatment at MDH	Referred for extractions under GA	Total
GDP	9	0	2	3	**14**
CDS	4	0	1	0	**5**
Not registered	0	1	1	1	**3**
Total	**13**	**1**	**4**	**4**	**22**

Key:

MDH: Paediatric department, Manchester Dental Hospital

GA: General anaesthesia

GDP: General Dental Practitioner

CDS: Community Dental Service

of disease with type of drink offered, failed to demonstrate a statistically significant difference, (Fishers Exact; p = 0.586). Furthermore, four (three with UCLP and one with CL) reported continued use of a feeding bottle, three of whom reported a prolonged night time feeding habit. No statistically significant differences were found when comparing dental caries with use of a feeding bottle, (Fisher's Exact; p = 0.446) or when comparing dental caries with prolonged use of a night feeding bottle, (Fisher's Exact; p = 0.437).

4.5   **Cost of the Programme (Table 4.15)**

It was considered important to record the cost of delivering the Programme as this information will be required when drawing conclusions and making recommendations related to the trial.

The total cost of providing the 12 month Programme was £1198.35, £978.12 for the test group, (n = 45) and £220.23 for the control, (n = 43). The cost per head in the test group was £21.74 and in the control £5.12. Given that the control group received the care already offered to infants attending the CLP Unit the extra cost of offering the Programme per head was £16.62. Taking an average referral rate of 85 CLP births per year to this Unit the additional cost of providing this Programme to all infants annually would therefore be approximately £1,413, with the total cost equating to £1,848. On the basis of costs incurred between March 2004 to January 2006 the total cost per 100 infants per Unit would be £2,174.

Table 4.15   **Record of costs incurred during the study period**

Item	Number/Time	Test Cost	Control Cost
Printing cost of dental health leaflet	225	£87.50 (225)	Not incurred
Cost of free flow feeder cups	45 (£1.30 each)	£58.50 (45)	Not incurred
Cost of toothpaste	223 (£1.00 each)	£180.00 (180)	£43 (43)
Cost of toothbrushes	45 (£1.25 each)	£56.25 (45)	Not incurred
Dental Therapist time			
(Band 6 point 28): Delivery of preventive programme	88 infants	30 mins x 45 @ £15 per hour = £337.50	15 mins x 43 @ £15 per hour = £161.25
Postal charges			
Toothpaste	135 x 56p	£75.60 (135)	N/A
Letters to GDP	33 x 23p	£7.59 (33)	N/A
Letters to CDS	28 x 23p	£2.76 (12)	£3.68 (16)
Telephone charges			
Calls to mothers for GDP details	17 x 2 min (0.03pmin)	£1.02	N/A
Calls to GDP's to check attendance	45 x 2 min (0.03 min)	£2.70	N/A
Administration time			
Clerical assistant (Band 3 point 7)	20 hours @ £7.30 per hour	£138.70 (19 hours)	£7.30 (1 hour)
Sundries			
Stationery, jiffy bags		£30.00	£5.00
Total		**£978.12**	**£220.23**
Cost per child		**£21.74**	**£5.12**

Total cost of providing the Programme to all infants annually based on 100 new referrals would be approximately £2,174

(based on costs incurred March 2004 to Jan 2006).

4.6   **Summary of Results**

At baseline 88 infants were recruited to the study, 87 completed the 12 month intervention and 82 were available for follow up when attending their MDT review aged three years. Following the intervention reported behaviour and knowledge data were collected. Differences at the borderline of statistical significance in reported behaviour were demonstrated in the areas of dental attendance after both 12 months and aged three years, and statistically significant differences were found for use of a high fluoride toothpaste after 12 months and type of drink offered after 12 months, showing a benefit for the children in the test group. A comparison of dental health knowledge over time revealed some differences in the following areas:

- Toothpaste use
- Level of fluoride in toothpaste
- Prolonged use of a feeding bottle
- Introduction of a feeder cup

 These will be considered in more detail in the discussion section.

4.6.1   Summary of dental health status at three year dental examination

A total of 82 children were examined. Overall 60 (73%) children were caries free. The dental examination recorded active dentinal caries requiring treatment in 17 (21%) children. Dental caries was evident across all cleft types. A sinus associated with a carious tooth was detected in three children. Following the dental examination four children were referred for dental extractions due to dental caries, under GA, (Table 4.16).

A discussion of these results is presented in Chapter 5.

Table 4.16

Overall view of dental health status recorded

at the three year dental examination

Cleft type n (%)	Caries free n (%)	Caries enamel only n (%)	Caries dentine n (%)	Sinus present n (%)	GA n (%)
CP 36 (44)	28 (34)	2	6	1	1
CL 17 (21)	12 (15)	1	4	2	2
UCLP 20 (24)	14 (17)	0	6	0	1
BCLP 9 (11)	6 (7)	2	1	0	0
Total 82 (100)	**60 (73)**	**5 (6)**	**17 (21)**	**3 (4)**	**4 (5)**

Key:

CP: Cleft palate

CL: Cleft lip

UCLP: Unilateral cleft lip and palate

BCLP: Bilateral cleft lip and palate

GA: General anaesthetic (referred for dental extractions)

Chapter 5

Discussion

5.0 **Introduction**

This randomised controlled trial was driven by the lack of evidence on the success and longer term outcomes of preventive dental care for children with cleft lip and/or palate (CLP). The reasons why such an intervention is needed are clear.

The CLP anomaly creates a burden of care both to the child and family from birth through to adulthood. Equally, poor dental health may ultimately affect the successful outcome of care for all children born with a cleft.

The oral health status of children with CLP has been the subject of many studies however the quality of the literature regarding the dental health status of children with CLP is limited. Wong and King (1998) identified that the varying methodologies used, together with the overall low study numbers, make comparisons between CLP studies difficult and unreliable. Individually, a number of studies have highlighted the prevalence of dental caries within CLP children to be higher than that of the general population (Johnsen and Dixon, 1984; Dahllöf et al., 1989; Bokhout et al., 1997 and Kirchberg et al., 2004), however others, Lucas et al. (2000), Hasslöf and Twetman (2007) argue against this, primarily due to the lack of robust evidence to support these claims.

I will discuss the findings in terms of the following topics:

- Recruitment to the trial

- Dental registration and attendance

- Provision of dental advice

- Dental health status

- Cost of providing the Programme

- Limitations

- Conclusions

- Recommendations for future action

5.1 Recruitment to the Trial

The numbers recruited matched the anticipated sample size and few were lost to follow up therefore the results were at the predicted levels. All cleft types were included in the trial together with children also reporting other medical history concerns. It has been argued that grouping all cleft types together is a methodological inconsistency, as by definition, a variation in cleft type may influence both the intensity of preventive advice practiced and the dental health status (Wong and King, 1998). A preventive programme should be relevant to all children attending the cleft Unit. Restricting the study to one cleft type to allow direct comparison of data would have raised difficulties in recruitment. Overall, the variation in cleft types recruited to this trial supported the prevalence of clefts in the United Kingdom (UK), (Derijcke et al., 1996). Whilst fewer females, (47%) with cleft palate (CP) than males, were recruited this is a convenience sample and is still representative of the cleft population in the North West and UK.

5.2 Dental Registration and Attendance

The majority of mothers (94%) at 12 months claimed their child was registered with a dentist, mirroring Williams et al. (2001) and supporting national guidelines, BSPD (2003), NICE (2004) and DoH (2005). This trial demonstrated the majority (86%) of children had received a dental examination at the 12 months data collection. Borderline, statistically significant differences at 12 months, ($p = 0.063$, 95% CI; 0.004–0.29) and aged three years, ($p = 0.054$, 95% CI; 0.006-0.246) supporting the Programme were found, (Table 4.7). Examination of the data suggests a methodological error in relation to the power calculation conducted regarding estimated levels of dental registration. The a priori power calculation

estimated the reported registration in the control group to be 50 per cent and that in the test to be 85 per cent. Both groups had registration rates which exceed these estimates. As the registration rates were so high at 12 months 94 per cent (test) versus 91 per cent (control), they have reached saturation levels and therefore in retrospect reported registration should not have been included as an outcome for the trial, with the Programme being unnecessary for registration. There is probably also a ceiling for the per cent attendance in the test group at 93 per cent.

Further investigation highlighted a flaw with the database used to record patient details. The system in place is only able to record contact details of general dental practitioners (GDPs), and not those under the care of the community dental service (CDS). Figures for the power calculation were drawn directly from the database without an investigation to examine whether care was provided by a GDP or CDS and in hindsight total registration may have been underestimated. Therefore, whilst the evidence has demonstrated high levels of registration and attendance it would be unfair to suggest this behaviour is directly related to this Programme.

Difficulties accessing registration with a dentist providing care within the NHS were reported by 12 (14%) mothers at 12 months and 11 (13%) at three years which is higher than that reported nationally (Morris et al., 2006). Recall of information may be biased, however the time frame between this trial data collection is shorter and therefore may be more reliable. Mothers who raised access concerns were offered a referral to a CDS clinic nearest to the family home; however, it is important to note some mothers had not achieved registration both at 12 months and three years and this is an area that needs to be addressed by the cleft team.

Whilst dental recalls are now risk based (NICE, 2004), children with a CLP would be assessed as having special needs and at high risk and therefore the recommendation would be that they are examined between three to 12 monthly intervals dependent on an individual needs assessment. Tickle et al. (2003a) reported the mean age for first dental attendance was 3.4 years (SD 1.3) and more recent national data has shown an increase in the number of children visiting a dentist before the age of two, Morris et al. (2006). After six months of the trial period all dentists providing care for infants in the test group were contacted. Despite being informed at recruitment that their patient was involved in the trial almost a quarter, although registered, had not received a dental examination. Thus, these dentists had failed to meet national guidance to promote awareness of the importance of a healthy mouth (NICE, 2004), and more importantly mothers had missed out on an opportunity to receive further preventive dental health information, which is a cornerstone for long term good oral health, (NICE, 2004; DoH, 2005; DoH, 2009).

5.3 Provision of Dental Advice

The trial addressed recommendations that a named member of the cleft team should commence dental health education during the infant's first year of life, (Shaw et al., 1996; CSAG, 1998). The majority of mothers at 12 months reported receiving advice. Kay and Locker (1996) reported dental health advice given at the chair side to be effective. Therefore it is important that GDPs are also offering dental health advice however, few mothers recalled receiving this from their local dentist. These results were not verified with the GDP and there is a possibility of recall bias however, these data would support Tickle et al. (2003a), whilst also demonstrating failure to implement advice from Levine and Stillman-Lowe (2009) and DoH (2009). Further work is required to add to the evidence base in this area.

5.3.1 Tooth brushing

Hinds and Gregory (1995) identified a variation in brushing behaviours in pre-school children in the North West of England. This trial provided tooth brushing advice to both groups at baseline and may have influenced all mothers regardless of social group, thus supporting DoH (2005) and DoH (2009). At recruitment almost half (47%) of the mothers reported they had started to brush their infant's teeth without any oral hygiene advice from the cleft team. Blinkhorn et al. (2001) highlighted mothers' required specific information with regard to their child's oral health. Provision of earlier, tailored advice possibly via the clinical nurse specialist (CNS) who would be aware of tooth eruption may address this issue, whilst a longer term study as shown by Davies et al. (2005) may encourage parents to adopt positive dental health behaviours. Further research is required to add to the evidence base.

5.3.2 Use of a fluoride toothpaste

National data reported 95 per cent of five year old children use toothpaste, (White et al; 2006) however, the fluoride level is not reported which is important in caries prevention, Marinho et al. (2003), DoH (2005) and DoH (2009). This trial has successfully demonstrated increased use of a toothpaste containing 1100 parts per million (ppmF) fluoride or higher, ($p < 0.001$), adding to the evidence base underpinning guidance to benefit a healthy dentition, BSPD (1996), Marinho et al. (2003), DoH (2005) and DoH (2009).

During the design of this trial the evidence recommended the use of a toothpaste containing 1100ppmF, whereas today, a level of 1450ppmF is recommended, (DoH, 2009). However, Walsh et al. (2010) have argued the lack of evidence to support or negate the clinical difference gained from the use of toothpaste containing higher fluoride levels than 1100ppmF whilst highlighting the potential risk of fluorosis linked with higher level fluoride toothpastes used for children under six years. In contrast, Wong et al. (2010) in a

recent Cochrane review examining topical fluoride use and fluorosis found weak evidence that mild fluorosis is associated with using different levels of fluoride.

Parental brushing with a smear of toothpaste when teeth erupt graduating to a pea sized amount from the age of three years is recommended, (BSPD, 1996; DoH, 2009; Levine and Stillman-Lowe, 2009). Knowledge over time, for both groups demonstrated a statistically significant change with fewer mothers stating that a smear of toothpaste should be used at 12 months than at baseline, (test group $p = 0.004$, control group $p = 0.021$). Hinds and Gregory (1995) reported despite advice many parents failed to follow recommended dental health behaviour guidelines. Whilst the results from this study go against the recommendations, it should be remembered that the median age of the children at the 12 months data collection point was 23.5 months. Therefore it is acceptable that mothers may be working towards increasing the amount of toothpaste used to brush their child's teeth, hence this result is not seen as negative or detrimental to dental health. Ultimately these results highlight mothers are open to information from other sources; acknowledgement must be given to the change in knowledge over time that cannot be accounted for by the provision of this Programme suggesting further research is required to examine this area.

Following the 12 month study period, all mothers in the test group reported they were using a high fluoride toothpaste however, less than half could state the recommended level of fluoride required underpinning the findings of Blinkhorn et al. (2003) and de Castilho et al. (2006) who also identified similar differences. Interestingly, more mothers of children diagnosed with dental caries, were unaware of the ideal level of fluoride in their child's toothpaste and the difference in knowledge between those mothers of children diagnosed caries free was statistically significant, ($p = 0.04$). National evidence has suggested that parents' link tooth brushing behaviour with improved oral health, (White et al., 2006) and

this may offer a reason for the reported variation between behaviour and knowledge. As a dental profession we link the level of fluoride toothpaste used with caries prevention, (DoH, 2009), whereas parents may believe the physical brushing behaviour to be more important.

5.3.3 Feeding practices

National guidance recommends weaning should begin at six months and use of a feeding bottle should be discouraged from the age of one year, (DoH, 1994b; DoH, 2009).

The continued use of a feeding bottle during the day and/or night, over the age of 12 months was reported by some mothers and this behaviour supports the findings of others, (Lin and Tsai, 1999; da Silva Dalben et al., 2003; Mutarai et al., 2008). Clinically, studies examining children with CLP have associated the use of a bottle with the presence of caries, (Lin and Tsai, 1999; Bian et al., 2001; Mutarai et al., 2008). Whilst it is recognised that this habit is detrimental to dental health, variation in culture and feeding habits make comparison of these data with this trial unreliable.

Interestingly, a comparison of knowledge from baseline to 12 months identified a statistically significant difference (p = 0.02) for mothers in the control group regarding the harmful effect a prolonged night bottle may have. Acknowledgement must be given to the provision of advice from other sources which were not recorded during this trial.

Despite the Programme, some mothers reported prolonged use of a night feeding bottle, though fewer reported this than previously reported nationally, (Hinds and Gregory, 1995). Recommendations of Mutarai et al. (2008) to promote the cessation of a feeding bottle for children with CLP should be considered as an area to be focused on and will mirror advice

given by DoH (1994b) and DoH (2009). The methodology used in this trial did not stratify to accommodate all cleft types, neither was it powered sufficiently to offer reliable, comparable data regarding the presence of dental caries. A larger study to allow comparison between varying cleft types and a detailed collection of feeding habits and liaison with the clinical nurse specialist (CNS) involved with each family may offer more reliable data with sufficient power to detect differences in prolonged bottle feeding.

The Infant Feeding Survey 2005 (SACN, 2008) reported almost a third of mothers were offering additional drinks other than milk or water from the age of four weeks. Whilst mothers involved in this trial also reported this behaviour, a positively statistically significant difference (p = 0.002) between groups at 12 months, was demonstrated. However, no differences were evident at three years suggesting this positive behaviour may fade over time. An explanation may possibly be due to the completion of weaning together with a larger social circle but this was not tested here.

At recruitment over half (58%) of the mothers had already introduced a feeding cup. The methodology used in this trial did not consider using the skills of the CNSs who offer feeding advice to the families from birth. The mothers' reported knowledge with regard to the introduction of a cup changed over time, against national guidance, (DoH, 1994b). One possible explanation for this could be at baseline mothers were offering the answer they had been provided with at their antenatal visits or from the literature; however at 12 months they were offering the answer more relevant to their personal experience gained from weaning their infant. Results from this trial have demonstrated that the dental health knowledge of mothers does not equate to positive behaviour underpinning de Castilho et al. (2006). The positive improvement in behaviour and knowledge seen in the 12 months data collection was

not apparent in the three year data collection. Further work in this area would need to be developed and tested to add to the evidence base.

5.4   Dental Health Status

Many studies that examine the dental health status of a population with a cleft include a wide age range, with a variety of cleft types, often spanning both children and adults, syndromic and non-syndromic. Hence comparison of results is generally difficult if not impossible. Indeed this study was not powered to detect important clinically significant differences in caries between study groups however, it is important to report the dental health status as recorded at the multidisciplinary team (MDT) review clinic appointment aged three years.

This study found almost three quarters (73%) of children were caries free demonstrating a lower caries prevalence than that reported by others in the field, (Bokhout et al., 1997; Paul and Brandt, 1998; Rivkin et al., 1999; Gregg et al., 1999; Lucas et al., 2000; Chapple and Nunn, 2001; Williams et al., 2001; Ahluwalia et al., 2004 and Mutarai et al., 2008), (Table 5.1). Examination of the data shown in Table 5.1 demonstrates the variation in age range and dmft recorded both within the UK and internationally, hence due to these and other confounding factors a direct comparison of the data is not possible.

Hewson et al. (2001) and Kirchberg et al. (2004) reported that children with a cleft have a higher risk of developing dental caries in their primary dentition yet Wong and King (1998) and Hasslöf and Twetman (2007) were unable to support these claims. All infants entered into this trial were considered caries free at baseline, indeed many had no teeth erupted at the time

Table 5.1

Recent studies reporting the decayed, missing and filled (dmft) dental caries

data for children diagnosed with cleft lip and/or palate

Study	Location	n	Age	dmft	Caries free n (%)
Trial data	**UK** Greater Manchester	82	44mths (mean)	0.51 (SD 1.45)	60 (73)
Bokhout et al. (1997)	**Netherlands** Amsterdam / Rotterdam	81	4 yrs	-	56 (69)
Paul and Brandt (1998)	**UK** London	114	3-18yrs	2.3	61 (54)
Rivkin et al. (1999)	**UK** Bristol	85	5-20yrs	-	5yrs 13 (57)
Gregg et al. (1999)	**UK** Northern Ireland	133	5yrs=72	-	36 (50)
Lucas et al. (2000)	**UK** London	60	3-15yrs	2.33	-
Chapple and Nunn (2001)	**UK** Newcastle	91	4-12yrs	4yrs 1.3	4yrs 12 (63)
Williams et al. (2001)	**UK**	239	5yrs	-	144 (60)
Ahluwalia et al. (2004)	**UK** London	81	6-16yrs	2.38	-
Mutarai et al. (2008)	**Southern Thailand**	69	26mths (mean)	9.19 (SD 6.04)	6 (9)

Key:

UK = United Kingdom

of recruitment. This study has demonstrated that despite the provision of high fluoride toothpaste, intensive dental health information and dental attendance, dental caries will develop, supporting the findings of Milsom et al. (2008) who suggested that dental caries will develop over time and therefore, preventive dental advice is equally important for those who are caries free together with those diagnosed with dental caries.

A fifth (21%) of the children examined were diagnosed with dentinal caries with five (6%) reporting this adjacent to the cleft area, therefore these results do not support those of Johnsen and Dixon (1984) who reported 14 (22%) children with anterior caries. Johnsen and Dixon (1984) suggested that children with CP presented with nursing caries but as their data was confined to anterior caries, comparison of caries data is limited.

The results of a larger, non cleft study from a similar geographical location and within the same age range by Davies et al. (2001) reported a higher dmft 1.4 and dmfs 2.76 compared to that found in this study, dmft 0.5 and dmfs 0.87. Differences in study groups negate a true comparison.

Despite the development of caries during this trial, the disease level is lower and mirrors work from other areas of health care, Boyd and Kinirons (1997), who suggest these results are due to centralised care. This is an area for further development perhaps involving other regional cleft Units to allow larger study numbers.

The BSPD (2001) believes that within the UK, dental services fail to meet the needs of many pre-school children and recent national surveys would suggest few primary teeth are currently being restored, (Hinds and Gregory, 1995; Lader et al., 2005; Pitts et al., 2006) with the care index for five year olds reported to be 12%, (Lader et al., 2005). The results from this trial

underpin these findings as none of the children had been offered restorations and four required a general anaesthetic for dental extractions, totalling 16 teeth.

Mothers involved in this trial reported a lack of information from their dental provider, as all were unaware of the presence and/or severity of the dental disease. Despite some mothers raising concerns, none reported receiving advice relating to the presence of dental caries from their GDP. Equally, none of the mothers reported a lack of treatment due to their child proving to be uncooperative; in fact the majority of mothers were unaware that their child required dental treatment. However Lucas et al. (2000) reported the development of dental caries despite frequent provision of dental health advice to parents; alternatively Tickle et al. (2003a) argued that GDPs offer preventive advice following the development of dental caries although this was not reported by mothers involved in this trial. Despite the provision of this Programme, dental caries even in the presence of intensive, preventive advice underpinning national strategies, DoH (2005) and DoH (2009) has developed.

BSPD (2003) recommend children are referred to a specialist if the primary carer is not able to provide dental treatment; this was not reported by any of the mothers. However, Shaw et al. (1996) suggested that dental treatment would be better provided locally and McDonagh et al. (2000) demonstrated parents would prefer care to be provided locally rather than in the regional cleft Unit. The methodology used failed to address the development of disease and provision of care to address this. The opportunity exists to develop the communication pathway opened during this Programme to promote preventive measures and allow discussion of treatment options should dental caries be diagnosed.

5.5   Cost of Providing the Programme

Kay and Locker (1996) suggested a cost effective method to reliably promote improved oral health behaviour has not yet been developed and this was reiterated by NICE (2004). Whilst the cost of providing this Programme has been recorded, its cost effectiveness regarding oral health both in the primary and permanent dentitions could not be investigated in this trial. This intervention reports the cost of the Programme in monetary terms, which is of interest for clinical budget planning; but it cannot provide evidence regarding the cost effectiveness of the behaviour change intervention. A postal delivery toothpaste programme has been shown to be cost effective by Davies et al. (2003) and therefore when resources are limited efforts should be concentrated in areas where most benefit will be gained. This is an area for further, longer term investigation. Importantly it must be remembered Milsom et al. (2008) stressed that even though some children present caries free they may not remain so, thus supporting a preventive programme for all children not only those presenting with disease.

5.6   Limitations

- Recruitment was conducted over a 22 month period. This was a longer time period than expected as I was unable to attend all post operative review clinics.

- All mothers were given information to read explaining the trial. Following their written consent, randomisation occurred on the same day. Consequently, mothers returning to the waiting room, whilst waiting to see other clinicians had the opportunity to talk to each other, and there is a possibility that there may have been contamination between groups with regard to the dental health information given. Further study should examine the methodology with consideration of assigning a session to either test or control thus avoiding this potential hazard.

- One of the primary outcomes, reported registration, was high in both groups at 12 months and three years, questioning the use of this outcome in a trial.

- Weaning is introduced at six months, (DoH, 1994b); therefore use of a feeding cup may have been discussed with the CNS. This may have influenced the mothers' responses during baseline data collection.

- Details of infants recruited to the trial were recorded on the database used by the regional cleft Unit. The database is unable to record data relating to infants receiving care from their local CDS. This is an area that needs to be addressed to allow easier communication between the Unit and the dental care provider.

- All dental examinations were conducted by one examiner, a specialist in paediatric dentistry, registered with the General Dental Council. Repeat examinations to verify dental chartings were not performed as the examiners' expertise in the field was considered sufficient and therefore Kappa scores were not calculated. The age and cooperation of the child together with time constraints on the day of examination also negated a second examination.

- The study did not set an objective to measure the effectiveness of tooth brushing as the research focused primarily on dental behaviour and knowledge. Previous work has shown difficulties when attempting to measure and record the presence of plaque in young children with CLP, (Wong and King, 1998), and therefore this still remains an area to be examined. A key element of a study with young children should focus on placing fluoride toothpaste in the mouth, (DoH, 2005; DoH, 2009). Expansion of the programme over a longer time frame may allow the development

of oral hygiene measurements in an attempt to examine the provision and effectiveness of tooth brushing by the mothers of infants within the study.

- Chapple and Nunn (2001) and Wong and King (1998) highlighted the difficulties faced when attempting to conduct a robust study within the CLP field. Consideration must be given to the numerous confounding factors that ultimately may affect the outcomes and comparison with other work, such as the inclusion of the varying cleft types, presence of a syndrome and the age group. A multi-centre study would offer a wider cohort and allow comparison between individual cleft types which has not been possible in this piece of work due to the few numbers within each group. The possibility to compare data with areas benefitting from water fluoridation and/or frequent topical fluoride application, examination of social group and the wider family network are topics that should be considered in a larger trial.

- Collection of the 12 months follow up data via telephone interview proved difficult in some cases. Some of the problems encountered included, an unrecorded change of address, a change of mobile telephone number and a return to work negating availability for interview during the day. Addressing these problems would allow an improved communication pathway for the families and the Unit.

- Children born with a cleft anomaly are cared for by a multidisciplinary team of varying professionals from birth. This trial failed to utilize the professional skills of other team members working on the cleft team. Development of this Programme should encourage all team members to both reinforce dental health messages and report any concerns to the dental health educator on the team. This approach may allow areas of concern to be raised prior to reaching an acute stage whilst also

providing the opportunity for training development as recommended by CSAG, (1998).

- This trial was designed to offer the Programme after the primary surgery had been completed. However, the CNSs are regularly involved with families when diagnosis of the cleft anomaly is made antenatally. Therefore the opportunity exists to introduce dental health education during the ante natal period, thus allowing the provision of focused advice both ante and post natally.

- This trial did not include liaison with the CNSs on the team. The CNSs will have knowledge of a medical history and/or social issues and therefore liaison between the CNS and the paediatric dental team may identify children at a higher risk. Increased communication between the dental care provider on the cleft team, the CNS, the GDP and the family may offer a way forward to ensure that all preventive measures are in place to avoid the development of dental disease or provide early intervention should it be necessary.

- This trial failed to develop a care pathway for primary care providers. Development of a pathway should be considered in order to offer focused, evidence based, preventive advice together with early intervention in order to maintain a healthy dentition.

5.7 Conclusions

Children born with a cleft anomaly can automatically be prioritised as children who require exemplary oral health, and if deemed necessary are entitled to the provision of dental treatment from a hospital based, paediatric dental service led by a Consultant in Paediatric Dentistry. The importance of good oral health has been discussed and concluded as

important for these children. Research is unable to predict who is at risk (Hasslöf and Twetman, 2007; Milsom et al., 2008) and therefore until more robust evidence is available the cleft team and local dental care providers must prioritize preventive dental health measures for this group of children from birth, (CSAG 1998). Whilst CSAG (1998) recommended the provision of preventive dental health advice from each regional cleft Unit the effectiveness of this recommendation had not been tested.

Provision of paediatric dental care must be evidence based in order to guide the development and delivery of a comprehensive care plan for all children born with a cleft. A well designed, randomized controlled trial testing an intensive, preventive dental health programme has been correctly conducted however it has failed to prove effective over time. Whilst initially this trial has positively demonstrated an increased use of a higher level fluoride toothpaste together with reduced use of drinks detrimental to dental health, this learnt behaviour and knowledge appears to fade over time. When comparing behaviour with knowledge it would seem that mothers are developing and broadening their knowledge and behaviour as their child grows. More importantly, the evidence would indicate that the development of dental caries necessitating, in some cases, dental extractions under general anaesthesia, can occur despite the provision of preventive dental health advice, and being under the regular care of a local primary care provider. Whilst this study fails to report the dental care offered by local providers it is able to demonstrate a level of untreated dental disease that is unacceptable in the management of this group of patients. This evidence should guide the regional cleft Units to the recommendation that all children with CLP must be under the care of either the regional cleft Unit or a registered specialist in paediatric dentistry based in the CDS. This would then allow all children with CLP to be under the care of a professional who has received specific training in their care. Alongside this, an improved database must be developed that recognises all dental care providers. The database must also

flag up concerns for example, with attendance, dental anomalies, the diagnosis of carious lesions and/or patients with additional needs, making good oral health an even higher priority. The inclusion of other cleft team members to reinforce preventive measures and alert the dental professional on the cleft team of any concerns should also be developed. Supporting Milsom et al. (2008) the development of a preventive dental health strategy by the regional cleft Unit, encompassing registered specialists in paediatric dentistry will target focused preventive measures for both the children who present with dental caries and perhaps more importantly those who are caries free.

The oral health of this group will always be important as their care expands over a long period of time. Absence of dental disease will allow provision of all available treatment options rather than a compromised plan that has needed to accommodate poor oral health.

5.8 Recommendations for Further Action

- This study highlights that an individual with an interest in paediatric dentistry should be employed on the regional cleft team to develop a strategy for improved dental health for this population.

- The provision of routine dental care should be coordinated from the regional cleft Unit, with a strong recommendation that parents requesting local care should receive this from a registered specialist in paediatric dentistry either based within a hospital or community led service.

- A dental care pathway should be developed to provide both intensive, preventive advice that can be carried out in the home; together with professional dental care that

encompasses regular topical application of fluoride and the early management of dental disease by an appropriately trained clinician.

- The provision of a longer term, multi centre study to include measurement of the cost effectiveness of the intervention is indicated.

- The longer term assessment of the dental health status of this study group via audit to report and compare their oral health with national data recorded by other regional cleft centres is indicated.

Overall this trial has demonstrated that despite the introduction of an intensive preventive dental health programme dental caries will still develop in some children. Long term follow up of the children involved in this study via national audit will provide further data to allow comparison with others attending the same Unit and Units across the UK. Initial results from this trial support the development of coordinated dental care, provided by specialists in paediatric dentistry. Continued research to test these recommendations for this important group is paramount in order to inform future care.

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Appendices

Appendix 1

Cleft Lip and Palate Unit
University Dental Hospital
Higher Cambridge Street
Manchester M15 6FH
Tel: 0161 275 6716

Dental Care for Cleft Lip and/or Palate Patients
Information Sheet

Dental decay can affect all children. It is very often painful and in many cases teeth may need to be filled or taken out. We wish to help young children keep their teeth healthy for life.

We would like to invite you to help us test two different dental health programmes. One is the current dental health programme offered within the Cleft Lip and Palate Unit. The second is a more intensive programme which will involve the researcher contacting your child's local dentist. We do not know which is the better so we are asking you to help us test them.

What will I have to do if I take part?
The study lasts for one year and will involve 86 cleft lip and/or palate infants and their parents. If you agreed to take part you would be asked to sign a form and answer a few questions about the dental care of your child. You will then be allocated by chance into one of two groups.

One group will receive the dental health programme currently used. Parents will be given dental health advice regards looking after their child's teeth. This will include information on toothbrushing, diet and visiting the dentist. You will be asked to look after your children's teeth using the information given to you by the researcher. The second group will receive the same advice which will be followed by a leaflet, the provision of a free flow feeder cup and three monthly deliveries of toothpaste for one year. The researcher will liaise with your child's dentist to ensure attendance and help will be offered to find a local dentist if this proves difficult. You will be asked to look after your child's teeth using the information, toothpaste and feeder cup given to you by the researcher. The verbal information and support given during the initial interview by the researcher to both groups will be the same.

At the end of one year every mother in both groups will be contacted by telephone. You will be asked the same questions again about the dental care of your child. This information will help us to discover which of the dental health programmes is better and what problems mothers have had.

Are there any possible risks involved?
No.

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Are there any possible benefits?
If one of the programmes is better than the other, then the mothers in the other group will be given the better programme if they so wish.

All cleft lip and palate units will be informed of the study results, allowing all children to benefit.

Do I have to take part?
No, taking part is voluntary. If you would prefer not to take part you do not have to give a reason. The Cleft Lip and Palate Unit will not be upset and your child's care will not be affected. If you take part, but later change your mind, you can withdraw at any time from the study without hinderance or detriment to your child's future care.

We would want to inform your child's dentist, if he/she has one, that you are involved in the study, with your permission.

What do I do now?
You can ask the researcher any further questions and let her know if you wish to take part in the study.

<div align="center">

Mrs Jeanette Mooney
Dental Therapist/Researcher
University Dental Hospital, Manchester
0161 275 6610

</div>

If you wish to obtain independent advice about this research you may contact:

<div align="center">

Professor A S Blinkhorn
University Dental Hospital
Higher Cambridge Street
Manchester M15 6FH

</div>

Appendix 2

Central Manchester University Hospitals NHS
NHS Foundation Trust

Consent Form

Preventive Dental Care for Cleft Lip and Palate Infants

Mrs Jeanette Mooney has explained to me the nature of the research, and I am clear about what my child and I would be asked to do as volunteers. She has given me my own copy of the volunteer information sheet, which I have read.

I consent to take part as a volunteer and understand that I am free to withdraw at any time without giving any reason, and without detriment to myself or my child.

I agree that my dentist may be informed of my participation in the trial.

Signed .... Date ....

Name (BLOCK LETTERS) ....

Witnessed ....Date ....

Name (BLOCK LETTERS) ....

I confirm that I have fully explained the purpose and nature of the investigation and the risks involved.

Signed .... Date ....

Name (BLOCK LETTERS) ....

Appendix 3

Baseline Data Collection/Behaviour Questionnaire

Infant Number ☐☐☐

D.O.B. ☐☐☐☐☐☐

Date of first interview ☐☐☐☐☐☐

Age (months) at first interview ☐☐

Time taken to conduct interview
(mins) ☐☐

Infant's Name   MDH No. ☐☐☐☐☐☐

Mother's Name

Medical History

Contact Details   Dentist Contact Details

Test Group Only

Posting date for toothpaste

2nd ☐☐☐☐☐☐ 3rd ☐☐☐☐☐☐ 4th ☐☐☐☐☐☐

Date letter sent to dentist   ☐☐☐☐☐☐

Date letter sent to request dental appointment locally   ☐☐☐☐☐☐

Date letter sent to parents following failed appointment   ☐☐☐☐☐☐

Further action:-

1.	Is your child registered with a local dentist for routine check-ups?	Yes = 1 No = 2 ☐

(If yes, ensure contact details are recorded on data sheet)

	(If no, would you be happy for the CLP Unit to arrange for your child to be seen by a local specialist paediatric dentist?)	Yes = 1 No = 2 ☐
2.	Is the dentist?	NHS = 1 CDS = 2 Private = 3 Hospital = 4 ☐
3.	Have you experienced problems registering your child with a dentist?	Yes = 1 No = 2 ☐

If yes, state ....

....

4.	Has your child attended the dentist for a routine check yet? If no, why?	Yes = 1 No = 2 ☐
5.	Do you brush your child's teeth?	Yes = 1 No = 2 ☐
	If yes, how often?	1 x day = 1 2 x day = 2 3 x day = 3 1 x week = 4 ☐

If no, why not? (state) ....

	Do you brush your child's teeth with a children's or adult toothpaste? (prompt ... which brand)	Adult = 1 Child = 2 Both = 3 None = 4 ☐
6.	Have you been given any information regards caring for your child's teeth?	Yes = 1 No = 2 ☐
7.	If yes, who by?	CLP health visitor = 1 ☐ Doctor = 2 Local dentist = 3 Other = 4

If other, please state ....

8.   Has the advice covered any of the following?   Yes = 1

No = 2

Brushing   ☐
Brushing the teeth in the area of the cleft   ☐
Problems caused by sugary foods/drinks   ☐
Use of an adult fluoride toothpaste   ☐
Use of fluoride drops/tablets   ☐
Importance of regular checkups i.e. every 6/12   ☐

Other information ....

9.   Is your child currently being fed by/drinking from:-   ☐☐☐
Breast fed = 1
Nuk teat + soft bottle = 2
Nuk teat + hard bottle = 3
Adjusted Nuk teat + soft bottle = 4
Standard teat + bottle = 5
Naso-gastric tube = 6
Gastrostomy = 7
Feeder cup = 8

Other = 9 (state) ....

10.   Does your child go to sleep with a drink during the night?   Yes = 1
No = 2   ☐

If yes, what type of bottle/cup is used? ....

What is in the bottle/cup? ....

11.   Does your child drink between meals during the day?   Yes = 1
No = 2   ☐

If yes, is a bottle/cup used? ....

What is in the cup/bottle? ....

Appendix 4

Dental Health Questionnaire

1. How often should your child's teeth be brushed?

☐

1 = 1 x week
2 = 1 x day
3 = 2 x day
4 = Do not know

2. What type of brush is best for your child?

☐

1 = Junior
2 = Baby
3 = Hard
4 = Do not know

3. How much toothpaste should be placed on the brush?

☐

1 = ½ inch
2 = Pea size
3 = Smear
4 = Do not know

4. How much fluoride should be in your child's toothpaste?

☐

1 = 1ppm
2 = 500ppm
3 = 1100ppm
4 = None
5 = Do not know

5. What food and drink can cause tooth decay in your child?
(You can give more than one answer)
1 = Sugary foods and drinks at meals
2 = Sugary foods and drinks between meals
3 = Milk in a feeding bottle during the night
4 = Water in a feeding bottle during the night
5 = Milk in a feeding bottle during the day
6 = Do not know

☐☐☐☐

6. At what age is it best to stop using a feeding bottle?
1 = When weaning begins (4-6 months)
2 = 12 months
3 = 2 years
4 = Do not know

☐

7. When should your child start using a feeder cup? □
   1 = When weaning begins (4-6 months)
   2 = 12 months
   3 = 2 years
   4 = Do not know

8. When may juice be given to your child? □
   1 = Between meals
   2 = During the night
   3 = At meals
   4 = Do not know

9. When should your child first see a local dentist for a check-up? □
   1 = 1 year
   2 = 2 years
   3 = As soon as possible
   4 = Do not know

10. How important is it for your child to visit a local dentist for □
    check-ups?
    1 = Very important
    2 = Important
    3 = Do not know

Appendix 5

Final Data Collection/Behaviour and Knowledge Questionnaires

Infant Number ☐☐☐

D.O.B. ☐☐☐☐☐☐

Date of second interview ☐☐☐☐☐☐

Age (months) at second interview ☐☐

Time taken to conduct interview
(mins) ☐☐

Infant's Name   MDH No.   ☐☐☐☐☐☐

Mother's Name

Contact Details

1. Is your child registered with a local dentist for routine check-ups?

Yes = 1
No = 2 ☐

2. Is the dentist?

NHS = 1
CDS = 2
Private = 3
Hospital = 4 ☐

3. Have you experienced problems registering your child with a dentist?

Yes = 1
No = 2 ☐

If yes, state ....

....

4. Has your child attended the dentist for a routine check yet?
If no, why? ....

Yes = 1
No = 2 ☐

5. Do you brush your child's teeth?

Yes = 1
No = 2 ☐

If yes, how often?

1 x day = 1
2 x day = 2
3 x day = 3
1 x week = 4 ☐

If no, why not? (state) ....

Do you brush your child's teeth with a children's or adult toothpaste? (prompt ... which brand)

Adult = 1
Child = 2
Both = 3
None = 4 ☐

6. Have you been given any information regards caring for your child's teeth?

Yes = 1
No = 2 ☐

7. If yes, who by?

CLP health visitor = 1 ☐
Doctor = 2
Local dentist = 3
Other = 4

If other, please state ....

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8. Has the advice covered any of the following?

Brushing ☐

Brushing the teeth in the area of the cleft ☐

Problems caused by sugary foods/drinks ☐

Use of an adult fluoride toothpaste ☐

Use of fluoride drops/tablets ☐

Importance of regular checkups i.e. every 6/12 ☐

Other information ....

9. Is your child currently being fed by/drinking from:-

☐☐☐

Breast fed = 1
Nuk teat + soft bottle = 2
Nuk teat + hard bottle = 3
Adjusted Nuk teat + soft bottle = 4
Standard teat + bottle = 5
Naso-gastric tube = 6
Gastrostomy = 7
Feeder cup = 8

Other = 9 (state) ....

10. Does your child go to sleep with a drink during the night?

Yes = 1
No = 2 ☐

If yes, what type of bottle/cup is used? ....

What is in the bottle/cup? ....

11. Does your child drink between meals during the day?

Yes = 1
No = 2 ☐

If yes, is a bottle/cup used? ....

What is in the cup/bottle? ....

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Dental Health Questionnaire

1. How often should your child's teeth be brushed?

☐

1 = 1 x week
2 = 1 x day
3 = 2 x day
4 = Do not know

2. What type of brush is best for your child?

☐

1 = Junior
2 = Baby
3 = Hard
4 = Do not know

3. How much toothpaste should be placed on the brush?

☐

1 = ½ inch
2 = Pea size
3 = Smear
4 = Do not know

4. How much fluoride should be in your child's toothpaste?

☐

1 = 1ppm
2 = 500ppm
3 = 1100ppm
4 = None
5 = Do not know

5. What food and drink can cause tooth decay in your child?
(You can give more than one answer)

☐☐☐☐

1 = Sugary foods and drinks at meals
2 = Sugary foods and drinks between meals
3 = Milk in a feeding bottle during the night
4 = Water in a feeding bottle during the night
5 = Milk in a feeding bottle during the day
6 = Do not know

6. At what age is it best to stop using a feeding bottle?

☐

1 = When weaning begins (4-6 months)
2 = 12 months
3 = 2 years
4 = Do not know

7. When should your child start using a feeder cup?
    1 = When weaning begins (4-6 months)
    2 = 12 months
    3 = 2 years
    4 = Do not know

    □

8. When may juice be given to your child?
    1 = Between meals
    2 = During the night
    3 = At meals
    4 = Do not know

    □

9. When should your child first see a local dentist for a check-up?
    1 = 1 year
    2 = 2 years
    3 = As soon as possible
    4 = Do not know

    □

10. How important is it for your child to visit a local dentist for check-ups?
    1 = Very important
    2 = Important
    3 = Do not know

    □

Appendix 6

Central Manchester University Hospitals **NHS**
NHS Foundation Trust

Tel: 0161 275 6612

Consent for Photography

Patient's Name: Date of Birth:

MDH No:

I hereby consent to the photography of myself and my child. The photographs taken will be used to produce a dental health education leaflet, aimed towards the care of cleft lip and palate infants. The leaflet will form part of a research project being conducted by Mrs J Mooney.

I understand that:

- During the photography, if I am unhappy, I am free to stop the session.
- Once the leaflet is produced, it may not be possible to withdraw photographs of myself and my child from the public domain.
- I am free to view the photographs before they are used in the leaflet and may withdraw my consent at that time.

Name of Operator: Signature: Date:

Name of Parent: Signature: Date:

I wish to view the photographs before they are used to produce the dental health education leaflet.

Name of Parent: Signature: Date:

I do not wish to view the photographs before they are used to produce the dental health education leaflet.

Name of Parent: Signature: Date:

University Dental Hospital of Manchester
Higher Cambridge Street, Manchester M15 6FH

Appendix 7

What Do I Do Now?

1. Register your child with a local dentist.

2. Take your child to see the dentist for regular check-ups.

3. Start brushing your child's teeth when they appear.
   Pay particular attention to the teeth in the area of the cleft.

4. Brush the teeth and gums twice a day with a small headed, baby toothbrush and adult toothpaste. The toothpaste must contain at least 1100 parts per million fluoride or more.

5. Introduce a free-flowing feeder cup when weaning begins.

6. Stop using feeding bottles by the time your child is one year old.

7. If needed, offer your child water and sugar-free snacks between meals.

Where Can I Get Help?

If you experience problems registering your child with a local dentist, you can:

Contact your local Community Dental Clinic, your health visitor will be able to help you find your nearest clinic.

Ring NHS Direct (0845 4647) for a dentist in your area.

Contact the
Cleft Lip and Palate Unit.
0161 275 6795

Looking After Your Child's Teeth

What Do You Need to Do?

Register your child with a local dentist

- Regular visits to a local dentist are very important.

- The dentist can offer you advice about your child's mouth.

- Your child will become relaxed and happy when visiting the dental clinic.

- The sooner you register your child with a dentist, the better. Call in or phone your chosen practice to make your child an appointment.

- Dentists can see children from birth.

Talk to Your Dentist

Your dentist will be able to help you with:

Toothbrushing

- Teeth must be cleaned twice a day as soon as they appear.

- Teeth in the area of the cleft may appear slightly discoloured or twisted. These teeth will need extra care.

- Use a small headed baby toothbrush and a smear of adult toothpaste to clean all the teeth and gums.

- Finish by smearing toothpaste onto the teeth in the area of the cleft. Do not rinse the toothpaste away.

- The toothpaste must contain at least 1100 parts per million fluoride or more. This is displayed on the tube of toothpaste *for example "sodium fluoride 1100ppm."*

- The fluoride in toothpaste will help to protect your child's teeth from decay.

- Your dentist can help you with brushing, especially in the area of the cleft.

Diet advice

- When teeth first appear they are healthy.

- Tooth decay is caused by giving sweet snacks and/or drinks frequently between meals.

- Tooth decay is often seen in children who drink frequently from a bottle.

Aim to:
- Offer tap water between meals and during the night.

- Introduce a free-flowing feeder cup when weaning begins. Yes, it is messy, don't give up!

- Stop using a bottle by the time your child is one year old.

- If juice is given, make sure it is well diluted and only given with meals.

- Do not give juice in a bottle or no-spill feeder cup.

Appendix 8

PRODUCT TECHNOLOGY (UK) LTD

SEALABLE TRAINER

THE 1st CUP
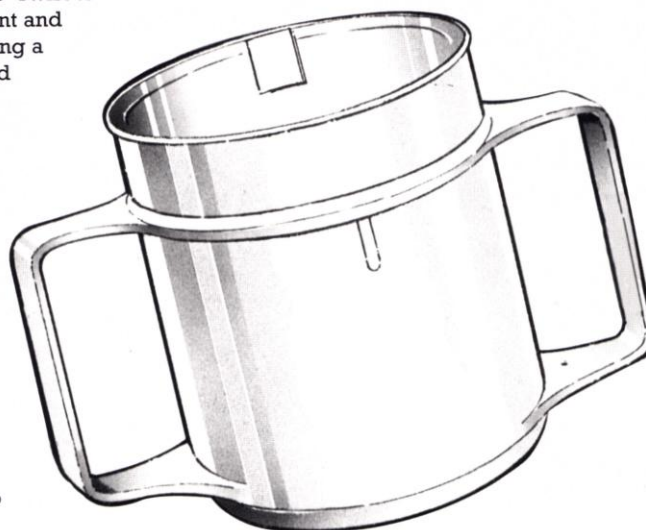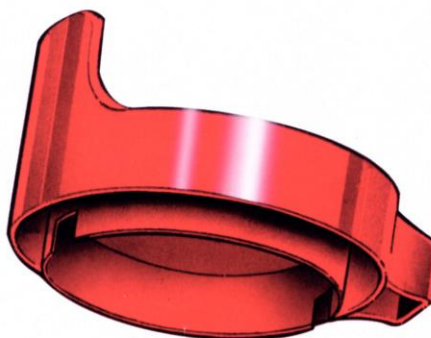
Snap-on TWIST to SEAL Lid

Unique patented 1st 'Trainer Cup' with free but balanced 'flow rate' and snap-on 'Twist to Seal' lid, carefully designed to provide benefits for both Mother and Baby.

☺ Ideal balanced 'flow rate', prevents sudden gushes of drink into the mouth - allowing baby to develop feeding confidence and natural drinking skills - a vital stage in progressive development!
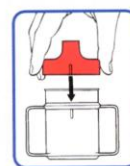
☺ Snap-on one piece 'Twist to Seal' lid, convenient and easy to use, allowing a drink to be carried until required - without leaking!

☺ Establishes good feeding practice - helping limit baby's teeth to prolonged exposure from sweet/acid drinks - baby drinks and finishes!

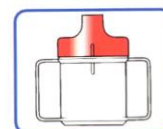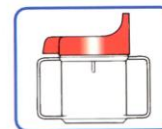☺ Hygienic - easy to clean, moulded from high grade food approved polymers - 140ml capacity.

SNAP-ON

TWIST TO SEAL

THUMB GRIP FOR EASY REMOVAL

OPEN | **SEALED**

The 1st Trainer Cup is in line with NOHPG Guidelines

Product Technology (UK) Ltd, Raglan House, Llantarnam Park, Cwmbran, Monmouthshire NP44 3AX
Tel: 01633 838080 **Fax:** 01633 838418 **Email:** producttechnology@ntlbusiness.com

British Patent Number 2206106B and Foreign Patents

Appendix 9

Cleft Lip and Palate Unit
University Dental Hospital
Higher Cambridge Street
Manchester M15 6FH
Tel: 0161 275 6716

Referral letter to CDO in local area of family home for appointment

Dear

We are currently writing to enlist your help in a randomised controlled trial. We are testing a dental health education programme for mothers of cleft lip and palate infants. Our aim is to ensure regular dental care, preventive advice and link local dental services to our tertiary care centre.

re

This young child attended the Cleft Lip and Palate Unit, University Dental Hospital, Manchester today and is not registered with a local dental practitioner. (Name)   mother has volunteered to join the trial. The parents have asked for a referral to your Community Dental Service clinic as it is close to home.

The importance of dental registration and regular dental recalls have been discussed with the parents, together with preventive dental advice about (Name)'s developing dentition. The twice daily use of an adult fluoride toothpaste and the early introduction of an easy-flow feeder cup containing water between meals has been recommended. I enclose a copy of a specially prepared leaflet given to the mother to reinforce information given in the clinic.

In order to monitor and manage (Name)'s dental health I would be most grateful if you could see this child and offer recalls at 4 monthly intervals. When you see the parent please could you support the advice in the leaflet and remind her of it at recalls. The family are aware of this referral and await an appointment. Should (Name) fail to attend your clinic, or you require any further information please contact us on 0161 275 6795.

Thank you for your kind attention and help.

Yours sincerely

Mrs Jeanette Mooney   Professor Anthony S Blinkhorn
            Unit of Paediatric Dentistry

Appendix 10

Central Manchester University Hospitals **NHS**

NHS Foundation Trust

Cleft Lip and Palate Unit
University Dental Hospital
Higher Cambridge Street
Manchester M15 6FH
Tel: 0161 275 6716

Letter to local dentist

Dear

We are currently writing to enlist your help in a randomised controlled trial. We are testing a dental health education programme for mothers of cleft lip and palate infants. Our aim is to ensure regular dental care, preventive advice and link local dental services to our tertiary care centre.

re

This young child attended the Cleft Lip and Palate Unit, University Dental Hospital, Manchester today, and we understand (Name) is registered with your practice. (Name's) mother has volunteered to join the trial.

The importance of dental registration and regular dental recalls have been discussed with the parents, together with preventive dental advice about (Name)'s developing dentition. The twice daily use of an adult fluoride toothpaste and the early introduction of an easy-flow feeder cup containing water between meals has been recommended. A healthy, caries free primary dentition introduces a positive approach to dental care which is of paramount importance in the long term care of (Name). Please could you see this child every four months for a recall. When you see (Name) please could you support the advice in the leaflet and remind (Name's) mother of the information given. Your support is very much appreciated.

If (Name) fails to attend your practice for care, or you require any further information, please contact us on 0161 275 6795.

Thank you for your kind cooperation.

Yours sincerely

Jeanette Mooney (Mrs)   Professor Anthony S Blinkhorn
                Unit of Paediatric Dentistry

Appendix 11

Cleft Lip and Palate Unit
University Dental Hospital
Higher Cambridge Street
Manchester M15 6FH
Tel: 0161 275 6716

Letter to parents who fail to register/attend dentist

Dear

re

I note from our records that (Name) has not yet registered with a dentist. If (Name) has attended a local dentist for a check-up please inform the Cleft Lip and Palate Unit and (Name)'s notes will be updated. It is very important that (Name) is seen by a dentist for regular check-ups to ensure the teeth are developing properly.

If you would like (Name) to be referred to a local Community Dental Clinic please inform the Cleft Lip and Palate Unit and I will arrange for an appointment to be sent to you for (Name).

I look forward to hearing from you. Our telephone number is 0161 275 6795 or you can complete the enclosed form and return it in the envelope provided.

Yours sincerely

Jeanette Mooney (Mrs)   Professor Anthony S Blinkhorn
                    Unit of Paediatric Dentistry

Enc. SAE + form

Cleft Lip and Palate Unit
University Dental Hospital
Higher Cambridge Street
Manchester M15 6FH
Tel: 0161 275 6716

Dental Registration Information

Name of child

Date of birth

Manchester Dental Hospital record number

Home address

If your child is registered with a local dentist please complete details below and return this form to us in the enclosed pre-paid envelope.

Name of dentist

Address of dental practice

Telephone number of dental practice

If your child is **not** registered with a local dentist, and you would like an appointment at a local Community Dental Clinic, please sign below. Return this form to us in the enclosed pre-paid envelope.

Please arrange a dental appointment for my child at a local Community Dental Clinic.

....
Name of parent   Signature   Date

Thank you.
Yours sincerely

Mrs Jeanette Mooney   Professor Anthony Blinkhorn
            Unit of Paediatric Dentistry