

# Supervised tooth brushing in Northland

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#### **Abstract**

#### Aim

The aim of this study was to improve the oral health of Northland children. The research questions were: (1) does a supervised tooth brushing programme reduce caries and improve oral health-related quality of life in a high caries community; and (2) can an in-school tooth brushing programme successfully be implemented in low-decile schools in Northland?

## **Background**

There are still clear inequalities in the oral health of New Zealanders, with Māori and low socio-economic status families experiencing a high proportion of oral disease, mainly dental decay. The Northland population has high proportions of Māori and a high number of the population reside in low socioeconomic status. Dental caries experience in children in Northland is the highest in the country, and there is no fluoridated water supply. Tooth brushing with fluoride toothpaste is known to reduce the incidence of dental decay. Studies of supervised brushing in schools have shown measurable improvements in oral health, (including a pilot study in Northland). A larger-scale study is needed to reach more children and to examine the feasibility of tooth brushing interventions in the New Zealand setting.

#### Methods

An ethical review process and funding application were made, along with consultation with the Northland District Health Board (NDHB) and Northland schools. A sample of Intermediate school-age children from five schools was chosen. The children had a full clinical dental examination with radiographs, completed a questionnaire (to assess oral hygiene behaviour and self-reported oral health-related quality of life), and were given a toothbrush and tube of toothpaste to take home. The International Caries Detection and Assessment System (ICDAS) was the index used to record the caries status of the teeth. Four schools were chosen to be control schools, and one of the larger Intermediate schools was chosen to be the intervention school. Children in the latter had a supervised tooth brushing programme throughout an entire school year. A baseline clinical examination with radiographs and questionnaire was repeated at the end of the school year (9 months later). Data were entered into a statistical programme and analysed. Follow-up Oral Health Related-Quality of Life (OHRQoL) data were analysed by calculating the change in score between the baseline and follow-up data for the Child Perception Questionnaire (CPQ11-14) scores and for each domain. Effect sizes were

analysed for each domain and CPQ total. Net caries increment and incidence were calculated for ICDAS data, and traditional DMF data with radiographic adjustment. Multivariate analysis was conducted on the caries data.

#### Results

This quasi-experimental study has demonstrated that a tooth brushing programme can be successfully implemented in a Northland Intermediate school. The study has shown that, over a one-year period, OHRQoL improved more for children who took part in a supervised tooth brushing programme with a 0.4 (moderate) effect size, than for those who did not with a 0.2 (small) effect size. The children who took part in the brushing programme had improvements in oral health, with more caries reversals and a lower prevalence of new carious lesions than those in the control group. The ICDAS net caries increment for the children in the tooth brushing group was a mean of 11.7 surfaces improved; those in the control group had a mean of 8.6 surfaces which had deteriorated over the course of the school year. Caries incidence for those in the tooth brushing group was 7.3%; the caries incidence for the control group was 71.5%. The multivariate analysis showed that membership of the brushing group was the only statistically significant predictor of a lower net caries increment. Tooth brushing at school removed all oral health inequalities.

## Conclusion

The aim of this study—to improve the oral health of Northland children—has been successfully achieved with a supervised tooth brushing programme. This programme has been the first large-scale, fully evaluated tooth brushing programme to be set up and run successfully in New Zealand. The findings show improved caries outcomes at one year for children involved in a supervised tooth brushing programme; it is the first New Zealand study to show this. It is also the first study in the world to show that an overall improvement in OHRQoL can occur in children who take part in a supervised tooth brushing programme. This reinforces the need for policy to consider other approaches to improve children's oral health in communities that experience high caries and poor oral health.

## Acknowledgement

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I sincerely thank the children of Northland who took part in the study and our tooth brushing supervisor at Kaitaia Intermediate school.

This project would not have been possible without the oral health research grant support from The Ministry of Health; thank you for generously supporting this important research.

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## Chapter 1

#### 1. Literature review

In this section, the aetiology of dental caries will be covered, along with the burden of disease internationally, in New Zealand and in Northland. Ways to measure and prevent dental caries will also be discussed, including the assessment of oral-health-related quality of life.

#### 1.1. Dental caries

Understanding the factors involved in the caries process is important for identifying opportunities to reduce the disease and its future burden in a community. Dental decay itself is a person-level disease. It occurs when acid is produced from the fermentation of carbohydrate by a dysbiotic supragingival microbiome (biofilm), resulting in demineralisation and then destruction of susceptible tooth surfaces (Selwitz *et al*, 2007). The aetiology of dental caries is complex and can be viewed from multiple standpoints: molecular/biochemical, microbiological, social, behavioural, health system, and even political (Divaris, 2016). Dental disease risk markers vary greatly; some are non-modifiable (for example ethnicity) and others are modifiable, such as sugar consumption.

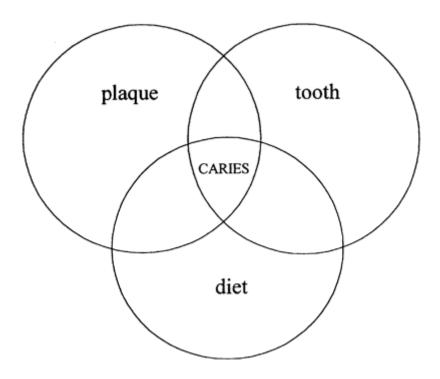
## 1.1.1. The aetiology of dental caries

Tooth enamel and dentine are made up of hydroxyapatite, a mineral form of calcium apatite. Formation of tooth material begins when specialised cells from the oral epithelium secrete a mineral matrix which hardens and crystallises. This hard tissue makes up the majority of the tooth structure and erupts into the mouth soon after maturation. From the time a tooth erupts in the oral cavity it is susceptible to dental caries. Dental plaque is a complex biofilm consisting of bacteria in a complex microbial community, in an extracellular matrix. Plaque sits on the surface of teeth. Some bacteria in dental plaque are acidogenic, which means that they produce organic acids when they metabolise fermentable carbohydrates such as glucose, fructose, sucrose or cooked starch. These acids move through the dental plaque and dissociate. The resultant hydrogen ions lower the pH at the surface of the tooth, forcing calcium and phosphate ions to diffuse out of the tooth into solution. This process is called demineralisation, and it results in dental caries. Mutans streptococci and lactobacilli are the bacteria most commonly associated with dental caries (Leene and Shaklar, 1974; Carlsson *et al*, 1975; Hechuan *et al*, 2013). If dental plaque is not removed, or if the environment remains acidic, the tooth will

continue to demineralise. If the process is not reversed or stopped, the carious lesion progresses, and a cavity is formed.

In the 1960s, Keyes and Jordan described the three main factors that are involved in the caries process (plaque, tooth and diet) using three overlying circles, which are displayed in Figure 1 (Keyes and Jordan, 1963).

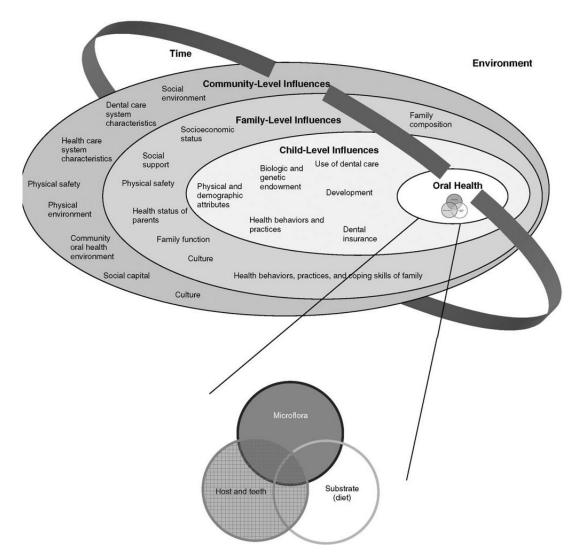
Figure 1. Keyes and Jordan's initial depiction of the factors involved in the dental caries process "The Keyes' Triad"



(Adapted from Keyes and Jordan, 1963)

Further research has brought to light details about the dental caries process, and the model has been expanded to also include other factors such as use of fluoride, saliva, time, the immune system, socioeconomic and environmental factors (Summit *et al*, 2001). The Fisher-Owens model of oral health (Figure 2) is the most recent model to depict oral health influences. It incorporates five important domains which are key determinants of health; genetic and biological factors, the social environment, health behaviours, dental care, and the aspect of time. The model consists of three layers, child, family and community-level influences which influence oral health via complex interactions.

Figure 2. The Fisher-Owens Model of Oral Health



(Adapted from Fisher-Owens, 2007)

#### 1.1.2. Dental caries in an international context

Dental caries is the most prevalent chronic disease globally. It is also the leading contributor to tooth loss worldwide, despite being largely preventable (Fejerskov, 2004; Fisher-Owens *et al*, 2007; Selwitz *et al*, 2009). Internationally almost all adults have experienced it; leading to pain and discomfort in a lot of cases (USHHS, 2000; Do, 2012; World Health Organization, 2015; Kassebaum *et al*, 2015). Considering the global burden of disease, a recent systematic review of studies found that oral diseases affect 3.9 billion people worldwide. Untreated caries in permanent teeth was the most prevalent condition and accounted for 15 million disability-adjusted life years (DALYs) globally, implying an average health loss of 224 years per 100,000 (Marcenes *et al*, 2013). The financial impact of oral disease includes the cost of private care,

estimated to be \$4.698 billion per annum as at 2009-2010 (US Department of Health and Human Services, 2000). The cost to society is also great, with tooth loss linked with poorer general health along with psychosocial and functional consequences (Locker, 1992). Dental caries also has a profound impact on people's quality of life, ability to gain employment and contributes to time off work or study (US Department of Health and Human Services, 2000). Changing global models of caries development due to greater sugar consumption in developed nations and effective oral hygiene and dental care being available only to higher socioeconomic status groups is creating patterns of gross inequality in oral health (Marthaler, 2004; World Health Organization, 2015).

Globally, 60–90% of school children are affected by dental caries (Marthaler, 2004; Whelton, 2004; Do, 2012; World Health Organization, 2015). The worldwide mean DMFT (decayed, missing or filled teeth) in of 12-year-old children in 2010 was recorded by the World Health Organization to be 2.4 (Peterson, 2000). The prevalence of child caries varies greatly between developed and underdeveloped countries, in which inequalities by social status or class, sex, ethnic group, geographic location and poor access to health services and care exist (World Health Organization, 2015).

The premature loss of primary teeth is a potential risk factor for poor arch length development, which is important for the correct alignment of permanent teeth (Alamoudi, 1999; Cardoso, 2005). Studies show oral health in childhood predicts oral health in adulthood along with behaviour and development and overall school performance (Schlomo and Kuh 2002; Thomson *et al*, 2004; Broadbent *et al*, 2008). It is therefore important for children to maintain oral health to avoid potential problems affecting both the dentition and their life overall.

#### 1.1.3. Dental caries in New Zealand

The 2009 National Oral Health Survey (NZOHS) found that one in three adults had untreated dental caries, making it the most common chronic disease among the adult population of New Zealand. One in three adults examined had active dental caries, and more than half of New Zealand adults do not visit the dentist on a regular basis, attending only when symptoms arise (Ministry of Health, 2010). A 20-year review of admissions to New Zealand Hospitals for dental care reported that the national rate of hospital admissions for dental care has increased nearly four-fold, from 0.76 per 1000 of population in 1990 to 3 per 1000 in 2009 and that the

majority of the admissions were for dental extractions and fillings, attributed to tooth decay (Whyman *et al*, 2013).

While the oral health of New Zealand children and adolescents (aged 2-17) has improved over the last few decades, only one in two of them are caries-free. Māori and Pacific children and those who live in a deprived area have a higher caries experience than those of European ethnicity or who are of high socio-economic status (SES) (Ministry of Health, 2010).

New Zealand was the first country in the world to introduce a School Dental Service. It began in 1921, in response to the poor dentition of the soldiers in World War I. Dental therapists serve to provide free comprehensive dental care services to all New Zealand children aged 0 to 12 (Tane, 2009). This later expanded and all children residing in New Zealand are able to seek free comprehensive oral health care until the age of 18. The Community Oral Health Service (COHS) is contracted by the Ministry of Health to deliver dental care. Each District Health Board (DHB) collects DMFT data annually for 5 and 12-year-old children. In 2014, 41% of 5-year-old children had experienced dental caries. The mean dmft among 5-year-olds in the same year was 1.8 teeth. By Year 8, data are collected for the permanent dentition. In 2014, the percentage of children in New Zealand with experience of caries was 42%, and their mean DMFT was 1.0.

#### 1.1.3. Dental caries in Northland

Most adults residing in Northland must obtain dental care in private dental practice, although there is a limited amount of relief-of-pain and emergency dentistry provided for low-income and medically compromised adults in community clinics and hospitals. The NZOHS found that one third of all adults suffer with dental caries (Ministry of Health, 2010). Since Northland has a large proportion of its population living in areas of high deprivation, with a high percentage of Māori, the proportion affected by dental caries is likely to be much higher. Previous epidemiological studies conducted in Northland, together with Ministry of Health statistics, show that dental caries experience in Northland children is among the highest in the country (Gowda *et al*, 2009a), and the situation in adults is likely to be similar.

In 2014 in Northland, the dmft score for 5-year-old children was 3.0, the highest in the country and almost double the national mean. For 12-year-old children, the mean DMFT score was 1.6,

again one of the highest scores in this age group nationally<sup>1</sup>. National and Northland dental caries data for the years 2010-2014 for ages 5 and 12 are displayed in Figure 2 and Figure 3.

-National ► Northland 4.5 4 3.5 3 2.5 2 1.5 3 1 0.5 0 2010 2011 2012 2014 2013 Year

Figure 3. Mean dmft for 5-year-old New Zealand children, 2010 to 2014

(Ministry of Health, 2015<sup>1</sup>)

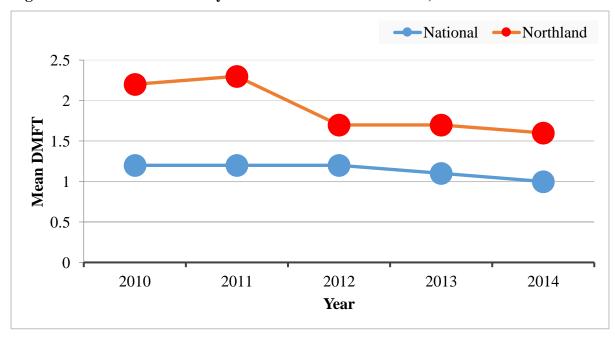


Figure 4. Mean DMFT for 12-year-old New Zealand children, 2010 to 2014

(Ministry of Health 2015<sup>1</sup>)

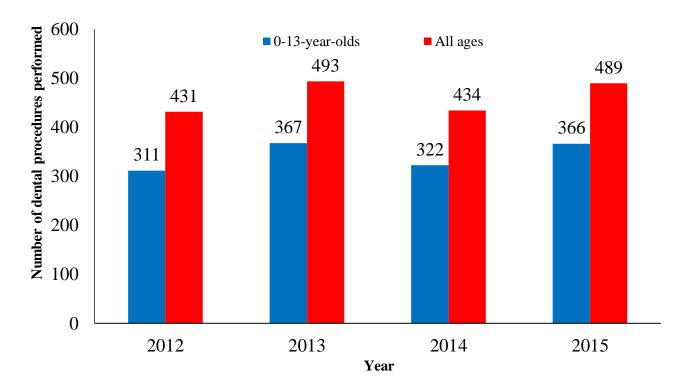
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<sup>&</sup>lt;sup>1</sup> www.health.govt.nz

A study conducted in Northland confirmed child caries rates in the region to be well above national averages. In 2009, Gowda *et al*, found the DMFT of 12-year-olds in four communities in Northland was 5.6 (SD=3.9) (Gowda *et al*, 2009a).

Dental caries is the most common reason for children to undergo general anaesthetics (GA) for dental treatment in Northland. The number of dental GAs performed by Northland DHB from 2012 to 2015 is presented in Figure 5. Most dental GAs are performed on children who require multiple extractions or who are uncooperative in the dental chair and require surgical intervention.

Figure 5. Dental treatment performed under General Anaesthetics at NDHB 2012-2015



(Northland District Health Board, 2016)

Low SES groups and Māori children experience a disproportionately higher rate of dental caries than high SES groups and NonMāori. The most recent dental hospital admission audit found that rates of admission are higher for Māori and Pacific peoples, and those living in areas with high deprivation, than for the overall population (Whyman *et al*, 2013). The Northland population has more than double those who opt for Māori as their primary ethnicity than

nationally (31.7% and 14.6% respectively). Northland has a large proportion of people who are categorised as low-SES. Of the total 148,000 population, 44,000 people are eligible to have a community services card with the unemployment rate in the region at 6.5% for people aged 15 years and over, while it is 5.1% for all of New Zealand. The Māori unemployment rate in Northland is 13.9% <sup>2</sup>.

## 1.2. Measuring dental caries

To accurately assess and quantify the extent to which dental caries is present in a population, an index for measurement is needed. An ideal index should represent the condition, be clear and simple, reproducible, reliable, quantifiable, allowing it to be statistically manipulated, include all possible manifestations of the condition and have a clear history of use. An index provides a repeatable measure that enables the assessment of various preventative activities and can help to assess the need for dental resources in a community. It is hard to categorise a complex disease such as dental caries into a scale because the disease process is continuous and there are stages representing minute loss of tooth structure that is currently not detectable using current technology. Clinically, visual signs (colour, cavitation) are relied upon to represent manifestations of the caries process. There are two main indices which can be used for representing dental caries: the Decayed Missing Filled (DMF) index (Klein *et al*, 1938; World Health Organization, 1997) and the International Caries Detection and Assessment System abbreviated to 'ICDAS' (ICDAS Co-ordinating Committee, 2009). These indices have strengths and weaknesses and may be appropriate for epidemiological surveys, clinical trials or both. Each measure is considered below.

#### 1.2.1. The Decayed Missing Filled (DMF) Index

Traditionally, dental caries experience has been represented by the Decayed, Missing or Filled (DMF) Index. The index was introduced by Klein, Palmer and Knutson in 1938 and adopted by the World Health Organization for conducting oral health surveys (Klein *et al*, 1938). There are two variations of the DMF index. The DMFT (Decayed, Missing or Filled Teeth) index counts the number of teeth which are decayed missing or filled due to caries, giving a total DMF score. When the DMF index is adapted to record the surface of each tooth, the Decayed, Missing or Filled Surface (DMFS) index is used; it is more precise and sensitive for representing the dental caries experience of an individual. The DMF indices can also be adapted

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<sup>&</sup>lt;sup>2</sup> www.stats.co.nz

to be used in the primary dentition, being reported in lower case letters (as dmft or dmfs). The DMF indices are the most common caries indices used internationally. The World Health Organization recommends using the DMFT for measuring and comparing the dental caries experience in populations (World Health Organization, 1997).

The DMF index has many strengths. It has a long history of use and is very well known. It can be combined with radiography to make a more accurate diagnosis and it takes into account the past and present caries experience of an individual. While the index is simple, valid and reliable, it also has many limitations. It relies on missing teeth and restorations arising solely due to caries; if the history of the tooth is not known, the score will not accurately represent the caries experience of the patient. Teeth not present due to orthodontic treatment or trauma may inflate the DMF score. There is also disagreement about how many surfaces to allocate to a missing tooth. If the minimum number is allocated, this could lead to an underestimation of caries experience, or if all surfaces are assumed carious for a 'missing' tooth, then it can lead to an overestimation for the individual (Broadbent and Thomson, 2005). A DMF score does not take into account caries in the initial stages because for a lesion to be counted as decayed, it needs to be clinically obvious and cavitated into dentine. The index records a small lesion the same as that of one which has progressed to the pulp. The DMF system does not give an indication of active caries, thus it can lead to an over estimation in caries prevalence. The final DMF score does not denote which surfaces or teeth are decayed, missing or filled, and so it does not give an accurate description of active caries experience or an indication of treatment need (Banava et al, 2012).

#### 1.2.2. The International Caries Detection and Assessment System (ICDAS)

The ICDAS is a six-stage, visual-based, standardised system using a simple standard examination process for detection and assessment of early and late stage dental carious lesions. The index was developed by the ICDAS Co-ordinating committee in 2002 to measure caries by stage of the carious process. The ICDAS is based on the efforts of a large group of researchers, epidemiologists, restorative and paediatric specialists and cariologists, along with a systematic review of the literature on clinical caries measures (Pitts and Ekstrand, 2013). The ICDAS system was developed to enhance understanding of the process of initiation and progression of dental caries in the fields of epidemiological and clinical research. The system was designed to serve as a response to the shortcomings of existing caries detection methods, with the ability to visually evaluate patients' tooth and restoration conditions with greater

accuracy (Banting *et al*, 2012). The original ICDAS system of 2002 was altered, reviewed and updated in 2009, and finally released as the ICDAS II index. For simplicity, the ICDAS coordinating committee now refer to the 2009 version of ICDAS II as the ICDAS system<sup>3</sup>.

The ICDAS system describes both coronal caries and caries associated with restorations and sealants. Diagnosis of caries and dental conditions with this system is said to lead to better diagnosis, prognosis, and clinical treatment (ICDAS Co-ordinating Committee, 2009). The system is accurate and reproducible and is helpful in the diagnosis of early carious lesions as well as long-term evaluations (Ferriera *et al*, 2010; Fontana *et al*, 2010). The examiner needs access to compressed air because teeth are first examined wet and then dried and re-examined. Each tooth surface is given a score for caries from 0 to 6, indicating the severity of the carious lesion (Figure 6). A code of 0 is sound; 1 and 2 are the initial stages of decay; 3 and 4 are for moderate decay; and 5 and 6 are allocated to advanced cavitated lesions. Each tooth surface is also given a restoration or sealant code, including the material used. There are numbers which denote the state of the tooth (for example, a tooth missing due to caries, orthodontic extraction or if it is unerupted). The full ICDAS system codes are shown in Figure 6 and Figure 7.

Figure 6. ICDAS Codes for Restoration Charting

ICDAS Restoration Code	
0	Unrestored, sound
1	Sealant, partial
2	Sealant, full
3	Tooth coloured restoration
4	Amalgam restoration
5	Stainless steel crown
6	Crown or veneer
7	Lost/broken restoration
9	Used (all surfaces of the tooth) for:
	97: Extracted due to caries
	98: Extracted not due to caries
	99: Unerupted

(Adapted from ICDAS Co-ordinating Committee, 2005<sup>3</sup>)

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<sup>&</sup>lt;sup>3</sup> www.icdas.org

Figure 7. ICDAS Codes for Caries Charting

ICDAS Caries Code	Caries observed
0	Sound
1	First visual change in enamel
2	Distinct visual change in enamel
3	Localised enamel breakdown
4	Underlying dentine shadow
5	Distinct cavity with visible dentine
6	Extensive cavity within visible dentine

(Adapted from ICDAS Co-ordinating Committee, 2005<sup>4</sup>)

An advantage of the ICDAS system is that it represents lesion progression stages in enamel, not relying on surface cavitation before caries can be diagnosed. It has been thoroughly tested and shown to be valid, reliable and predictable (ICDAS Co-ordinating Committee, 2009; Banting *et al*, 2012). Other caries assessment systems rely on conflicting levels of disease activity before a diagnosis of caries; but, with ICDAS, standardised definitions and levels of the disease process have been clearly defined using histological verification (Ekstrand *et al*, 1995). The ICDAS system provides patients, clinicians and epidemiologists with accurate information about caries status, thus giving a better indication of treatment needs.

A disadvantage of the ICDAS is that it is a complicated index requiring extensive training and calibration. It is also not yet as widely used as the DMF index, and so dental professionals are not as familiar with its use. The ICDAS requires teeth to be dried off and carefully examined, so compressed air and the use of a probe are required, and these may be limited in some epidemiological settings (Banava *et al*, 2012). The examination takes considerably longer, increasing the burden for both examiner and patient. This may (in turn) lead to greater costs to the survey or project.

The ICDAS is gaining acceptance as a new and evolving standard for caries diagnosis internationally<sup>4</sup>. The system is versatile in that it can be collapsed into DMFS and DMFT scores, so the data can then be compared with epidemiological data collected using the DMF system.

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<sup>4</sup> www.icdas.org

#### 1.3. Prevention of dental caries

#### 1.3.1. Fluoride

The worldwide decline in dental caries since the 1970s has been attributed to the use of fluoride in the form of toothpastes and community water fluoridation. Fluoride is the most efficient, cheap and safe dental public health tool used to prevent dental caries (Jones *et al*, 2005). One of the World Health Organization's policies is to support the widespread use of affordable fluoride toothpaste in developing countries (World Health Organization, 1994).

Fluoride works in several ways to prevent tooth decay. It inhibits demineralisation when present in solution, even at low levels. Fluoride enhances remineralisation when in the saliva. In flowing over plaque, its buffering components neutralise the acid and the pH rises back towards neutral. It speeds up the growth of a new surface on partially demineralised crystals in the enamel as the hydroxyapatite structure incorporates fluoride as fluorapatite, which strengthens the mineral lattice. It also inhibits cariogenic bacteria by forming a hydrogen fluoride complex when acid is formed; travelling into the bacteria cell, it then dissociates again, and this interferes with essential enzyme activity in the bacteria (Featherstone, 1999).

Fluoride can be ingested daily (as part of tablets, milk or water) or it can be applied topically in toothpastes, gels, varnishes or mouth rinses. Those who have lived in an area with a fluoridated reticulated water supply for 75% or more of their life have 30% less decay than those living in non-fluoridated areas (Ministry of Health, 2010). Fluoride prevents an estimated 58,000 to 267,000 decayed, missing and filled teeth per year in New Zealand (Ministry of Health, 2006). The Centers for Disease Control and Prevention recognised water fluoridation as one of the 10 great public health achievements of the 20th century. Fluoridation of water supplies can help to reduce inequalities in dental disease burden; all ethnic groups, the young, old, rich and poor benefit from community water fluoridation. There is no credible evidence to suggest that fluoride at low levels causes any adverse health effects (The Royal Society of New Zealand, 2014). At present, there are 84 fluoridated water supplies in New Zealand, supplying approximately 56% of New Zealanders with fluoridated drinking water (National Fluoridation Information Service, 2012). Northland has no areas with optimal fluoride levels, and so Northland residents do not benefit from this important caries-preventive public health measure.

Tooth brushing with fluoride toothpaste and/or rinsing with a fluoride mouth rinse has been shown to reduce dental caries incidence (Marinho *et al*, 2004a). Toothpaste is an ideal way to

deliver fluoride to the tooth surface, since brushing removes plaque and the dentifrice delivers fluoride directly to the tooth surface. Fluoride toothpastes have a similar degree of effectiveness to mouth rinses for the prevention of dental caries (Marinho *et al*, 2004b). A cost-effectiveness study in Chile assessed the varying ways of preventing caries for a child population. It examined salt fluoridation, community water fluoridation, milk fluoridation and an APF-Gel application, sealants and a supervised tooth brushing programme. Primary cost effectiveness analyses were conducted to show net social savings by the DMFT averted. The authors found that salt-fluoridation was the most cost-effective intervention and that community and school-based dental caries interventions were a cost-effective use of society's financial resources (Marino *et al*, 2012).

The concentration of fluoride in toothpaste is important; toothpaste at 1450-1500ppm fluoride content prevents caries more effectively than toothpastes with a lower fluoride content of 1000ppm (Conti *et al*, 1988; Tewtman *et al*, 2003; Topping and Assaf, 2005; Walsh *et al*, 2010).

A Cochrane review of the literature has established that tooth brushing with fluoride toothpaste reduces dental caries incidence. Children who brush their teeth at least once a day with toothpaste that contains fluoride will have less dental caries experience (Marinho *et al*, 2004a).

## 1.3.2. Supervised tooth brushing

Tooth brushing is the most significant and widespread oral hygiene behaviour used in the world (Marinho, 2009). It has been proven to be the single most effective oral hygiene behaviour in reducing dental caries and maintaining periodontal health (Attin and Hornecker, 2005). The New Zealand Ministry of Health recommends children are supervised while brushing their teeth by a responsible adult until age 8 (Ministry of Health, 2009). The NZOHS found that only 42% of children in New Zealand brush twice daily with fluoride toothpaste (Ministry of Health, 2010). A review of tooth brushing studies showed that an effective tooth brushing programme is associated with a lower prevalence and incidence of caries. The quality of tooth brushing rather than frequency is an important factor, and so brushing meticulously once per day is sufficient to prevent dental caries (Attin and Hornecker, 2005). Supervision is an act of directing, managing or oversight. When a trained adult is supervising a tooth brushing programme, they are responsible for children using the correct amount of toothpaste, ensuring

the supplies are adequate and overseeing and assisting children brushing their teeth for an adequate amount of time.

A Jordanian study compared two groups of children. One group received oral hygiene instruction and the other group received oral hygiene instruction as well as a supervised daily tooth brushing programme with fluoride toothpaste. After four years, the caries experience in the non-brushing group was significantly worse than in the tooth brushing group, with relative risks of 3.1 and 6.4 times (for age 6 and 12 years respectively). This brushing programme was found to be an effective school-based caries preventive programme for high risk children than dental education alone (Al-Jundi *et al*, 2006).

An intervention study conducted in Iran investigated whether improvements in oral health behaviour and the oral health of school children could be achieved by targeting parents and school staff. Children were divided into three groups, with one group (the control) having no intervention, one group having interventions that targeted the child only, and the third group given comprehensive strategies to encourage the children, their parents and school staff to increase the frequency of tooth brushing and flossing. After six months, it was found that children who were in the comprehensive intervention group brushed and flossed significantly more frequently and had significantly better gingival health than those who received the child-only intervention or the control group. The authors concluded that parents and school staff played an important role in promoting children's oral health and that health education should involve organised strategies to encourage children, their parents and school staff to improve oral health behaviour (Yekaninejad *et al*, 2012).

Two decades ago, Kay and Locker reviewed the evidence on the effectiveness of oral health education. They concluded that oral health education could be effective in improving oral health knowledge and behaviour, and has a small positive temporary effect on plaque accumulation, but it has no significant effect on preventing dental caries (Kay and Locker, 1996). The study was replicated a decade later (Chan *et al*, 2005), with very similar findings.

A recent meta-analysis conducted by the Cochrane Library considered 38 trials from 1996-2014 assessing community-based health care interventions for promoting child oral health. A combined oral health education programme with supervised tooth brushing or professional preventive oral care was found to reduce dental caries in children. They found that there was

limited impact from dietary advice and oral health education alone (de Silva et al, 2016).

## 1.3.3. International tooth brushing trials

Tooth brushing trials in schools date back as far as the 1950s (Jordan *et al*, 1957). Internationally, there have been many tooth brushing trials and reviews over the last 60 years.

A systematic review conducted in 2003 by Twetman *et al* investigated the caries-preventive effect of fluoride toothpaste on the young permanent dentition. It found strong evidence to support daily tooth brushing with fluoride toothpaste, with a greater caries-preventive effect than placebo toothpaste. Toothpaste with 1500ppm fluoride had a superior preventive effect to 1000ppm fluoride containing toothpaste, and a higher caries reduction was observed in studies with supervised tooth brushing programmes than in those with non-supervised programmes (Twetman *et al*, 2003).

A clinical trial testing the effectiveness of daily supervised tooth brushing in Chinese kindergartens (along with oral health education for parents) was investigated. The trial had two groups of 250 kindergarten children. The test group had brushing sessions with 1100ppm fluoride at kindergarten for two years, as well as their parents receiving oral health education. The control group had no intervention. The intervention group had a statistically significantly lower dmfs after two years and had better at-home brushing (Rong *et al*, 2003).

In the late 1990s, a tooth brushing trial involving 500 children from deprived areas was conducted in Dundee. The study used local mothers who were trained as brushing supervisors. Each school had a control class and an intervention (brushing) class. The intervention was supervised daily brushing with 1000 parts per million (ppm) fluoride toothpaste. The children's first permanent molars were examined every 6 months, with the intervention group having significantly lower caries prevalence after two years (32% and 56% respectively). The study found that targeting a fluoride tooth brushing programme in a high-caries-risk community led to a significantly lower caries increment (Curnow *et al*, 2002).

A two-year trial of a teacher-supervised tooth brushing project from 2000 to 2002 was initiated for primary school children in some of the socially deprived communities of London. Significantly lower caries experience was found in the intervention group than in children who did not have daily school tooth brushing sessions. The authors stated that, if the findings were

translated to the child population at risk in the United Kingdom, the additional reductions in caries would represent a substantial national reduction in dental treatment needs (Jackson *et al*, 2005).

In 2006, Scotland introduced a nationwide oral health improvement initiative called *Child Smile*. The project involved a daily tooth brushing programme for pre-school and early primary school children. National oral health survey data showed a dramatic decline in dental caries experience in 5-year-old children three years after the intervention was introduced (Macpherson *et al*, 2013). Further analysis of the financial cost of the *Child Smile* tooth brushing programme has been undertaken, along with determining the cost savings through improvements in dental health of 5-year-old children through avoided dental extractions and fillings. The cost analysis showed savings ranging from £1.2 million in 2003/04 to £4.7 million in 2009/10. The population standardised analysis by deprivation groups also showed that the largest decrease in modelled costs was for the most deprived cohort of children (Anopa *et al*, 2015).

A public health intervention entitled 'Smile Grenada' was introduced in the nonfluoridated Island of Grenada in the South Caribbean in 2010. The study involved a supervised tooth brushing programme with a fluoride toothpaste, fluoride varnish application and fissure sealant placements. There were 1,000 children examined at baseline and 2,000 children examined at follow-up two and a half years later. The increase in children examined at follow up was due to a policy change whereby consent was no longer required to examine the children for this national survey. There were statistically significantly fewer decayed surfaces at follow-up. The authors concluded that it was a locally sustainable model for improving oral health in children (Wolff *et al*, 2016).

Following a review into the evidence of caries-preventive measures at an international collaborative meeting in 2014 (European Organisation for Caries Research), successful strategies to decrease caries in children and adolescents with persistent higher caries levels of disease levels were published. The use of fluorides was recommended, especially tooth brushing with fluoridated toothpaste and collective measures such as water fluoridation (Splieth *et al*, 2016).

## 1.3.4. National tooth brushing trials

While there have been many school-based tooth brushing trials previously conducted internationally, the author has been unable to find any published large-scale brushing programmes conducted in New Zealand to date. However, there have been many small-scale, unevaluated, unsustainable tooth brushing projects in New Zealand.

## 1.3.5. Northland tooth brushing trials

A small-scale pilot study was conducted in Northland at Opononi Area School with 30 6- to 8year-old primary school children from 2008 to 2011. The Plaque Index and Gingival Index were assessed by dental therapists, and the children were given oral health education by therapists before and throughout the trial. Teachers were responsible for supervising the daily tooth brushing after lunchtime. Dental therapists were responsible for implementing oral health education sessions and collecting the clinical data. Qualitative data were collected; focusing on the teachers' and dental therapists' experiences and perceptions before, during and at the end of the trial. The mean plaque score was 1.5 at baseline and 0.7 at follow-up (Silness and Loe, 1964 Plaque Index), with a similar positive outcome in gingival scores. The pilot study's main finding was the reliance on the teacher's personal initiative to have the tooth brushing sessions after lunchtime. The brushing was inconsistent because the teacher was often too busy to implement the brushing programme. Although the brushing was irregular, there appeared to be a positive clinical outcome. Teachers' feedback covered problems with toothbrush storage and the need for good quality toothbrushes (because some broke) and good organisation. By the second year of the trial, teachers commented that tooth brushing had become routine and children were reminding teachers about the tooth brushing sessions after lunch. Data from the dental therapists showed that they were enthusiastic about giving oral health education, but that they felt the programme was a bit lengthy. The overall conclusion from this pilot study was that the tooth brushing programme was successful in improving the cleanliness of the teeth and health of the gums. The trial made tooth brushing with a fluoride toothpaste routine for the rural, highly deprived, predominantly Māori primary school children residing in a nonfluoridated community (Gowda, 2011). The success of a programme such as this depends on the dental clinicians, school staff, parents and children all being involved and engaged in planning and running the programme from its commencement. The author recommended future extension of the school-based tooth brushing programme to all decile 1 to 5 primary schools in Northland to further improve the oral health status of all children and assist in reducing oral health inequalities (Gowda, 2011).

Following on from this, a tooth brushing study in Northland was conducted involving four decile 4 primary schools, with a total of 240 primary school children. The trial involved teacher-led daily brushing sessions in school, along with oral health education and the advertising of free dental services. This study ran for a year, but it had a high drop-out rate and no means of formal evaluation. Feedback from the project indicated that it relied on the teachers to conduct the brushing sessions, with some more enthusiastic than others. One of the recommendations from this project was that, for the long-term sustainability of a programme, it is important to have support from teachers and the community rather than just the principal and oral health promotion team leading and running the project (Ali and Dones, 2013).

Overall previous tooth brushing projects have indicated the importance of robust methodology. A supervisor with supplies and organisation skills along with evaluation protocol using a calibrated examiner and appropriate index are needed for future tooth brushing projects.

## 1.4. Quality of life and oral health

The definition of health has moved away from simply being free from disease, and is now defined as 'a state of a complete state of physical, mental, and social well-being' (World Health Organization, 2015). It is a subjective state, and so to measure it, one needs to assess the social and emotional aspects as well as disease status. Measuring disease status alone does not give an indication of the sufferer's day-to-day function or wellbeing (Shearer *et al*, 2007). An examination of a person's oral health is not complete without a quality of life assessment. Oral health-related quality of life (OHRQoL) measures are designed to incorporate symptoms; physical functioning, emotional and social well-being, into a biopsychosocial health model. The measure has an important role in understanding subjective patient evaluations of and experience with oral health.

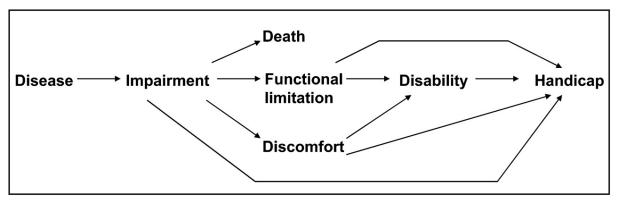
Oral health affects general health by causing considerable pain and suffering as it can change a person's appearance, how they speak, chew, taste food and socialise and in turn it can affect their quality of life. Millions of people suffer daily with toothache, which can result in a large impact on individuals and society (World Health Organization, 2015).

#### 1.4.1. Measuring OHRQoL

Measuring OHRQoL is a different approach from traditional dental assessment tools as it focuses on a person's social and emotional experience as well as physical functioning.

OHRQoL evaluations can enhance clinical research by estimating a needs assessment of a population or a specific group (Gendersen *et al*, 2013). Developing a measurement for OHRQoL should begin with a framework. Locker's model of oral health is an example of a framework that has been used to develop these scales.

Figure 8. Locker's Conceptual Framework model of oral health 1988 showing potential Impact of Oral disease on daily life.



(Adapted from Locker, 1988)

Developing a self-reported questionnaire to assess OHRQoL in children must take into account the child's ability to speak, read and think in abstract terms as well as their age-related ability to understand concepts (McGrath *et al*, 2004; Locker *et al*, 2007). An OHRQoL measure for children also needs to be reproducible; that is it should have test-retest reliability. It must also have internal consistency which is the relative absence of bias or systematic error, or the correlation among items comprising an instrument. A measure must also be valid; that is, it should measure what it is supposed to measure.

A quality of life assessment tool can be either a global measure or a multi-item scale. Global measures involve a single question, and aim to capture and summarise everything in the question. Multi-item scales involve a series of questions, grouped into domains which each assess a different aspect of a person's oral health, these are often condensed into a short form version, which is usually further validated and tested for reliability.

There were multiple measures of quality of life included in this questionnaire; the Child Perceptions Questionnaire (CPQ<sub>11-14</sub>), Caries Impacts and Experiences Questionnaire for Children, Child Oral Health Impact Profile (COHIP) and the Child Health Utility 9D,

(CHU9D). These measures were chosen as they will be useful to compare with children in other studies and to extend the literature. For the purpose of this masters thesis the  $CPQ_{11-14}$  will be analysed.

#### 1.4.2. Global measures

Global measures are also known as single-item ratings. They aim to capture an individual's oral health in a single broad question. The answer can be categorised on a Likert scale such as 'How would you rate your oral health today?', with options ranging from 'Excellent' to 'Poor' or on a visual scale, for example, smiley faces depicting different scenarios from happy to sad (Howard and Freeman, 2007; Bennadi and Reddy 2013).

## 1.4.3. The Child Perceptions Questionnaire (CPQ)

The Child Perceptions Questionnaire (CPQ) was developed in Canada between 2002 and 2006. It is for children from age 6 to 14 years. The measures consist of a parental-caregiver perceptions questionnaire (PPQ), a Family Impact Scale (FIS) and an age-specific questionnaire for children. The three age-specific child questionnaires are for children aged 6 to 7 years (CPQ<sub>6-7</sub>), children aged 8 to 10 years (CPQ<sub>8-10</sub>) and children aged 11 to 14 years (CPQ<sub>11-14</sub>) (Jokovic *et al*, 2002; Jokovic *et al*, 2004). The younger age questionnaire has never been used, however. The CPQ aims to evaluate the impact of oral and orofacial conditions in children at the functional, emotional, and social level.

The CPQ measures consist of a series of self-reported questions along with two global questions which are used for validation purposes. Response options and scores for each item are: "Never" (scoring 0); "Once or twice" (1); "Sometimes" (2); "Often" (3); and "Every day or almost every day" (4). With the two global questions, participants are first asked to rate the health of their teeth, lips, jaws and mouth; they are asked how much the health of their teeth, lips, jaw or mouth affects their life overall. The global questions are used alongside the CPQ.

The  $CPQ_{8-10}$  measure contains 25 questions with two global questions and the remainder of the questions are divided into four domains, oral symptoms (OS), functional limitation (FL), emotional well-being (EW), and social well-being (SW). The children are asked to rate the health of their lips, teeth or mouth has affected them in the last four weeks.

The CPQ<sub>11-14</sub> questionnaire was originally a 37-item measure but it has more recently been shortened to four 16-item and 8-item measures (regression and impact versions). It consists of 18 questions, with two global questions and the remainder of the questions divided into four domains, oral symptoms (OS), functional limitation (FL), emotional well-being (EW), and social well-being (SW). The short-form impact 16-item version has been validated and tested for reliability (Jokovic *et al*, 2006; Foster Page *et al*, 2008). This short-form questionnaire is the most used measure to date and has been translated and validated in many countries (Gilchrist *et al*, 2014). The CPQ has been translated into Arabic, Brazilian, Cambodian, Chinese, Danish German, Malay, Thai and Russian, and it has been used in many epidemiological studies (Li *et al*, 2008; Martins *et al*, 2009; Foster Page *et al* 2011; Bekes *et al*, 2012; Bhayat and Ali, 2014; Salinas-Martínez *et al*, 2014; Turton *et al*, 2014; Nunez *et al*, 2015; Kumar *et al*, 2016).

More recently, confirmatory factor analysis of the CPQ<sub>11-14</sub> from an international collaboration involving multiple studies has shown that there appear to be two main factors, with the four domains falling into two underlying factors (constructs): the first comprises the items in the OS and FL subscales; the second includes all EW and SW items, the 'symptoms/function' subscale and the 'well-being' subscales, respectively. This secondary cross-sectional analysis of the CPQ<sub>11-14</sub> using data from Australia, New Zealand, Brunei, Cambodia, Hong Kong, Malaysia, England, Thailand, Germany, Mexico and Brazil found that the measure performed well, with robust and mostly consistent psychometric characteristics. The authors concluded that the CPQ<sub>11-14</sub> appears to be a sound, robust measure which should be useful for research, practice and policy (Thomson *et al*, 2016).

Gilchrist and colleagues conducted an extensive literature review and analysis of OHRQoL measures for children, examining the content validity, internal consistency, construct validity, reproducibility and responsiveness and interpretability of many of these measures. They concluded that, when considering studies conducted before 2012, the short form CPQ<sub>11-14</sub> Impact Short Form (ISF) was shown to have excellent and fair validity (Gilchrist *et al*, 2014).

The Parental-CPQ (P-CPQ) and Family Impact Scale (FIS) have been tested on a sample of New Zealand families of children undergoing dental treatment under general anaesthetic and found to be sound measures to use when children are too young to fill in a questionnaire

(Malden *et al*, 2007). More recently, the CPQ<sub>11-14</sub> has been proven to perform acceptably in children as young as 5 years-old (Foster Page *et al*, 2014).

## 1.4.4. Oral health and oral health-related quality of life

Strong evidence exists that children who with higher caries experience have poorer OHRQoL (Jokovic *et al*, 2002; Li *et al*, 2008; Nunez *et al*, 2015; Kumar *et al*, 2016). Children with a more severe malocclusion also have poorer OHRQoL (Marshman *et al*, 2005; Foster Page *et al*, 2013; Healey *et al*, 2016). Untreated dental caries and missing teeth due to caries has also shown to negatively impact OHRQoL (Feldens *et al*, 2016).

There are no studies reporting on whether a supervised tooth brushing programme improves OHRQoL. However, in Ireland, a tooth brushing programme ('Winning smiles') was conducted whereby 200 children from schools in areas of high deprivation were given a brush and toothpaste and encouraged to brush their teeth at home with fluoridated toothpaste. The children received oral health education to improve their brushing technique. OHRQoL data were collected at baseline and at follow-up (one year later). The intervention had a significant effect on tooth brushing, fluoride toothpaste knowledge and an effect on OHRQoL at the 6% level. They demonstrated that a school-based tooth brushing educational intervention has a positive effect on behaviour and on OHRQoL (Friedman *et al*, 2006).

#### 1.4.5. Oral health-related quality of life in New Zealand

New Zealand researchers have been at the forefront of OHRQoL research for the last two decades. A number of studies have shown that the CPQ measure is valid, consistent and reliable among New Zealand children (Foster Page *et al*, 2005; Foster Page *et al*, 2008; Foster Page *et al*, 2010; Foster Page *et al*, 2011; Foster Page *et al*, 2013; Foster Page *et al*, 2014; Thomson *et al*, 2016). A longitudinal study of Taranaki young adolescents from age 12 to 15 using the CPQ<sub>11-14</sub> found the measure has adequate responsiveness (Foster Page *et al*, 2010). The study also demonstrated the CPQ measure to be valid and reliable for determining the impact of malocclusion and dental caries on those Taranaki adolescents (Foster Page *et al*, 2013). In Northland, the 16-item short-form impact version of the CPQ<sub>11-14</sub> was used to assess a sample of 187 children (aged 12 and 13 years old) in 2008. The Northland children had a DMFS of 4.9 and had a mean CPQ<sub>11-14</sub> score of 11.5. The measure performed well in this predominantly Māori population with high caries experience (Foster Page *et al*, 2011).

#### 1.5. Overview of the literature

There are still clear inequalities in the oral health of New Zealanders, with Māori and low socio-economic status families experiencing a high proportion of oral disease, mainly dental decay. The Northland population has high proportions of Māori and a high number of the population reside in low socioeconomic status. Dental caries experience in children in Northland is the highest in the country, and there is no fluoridated water supply. Tooth brushing with fluoride toothpaste is known to reduce the incidence of dental decay. Studies of supervised brushing in schools have shown measurable improvements in oral health, (including a pilot study in Northland). A larger-scale study is needed to reach more children and to examine the feasibility of tooth brushing interventions in the New Zealand setting.

This research involves a supervised tooth brushing trial of intermediate-aged school children in Northland with high caries experience. All children had routine dental examinations at the beginning of the study using the ICDAS index to record dental caries. Half of the children participated in a supervised tooth brushing session each school day. Examinations were repeated at the end of the school year. The data will show whether a tooth brushing programme is effective for a population suffering from high levels of dental disease.

## 1.6. Study hypotheses

Children who participate in the supervised school brushing trial will have lower caries increments than those who have not participated.

The tooth brushing group will have better oral-health-related quality of life after a year than those in the control group.

A tooth brushing programme in a low decile Northland Intermediate school will be able to be successfully implemented.

## Chapter 2

#### 2. Methods

#### 2.1. General approach

Tooth brushing studies globally have been shown to prevent dental caries, but few studies have assessed quality of life and how it is affected in children who participate. There have not (to date) been any published New Zealand studies which have used the ICDAS tool for recording dental caries. Previous tooth brushing studies conducted in Northland have not employed a supervisor to run the programme, and they have been unsustainable. This study aimed to evaluate children's caries experience before and after they have had a tooth brushing programme in place for one year, and record the impact this has on their OHRQoL. It also aims to compare the oral health outcomes and OHRQoL with those of children who have not had a supervised tooth brushing programme implemented.

Initially, an ethical review process and funding application were made, along with consultation with the Northland District Health Board (NDHB) and Northland schools. A sample of Intermediate school-age children from five schools was chosen. The children at each school were given consent forms to take home and return, and assent was also obtained from them. The children had a clinical dental examination with radiographs, completed a questionnaire (to assess oral hygiene behaviour and self-reported OHRQoL), and were given a toothbrush and tube of toothpaste to take home. Four schools were chosen to be control schools, and one of the larger Intermediate schools was chosen to be the intervention school. Children in the latter had a supervised tooth brushing programme throughout an entire school year. A baseline clinical examination with radiographs and questionnaire was repeated at the end of the school year (9 months later). Data were entered into a statistical programme and analysed.

#### 2.2. Ethical considerations

Ethical approval for this research project was sought and granted by the Health and Disability Ethics Committee (HDEC) Northern A Health and Disability Ethics Committee (14/NTA/176). Ethical approval was also sought from NDHB, Te Kaunihera (NDHB Council of Elders) and the Regional Ethics Committee, who granted ethical approval to conduct the research study in Northland (Appendix I). The trial was also registered with the Australia and New Zealand clinical trials registry (ACTRN12617000846325).

## 2.3. Sampling procedure

## 2.3.1. Sample size

The study aimed to study a population of Northland 10-to-13-year-old high-caries-risk children. The sample size calculation was made for this study using data from a number of studies of a similar size and an expected caries change of 10%. The sample size calculation took into consideration two arms of the study and that the ICDAS is a more sensitive measure than the DMF. Mean DMF scores require a large sample size to detect a difference. By contrast, ICDAS as an index can record more subtle changes in caries, and so scores require fewer participants to detect a 10% difference. The calculation also took into account that data collection would occur at two time points (following one and two years of the study). This thesis reports only on the one-year data for the intervention and control arm of the trial.

Two previously conducted tooth brushing studies were used to calculate a sample size based on their findings and a detectable difference between the two arms using the following assumptions (Rao *et al*, 2007; Kraivaphan *et al*, 2013):

- (1) ICDAS will detect a 10% difference in caries increment between the two intervention arms;
- (2) this difference will be detectable at 2-year follow-up;
- (3) standard deviations of 1;
- (4) power = 0.8;
- (5)  $\alpha = 0.05$ , two-sided t-test; and
- (6) 15% lost to follow-up (attrition over two years).

A total sample size of 104 (n=52 per treatment group) was required.

## 2.3.2. Sample strategy

The study was discussed with appropriate NDHB oral health management staff, who had previous experience carrying out a tooth brushing project. Owing to the large geographical area of Northland and relatively low population size, along with the target age group of 10-to-13-year-olds, several schools were identified as appropriate for inclusion in the study.

The New Zealand Ministry of Education allocates a number from 1 to 10 based on the extent to which the school draws their children from low socioeconomic status (SES) communities. This area-based measure of SES is popularly known as the "school decile" system. Deciles are

a measure of the SES position of a school's student community relative to other schools throughout the country, and is a population (as opposed to an individual) based measure. Decile 1 schools are the 10% of schools with the highest proportion of students from low socioeconomic communities, whereas decile 10 schools are the 10% of schools with the lowest proportion of students from low SES communities. They are calculated based on census data. Decile 1 schools Kaitaia Intermediate and Kaikohe Intermediate were selected, along with Dargaville (decile 4), Raurimu Ave (decile 2) and Bream Bay College (decile 5).

Kaitaia Intermediate School is located in the town of Kaitaia in the Far North region. The school has a roll of 214 and is a decile 1 school. The school predominantly comprises students who identify as Māori (77%).

Kaikohe Intermediate School is located in the central township of Kaikohe in the mid-north region of Northland. The school roll consists of around 129 students, of whom 95% identify as Māori. It is a decile 1 school.

Dargaville Intermediate School is a school in the center of the western town of Dargaville. The school has 75 students in the roll who were targeted for this study. It is a decile 4 school and 39% of the students identify as Māori.

Raurimu Ave School is a small combined primary and intermediate school located in the suburb of Onerahi in Whangarei. It has a total of 8 students in the age range for this study; 75% are Māori, and it is a decile 2 school.

Bream Bay College has Year 7-13 school students, and is located 20 minutes south of Whangarei. It is a decile 5 school with 38% of the students identifying as Māori.

Kaitaia Intermediate had the highest school roll in one of the areas of highest deprivation. Accordingly, it was selected to be the intervention school. Excluding Kaikohe Intermediate, the control schools in the study have higher decile ratings and a higher proportion of European students.

All of the identified school principals were contacted and the study was discussed with relevant staff. Every school principal contacted was positive and confirmed their school's commitment

to take part in the study.

The researchers contacted NDHB oral health management staff to discuss and organise the timing of the study. This included timings of school visits for examinations, clinic availability and the feasibility of staff to assist with data collection.

#### 2.3.3. Inclusion and exclusion criteria

Included in this study were: Year 7 and 8 children, children who attend Bream Bay College, Dargaville Intermediate, Kaikohe Intermediate, Kaitaia Intermediate or Raurimu Ave School; children who plan on staying at the school for 1-2 years (depending on year level); and those with informed consent signed by the parent or legal guardian and child assent signed by the participant.

The exclusion criteria for this study were: A child with a medical condition, allergy or adverse reaction to any of the constituents of toothpaste; children with a fixed orthodontic appliance which covers the teeth and would not be able to have an ICDAS clinical examination; and those children who have not been granted parental consent and/or who have not given assent.

#### 2.4. Consent

Parental consent forms were sent home to all year 7 and 8 children. The parental consent was tested to have a reading age of 10 years. Contact details of the researchers were included with the consent forms for participants or parents to contact if there were any questions or concerns relating to the study. Written parental consent and written child assent were both required before participation in the study. The child was also verbally asked for consent before the clinical examination. At the intervention school the research supervisor was responsible for sending home and collecting the consent forms. At the control schools, NDHB staff completed this process, with some assistance from the teaching and office staff. The consent form is in Appendix II and III.

## 2.5. Clinical examinations

Clinical examinations took place in a mobile dental unit in four of the schools, and a fixed clinical facility was used on the Dargaville Intermediate school site. Additional staff from NDHB assisted with collecting children from class and helped with administrative tasks.

The baseline data were collected over three weeks in February 2015, and the follow-up data were collected over the last three weeks of November 2015. In the event that the examiner found an oral condition that required further treatment, an appropriate referral was made. All participants were given a tube of toothpaste and a soft toothbrush to take home at the end of their examination. Each participant was given a unique identification number, which was used instead of his/her name to maintain the participant's confidentiality.

## 2.5.1. Examination technique

A standardised examination technique was used for all clinical examinations. The child was reclined partially on the clinic chair and the examiner was seated behind the child. A standard LED headlight was used for all clinical examinations. The clinical examination took place following the taking of posterior bitewing radiographs. The teeth were first charted as unerupted, missing or present as well as whether they were primary or permanent. The teeth were examined beginning with the most distal molar in the 1<sup>st</sup> quadrant, moving around to the last molar in the 2<sup>nd</sup> quadrant, and following on with the 3<sup>rd</sup> and 4<sup>th</sup> quadrants.

A sterile dental mirror, probe and triplex syringe along with cotton rolls was set up on a sterile tray for each participant. Plaque or debris was firstly wiped off the teeth using a cotton roll. Each tooth was examined wet with cotton rolls in buccal and labial spaces and compressed air was used to facilitate examining the teeth.

The ICDAS was used to record the condition of the teeth. The ICDAS is a standardised system which detects early and late stage caries lesions, along with restorations at the surface level, using a simple standard examination process. The method requires teeth to be dried and clean of plaque. These guidelines were followed for this clinical study.

The ICDAS uses a two-number-per-surface coding system which identifies restorations/sealants with the first digit, followed by the appropriate caries status code. A restoration code was recorded for each surface of each tooth (Table 2.1).

Table 2.1. ICDAS codes for restoration charting

ICDAS Restoration Code	
0	Unrestored, sound
1	Sealant, partial
2	Sealant, full
3	Tooth-coloured restoration
4	Amalgam restoration
5	Stainless steel crown
6	Crown or veneer
7	Lost/broken restoration
9	Used (all surfaces of the tooth) for:
	97: Extracted due to caries
	98: Extracted not due to caries
	99: Unerupted

(Adapted from ICDAS Co-ordinating Committee, 2005<sup>5</sup>)

The ICDAS caries detection codes for coronal caries ranged from 0 to 6 depending on the severity of the lesion. There are minor variations between the visual signs associated with each code. The surface caries codes are displayed in Table 2.2.

Table 2.2 ICDAS codes for caries charting

ICDAS Caries Code	Caries observed
0	Sound
1	First visual change in enamel
2	Distinct visual change in enamel
3	Localised enamel breakdown
4	Underlying dentine shadow
5	Distinct cavity with visible dentine
6	Extensive cavity within visible dentine

(Adapted from ICDAS Co-ordinating Committee, 2005<sup>5</sup>)

## 2.5.2. Data recording

The restoration score for each surface, followed by the caries score for each surface of the tooth, was called out by the examiner to the recorder. The data were recorded manually on a standard ICDAS scoring sheet (Appendix IV). The radiographs were read in the days following the examination and those data recorded on the back of the ICDAS form (Appendix V).

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<sup>&</sup>lt;sup>5</sup> www.icdas.org

#### 2.5.3. Calibration

One examiner undertook all of the clinical examinations. The examiner was an experienced clinical dentist who has collected epidemiological data for previous dental surveys. The examiner firstly trained in the use of ICDAS codes using an e-learning programme online and study leading up to an online assessment<sup>6</sup>. The online resource and assessment involved learning the codes, and assessing the surfaces of photographed teeth to categorise the surface with a code. Calibration of the examiner took place before the first data collection in February 2015 with an experienced research clinician Dr Lyndie Foster Page. Calibration was conducted on extracted teeth using the ICDAS codes, prior to examining five patients and discussing each surface presentation. To ensure consistency of the examiner, repeat examinations were conducted on 10% of the sample at the time of data collection for intra-examiner reliability.

## 2.6. Radiograph examination

Bitewing radiographs were taken for each participant at the time of the clinical examination. At the time of this study, the NDHB were transitioning from manual radiography to digital imaging. Most of the radiographs taken at baseline were conventional, and most of the radiographs taken at follow-up were digital, but the same technique was used to take all radiographs. Each child's dental records were checked beforehand, to ensure they had not had bitewings taken within 3 months, so that there was no unnecessary radiation exposure. If bitewings had been taken within three months (baseline data collection only), those were used for the study.

## 2.6.1. Radiograph technique

The participant sat in a partially reclined dental chair. The clinician placed the standard size 1 film into a bitewing holder and took a radiograph on the left side then replaced the film and took the bitewing on the right side. The orientation marker was placed in the correct corner to minimize mounting error. The exposure on the x-ray unit was set at between 0.25 and 0.32 seconds for the manual radiographs and 0.20 to 0.25 for digital radiographs. This was set and calibrated at the start of each clinical examination day by the examiner. Manual radiographs were mounted in plastic sleeves, dated and labeled. Digital radiographs were processed with a scan duo and archived using the NDHB Dental Titanium software as part of the patient's record.

<sup>6</sup> www.icdas.org

#### 2.6.2. Radiograph reading and recording

Manual radiographs were read using a standard light box. Digital radiographs were read using a standard desktop computer. One code was given for each tooth surface (mesial, occlusal and distal for the second molar tooth to the canine in each quadrant). It was also noted whether the tooth was primary or permanent. The P classification system codes are displayed in Table 2.3.

Table 2.3. P Classification system for radiographic examination

P Score	Caries observed
0	Sound tooth surface
1	Radiolucency to outer half of enamel
2	Radiolucency to inner half of enamel
3	Radiolucency extends < 0.5mm into dentine
4	Radiolucency extends >0.5mm into dentine
5	Radiolucency extends into inner half of dentine
96	Unable to be scored - overlap
97	SSC present
98	Tooth missing for reasons other than caries
	(all tooth surfaces will be coded 98)
99	Unerupted
	(all tooth surfaces will be coded 99)

(Adapted from ICDAS Co-ordinating Committee, 2005)

#### 2.6.3. Calibration

All radiograph machines undergo regular calibration within the NDHB. All radiographs were taken by the same examining dentist. All radiographs were read by the same clinician. The clinician reading the radiographs was highly experienced with using the P classification system.

#### 2.7. Questionnaire

The questionnaire given to each participant consisted of 68 questions at baseline, and 69 questions at follow-up. It was made up of 6 basic oral hygiene questions, the Child Perceptions Questionnaire (CPQ<sub>11-14</sub>), Caries Impacts and Experiences Questionnaire for Children, Child Oral Health Impact Profile (COHIP) and the Child Health Utility 9D, (CHU9D). The Questionnaire is included as Appendix VII. The additional question in the questionnaire at follow-up asked the child whether they felt their oral health had improved since the start of the year. The questionnaire was designed and tested for a reading age of 8 years of age.

The questionnaire was issued before the clinical examination. Each child filled in the questionnaire unless physically unable. A staff member was available to help or give an explanation or definition if required. After the child completed the questionnaire, a staff member checked all of the pages to ensure they had been filled in. The questionnaire was kept with the clinical examination paperwork and consent form, with the corresponding ID label. The questionnaire was given a second time to a random sample of approximately 30 children two weeks after the initial examination, in order to evaluate test re-test reliability.

## 2.7.1. Questionnaire details

A self-reported OHRQoL measure was used to gauge how the children's oral health affects their overall wellbeing. The short-form 16-item impact CPQ<sub>11-14</sub> was given to each participant at baseline and at follow-up. The CPQ<sub>11-14</sub> ISF Child Perception's Questionnaire has 16 items which are into grouped into two domains; 'symptoms/function' (combined oral symptoms and functional limitations domain) and 'well-being' (combined emotional and social well-being) domains (Thomson *et al*, 2016). Response options and scores for each item were: "Never" (scoring 0); "Once or twice" (1); "Sometimes" (2); "Often" (3); and "Every day or almost every day" (4). Two global oral health questions were also reported. First, they were asked to rate the health of their teeth, lips, jaws and mouth (response options: 'Very good', 'Good', 'OK' or 'Poor'). Second, they were asked how much their teeth, lips, jaw or mouth affects their life overall (response options: 'Not at all', 'A little bit', 'Some' or 'A lot'). An overall CPQ<sub>11-14</sub> score was computed by summing the appropriate item scores for each measure, with a higher score indicating poorer OHRQoL.

The questionnaire given to the children included 6 self-report oral hygiene questions, to investigate how they looked after their teeth at home. Five of the questions were dichotomous (for example: 'Do you have a tooth brush at home?' Response item 'Yes' or 'No'). The final question asked 'How often do you brush your teeth?' with response options of 'Never', 'one time per week', 'one time per day' and 'twice or more each day'.

Test-retest reliability was examined with 38 children repeating the questionnaire two weeks later for the baseline questionnaire and 28 children repeating the questionnaire at one-year follow-up.

## 2.8. Sociodemographic characteristics

Sociodemographic information was collected. This included each participant's sex, age (years), school details, ethnicity and address. Children were grouped into 10 to 11 and 12 to 13 year age groups. Ethnicity was collected as New Zealand European, Māori, Pacific Island or other; the children were later grouped into Māori or NonMāori.

Participants' NZDep scores were calculated by identifying their individual meshblock by entering street addresses on an online tool called "StatsMaps" provided by Statistics New Zealand, then finding the corresponding NZDep score for each meshblock using NZDep2013 spreadsheet provided by the University of Otago website (University of Otago, 2013). The school decile scores were identified using 2015 school decile scores provided by the Ministry of Education (Ministry of Education, 2015).

This information was entered along with clinical data into a master Microsoft Excel spreadsheet, which was later transferred to a statistical software package for analysis.

# 2.9. Implementation of tooth brushing programme

Kaitaia Intermediate School was the designated intervention school and had a tooth brushing programme implemented at the beginning of 2015. The funding of consumables and the supervisor is discussed in the following sections.

## 2.9.1. Funding

A research grant application was submitted to the Ministry of Health in August 2014, and the project was then funded by the New Zealand Ministry of Health Fund. This allowed the project to be implemented.

## 2.9.2. Supervisor recruitment

The appointment of a research supervisor at Kaitaia Intermediate was discussed with the school principal and deputy principal in the year preceding the introduction of the programme. There was an existing teacher aide who worked part-time within the school who had an interest in oral health and was familiar with Te Reo, working in both English and bi-lingual classrooms. The teacher aide was enthusiastic to get the project up and running in the school, and she had exceptional organizational skills. She was appointed to the research supervisor role in January 2015 before the school term began. The research supervisor lives in the community and knew

the children who went to the school, along with the parents and families in the area. She was also Māori.

## 2.9.3. Implementation

Meetings were held with Kaitaia Intermediate school staff in November 2014, and again at the beginning of 2015, to inform the teachers of the main aims of the study, and to discuss how the tooth brushing programme would be implemented.

The research supervisor was present after lunchtime to run the daily tooth brushing sessions. She was also responsible for packing up and keeping the brushing area tidy, ordering further supplies and ensuring that cross infection control standards were maintained. Kaitaia Intermediate children were given an additional labelled toothbrush, toothpaste and case to use at school. This was stored and looked after by the research supervisor. The brushing took place in the classroom or on the sheltered deck area directly outside the classrooms. The children were taught the modified Bass technique and were timed for 2 minutes by the supervisor every day in brushing their teeth. They then had to spit into a clean paper towel which was then disposed of. The children did not rinse the toothpaste off after brushing. The supervisor was also responsible for recording participants' attendance in the programme. Any children who were not present for 80% of the tooth brushing sessions were not used in the final data analysis.

## 2.9.4. Equipment

The equipment used for daily tooth brushing intervention and the supervisor's consumables was purchased using grant funding, but supplied by the NDHB. The items needed were the toothbrushes, toothpaste, cases, paper towels, gloves for the supervisor to deal with waste and rubbish bags. There was also a small amount of stationery required for recording participants', consent and attendance at brushing sessions. The clinical examination facilities, instruments and consumables used were supplied by NDHB.

#### 2.9.5. Evaluation

Interim evaluation of the project was made by giving the teachers and research supervisor an open-ended questionnaire (Appendix VI) at six months. This allowed teachers to provide feedback on the positive and negative aspects of the programme, as well as any improvements that could be made. Contact with the research supervisor and school was kept through visits,

phone calls, text messages and email. There were several meetings with staff, the research supervisor and researchers throughout.

## 2.10. Follow-up data collection

In November 2015, a repeat data collection took place, capturing similar data to baseline, with one additional question in the questionnaire.

#### 2.11. Data analysis

The data were manually entered from the paper forms into a Microsoft Excel spreadsheet, then transferred and analysed using the IBM Statistical Package for Social Sciences (SPSS) version 23.0. Assistance from a biostatistician was sought for the more complex analysis of data and any multivariate analysis. The computation of descriptive statistics was followed by bivariate analyses, which used Chi-square tests for comparing proportions; Mann–Whitney or Kruskal–Wallis tests were used (as appropriate) for comparing scores for continuous variables where these were not normally distributed. Where continuous variables were normally distributed, ANOVA was used to compare means. The alpha value was set at 0.05.

The baseline OHRQoL data were analysed firstly by grouping the CPQ<sub>11-14</sub> scores into two domains, the symptoms and well-being domains. This was then cross tabulated with global measures. Responses to global measures were combined (excellent and very good, poor and fair, some, a lot and very much) due to the number of responses being low for some of the categories. Internal consistency reliability (Cronbach's alpha) was calculated. Responses were analysed for sociodemographic characteristics and for intervention groups. Test-retest reliability of the questionnaire was assessed using Intraclass Correlation Coefficients (ICC). The ICC was calculated as the proportion of total variance in the measure (participant variability) that was due to the true differences between responses in the first and second questionnaire.

Follow-up OHRQoL data were analysed by calculating the change in score between the baseline and follow-up data for each domain and the total CPQ scores. Effect sizes were analysed for each domain and CPQ total by dividing the mean of change scores by the standard deviation of the pre-treatment scores. Effect sizes have the ability to give a dimensionless measure of effect. Effect sizes of less than 0.2 indicate a small clinically meaningful magnitude of change, 0.2 to 0.7 a moderate change, and greater than 0.7 a large change.

Baseline caries data were analysed first by summarizing the primary and permanent dentition ICDAS scores (0-6) by sociodemographic characteristics and group. The number of decayed missing and filled surfaces were then calculated based on an ICDAS 3 or higher being 'decayed' for primary and permanent dentition. The scores were "radiographically adjusted" using the bitewing score readings during the analysis whereby a P3 or higher lesion was adjusted to be a 'decayed' surface. Caries prevalence was calculated using the definition of one surface or more with an ICDAS 3 or higher as a case of caries. This was presented by sociodemographic characteristics and group, and calculated for the primary and permanent dentition, as a raw number and percentage.

The analysis of caries data after follow-up was computed by comparing baseline and follow-up status for each surface level. Net caries increment was calculated by adding the number of changes in status from sound (ICDAS 0) to demineralized (ICDAS 1 and 2) or to decayed (ICDAS 3+) or to filled or both or from filled to decayed, demineralised or filled and then subtracting the number of reversals. Traditional net caries increment was calculated by identifying transitions from sound (ICDAS 0,1 and 2) to decayed (ICDAS 3+) or to filled or both or from filled to decayed and filled, and then correcting for reversals.

"Traditional" caries incident cases (DMFS) were those who had a net caries increment of 1 or more decayed (ICDAS 3+) or filled surfaces. Incident caries cases were also calculated using demineralisation (ICDAS 1 and 2) as a net increment. DMFS increment and incidence was calculated for grouped surfaces of the teeth (smooth surfaces, pit and fissure, proximal and facial).

Multivariate analysis was conducted using SPSS multivariate linear regression modeling with net caries increment as the dependent variable. Sociodemographic characteristics, intervention group, baseline DMFS and OHRQoL were included in the model. A progressive elimination of insignificant variables was undertaken. An additional logistic binary regression was performed to examine whether those whose caries increment improved or deteriorated was associated with sociodemographic characteristics, intervention group and OHRQoL.

## Chapter 3

#### 3. Results

#### 3.1. Baseline data

In this section, the baseline data collected in February 2015 have been analysed and presented.

## 3.1.1. Participation rate

There is a total of five intermediate schools in the Northland region, all located in main centers. The majority of children in year 7 and 8 who live rurally attend schools that are combined with a primary school and/or a high school. Three of the five main intermediate schools (Kaitaia, Dargaville and Kaikohe Intermediate) were included in this study. The two Intermediate schools not included were located in Whangarei in less deprived communities. The two other schools included in the study were Raurimu Ave School (combined primary and intermediate) and Bream Bay College (combined college and intermediate).

The sample included 487 school children aged 10 to 13 years. Consent forms were returned from 335 children (68.8%). One school served as the intervention school and the remaining four schools made up the control group (Table 3.1). There were 159 children in the intervention group and 176 in the control group. There was an overall participation rate of 69% in the study. The schools had varying participation in the study, with Dargaville having the highest participation rate (80%) and Kaikohe having the lowest rate (56%).

Table 3.1 Consent to participate by school

School	Consented	Non-Consent/Did not return form
	N (%)	N (%)
Control		
Dargaville Intermediate	60 (80.0)	15 (20.0)
Bream Bay College	38 (62.3)	23 (37.7)
Raurimu Ave School	6 (75.0)	2 (25.0)
Kaikohe Intermediate	72 (55.8)	57 (44.2)
Control Total	176 (64.4)	97 (35.6)
Intervention		
Kaitaia Intermediate	159 (74.3)	55 (25.7)
Total	335 (68.8)	152 (31.2)

Overall, just over two-thirds of invited children chose to participate, with a slightly higher rate in the intervention school than in the control schools.

All children included at baseline were dentally examined (including PBW radiographs) and completed a self-reported questionnaire. The subsequent data come from that examined baseline sample of 335 children.

## 3.1.2. Sociodemographic characteristics of participants

All children who obtained parental consent gave assent to be part of the study. The exclusion criteria did not preclude any of the children taking part. The sociodemographic characteristics of the baseline sample are presented by school in Table 3.2.

Table 3.2 Sociodemographic characteristics of children by school

		School								
	Bream Bay	Dargaville	Kaikohe	Kaitaia	Raurimu Ave					
	N (%)	N (%)	N (%)	N (%)	N (%)					
					- (4.0)					
Total	38 (11.3)	60 (17.9)	72 (21.5)	159 (47.5)	6 (1.8)					
Sex										
Male	21 (55.3)	34 (56.7)	32 (44.4)	74 (46.5)	1 (16.7)					
Female	17 (44.7)	26 (43.3)	40 (55.6)	85 (53.5)	5 (83.3)					
Age										
10-11	23 (60.5)	59 (98.3)	43 (59.7)	89 (56.0)	6 (100.0)					
12-13	15 (39.5)	1 (1.7)	29 (40.3)	70 (44.0)	0(0.0)					
Ethnicity										
NonMāori	32 (84.2)	36 (60.0)	3 (4.2)	42 (26.4)	0(0.0)					
Māori	6 (15.8)	24 (40.0)	69 (95.8)	117 (73.6)	6 (100.0)					
NZDEP13										
High	9 (24.3)	45 (80.4)	67 (94.4)	126 (81.3)	0(0.0)					
Medium	23 (62.2)	8 (14.3)	4 (5.6)	27 (17.4)	0(0.0)					
Low	5 (13.5)	3 (5.4)	0 (0.0)	2 (1.3)	6 (100.0)					
School Decile	5	4	1	1	2					

Four of the schools had a similar number of females and males, with Bream Bay College and Dargaville having slightly more males and Kaitaia and Kaikohe having slightly more females. Raurimu Ave School had mainly females, although this was a very small sample. Most children were in the 10-11-year age group. All children recruited from Dargaville were year 7, which gave them a lower overall age. The percentage of Māori children attending Kaikohe and Raruimu Ave School was higher than for the other schools. Bream Bay school children were predominantly NonMāori. Most of the children in the study resided in high-deprivation areas. Bream Bay College children (decile 5) had the greatest proportion of children living in low- or medium-deprivation areas.

Children from Kaitaia Intermediate were designated to be the intervention group, while the children from the other four schools (Dargaville, Bream Bay, Kaikohe and Raurimu Ave) made up the control group. Table 3.3 summarises the sociodemographic characteristics of the children by group.

Table 3.3 Sociodemographic characteristics of children in the control and intervention groups

Characteristic	Control	Intervention	Total Number	
	N (%)	N (%)	N (%)	
Total	176 (52.5)	159 (47.5)	335 (100.0)	
Sex	` ,	, ,	,	
Male	88 (50.0)	85 (53.5)	173 (51.6)	
Female	88 (50.0)	74 (46.5)	162 (48.4)	
Age				
10-11	131 (74.4) <sup>a</sup>	89 (56.0)	220 (65.7)	
12-13	45 (25.6)	70 (44.0)	115 (34.3)	
Ethnicity				
NonMāori	71 (40.3) <sup>a</sup>	42 (26.4)	113 (33.7)	
Māori	105 (59.7)	117 (73.6)	222 (66.3)	
NZDep13				
High	127 (74.7)	126 (81.3)	253 (77.8)	
Medium	35 (20.6)	27 (17.4)	62 (19.1)	
Low	8 (4.7)	2 (1.3)	1 (3.1)	
School Decile				
1	72 (40.9)	159 (100.0)	231 (69.0)	
2	6 (3.4)	-	6 (1.8)	
3	-	-	-	
4	60 (34.1)	-	60 (17.9)	
5	38 (21.6)	-	38 (11.3)	
School				
Bream Bay College	38 (21.6)	-	38 (11.3)	
Dargaville Intermediate	60 (34.1)	-	60 (17.9)	
Kaikohe Intermediate	72 (40.9)	-	72 (21.5)	
Kaitaia Intermediate	-	159 (100.0)	159 (47.5)	
Raurimu Ave School	6 (3.4)	-	6 (1.8)	

 $<sup>\</sup>frac{a}{p} < 0.05$ 

There was a significantly greater number of younger and NonMāori children in the control group. All of the children in the intervention group were in a decile 1 school.

# 3.1.3. Dental caries experience at baseline

## 3.1.3.1. ICDAS

Dental caries data were collected using the ICDAS system. Repeat clinical examinations were conducted on 33 children. The intra-examiner reliability was 0.85.

Each surface of every tooth was allocated a score for caries and for any restoration present. The mean number of permanent dentition surfaces in each ICDAS caries category is summarised by sociodemographic characteristics in Table 3.4.

Table 3.4 Mean number of permanent dentition surfaces in each ICDAS caries category, by sociodemographic characteristics (SD)

	ICDAS 0 Sound	ICDAS 1 White spot	ICDAS 2 Brown spot	ICDAS 3 Enamel cavitated	ICDAS 4 Grey shadow	ICDAS 5 Dentine cavitated	ICDAS 6 Large cavitation
Total	60.0 (20.4)	25.4 (12.1)	3.6 (3.7)	0.3 (0.8)	0.3 (0.8)	0.0 (0.2)	0.3 (2.7)
Sex	,	- ' ' '	( ,	()	()	,	(,
Male	58.3 (19.0)	25.4 (12.0)	3.3 (3.1)	0.3 (0.7)	0.2 (0.6)	0.0 (0.2)	0.5 (3.8)
Female	61.7 (21.5)	25.3 (12.3)	3.9 (4.1)	0.3 (0.8)	0.4 (0.9)	0.0 (0.1)	0.1 (2.7)
Age							
10-11	59.5 (20.6)	24.3 (12.0) <sup>a</sup>	3.2 (3.3) <sup>a</sup>	0.3 (0.7)	$0.2 (0.6)^{a}$	0.0 (0.2)	0.4 (3.3)
12-13	61.2 (19.9)	27.3 (12.3)	4.5 (4.2)	0.4 (0.8)	0.4 (1.1)	0.0 (0.1)	0.1 (0.8)
Ethnicity							
NonMāori	57.5 (19.8)	22.7 (12.7) <sup>a</sup>	3.2 (3.5)	0.2 (0.6)	0.3 (1.0)	0.0 (0.2)	0.2 (0.9)
Māori	61.3 (20.6)	26.7 (11.6)	3.9 (3.8)	0.3 (0.8)	0.0 (0.1)	0.0 (0.1)	0.4 (3.3)
NZDEP13							
High	59.9 (20.3)	25.7 (12.2)	$4.0 (3.8)^a$	0.3 (0.8)	0.3 (0.8)	0.0 (0.1)	0.3 (2.8)
Medium	60.1 (20.8)	25.2 (11.9)	2.8 (3.3)	0.2 (0.6)	0.3 (0.8)	0.0 (0.3)	0.4 (3.0)
Low	64.2 (23.6)	20.4 (10.9)	2.7 (3.8)	0.1 (0.3)	0.0(0.0)	0.0 (0.0)	0.0(0.0)
Group							
Control	63.3 (20.2) <sup>a</sup>	29.0 (12.6) <sup>a</sup>	3.6 (3.6)	0.3 (0.7)	0.2 (0.6)	0.0 (0.1)	0.4 (3.2)
Intervention	56.4 (20.1)	21.3 (10.2)	3.7 (3.7)	0.3 (0.8)	0.4 (1.0)	0.0 (0.2)	0.3 (0.8)

<sup>&</sup>lt;sup>a</sup> p < 0.05

The children in the younger age group had significantly fewer ICDAS 1, 2 and 4 lesions. Māori children had significantly more ICDAS 1 (white spot lesions) than NonMāori. Those in the high NZDep13 group had significantly more ICDAS 2 (brown spot) lesions than those in the medium and low-deprivation groups. The control group had significantly more sound surfaces and more ICDAS 1 (white spot lesions) at baseline than those in the intervention group.

The mean number of permanent dentition surfaces in each ICDAS restoration code is summarised by sociodemographic characteristics in Table 3.5.

Table 3.5 Mean number of permanent dentition surfaces in each ICDAS restoration category, by sociodemographic characteristics (SD)

	Partial Sealant	Full Sealant	White restoration	Amalgam	Stainless steel crown	Other crown/lost filling/temp filling
Total	3.0 (2.4)	2.2 (2.9)	0.3 (1.1)	0.3 (0.9)	0.1 (1.0)	0.0 (0.1)
Sex	` /	` '	` '	` ,	` '	
Male	2.8 (2.0)	2.0 (2.6)	0.4 (1.1)	0.3 (0.8)	0.2 (1.5)	0.0 (0.1)
Female	3.2 (2.6)	2.5 (3.1)	0.3 (1.0)	0.3 (1.0)	0.0(0.0)	0.0 (0.1)
Age						
10-11	2.9 (2.2)	2.2 (2.9)	0.4 (1.2)	$0.1 (0.5)^{a}$	0.1 (1.1)	0.0 (0.1)
12-13	3.2 (2.7)	2.3 (2.9)	0.3 (0.8)	0.5 (1.3)	0.1 (0.9)	0.0 (0.1)
Ethnicity						
NonMāori	2.4 (2.0)	2.0 (2.7)	0.2 (0.8)	0.2 (0.6)	0.2 (1.7)	0.0 (0.1)
Māori	3.3 (2.5)	2.4 (2.9)	0.4 (1.2)	0.4 (1.2)	0.0(0.3)	0.0 (0.1)
NZDEP13						
High	3.0 (2.3)	2.4 (2.9)	0.4 (1.2)	0.3 (0.9)	0.1(0.7)	0.0 (0.1)
Medium	2.8 (2.4)	1.6 (2.7)	0.2 (0.7)	0.3 (1.2)	0.2 (1.2)	0.0(0.1)
Low	2.7 (3.5)	2.1 (2.1)	0.2 (0.4)	0.0(0.0)	0.0(0.0)	0.0(0.0)
Group						
Control	3.1 (2.5)	$2.7(3.1)^a$	$0.2 (0.6)^a$	0.3 (0.9)	0.0(0.0)	0.0 (0.1)
	2.8 (2.2)	1.8 (2.6)	0.5 (1.4)	0.3 (0.9)	0.2 (1.5)	0.0 (0.1)
Intervention						

 $<sup>\</sup>overline{^a\;p<0.05}$ 

There was a significantly higher mean number of surface codes for amalgam restorations in the 12-to-13-year-old age group. There were no other significant differences in mean restoration surface scores by sociodemographic characteristics.

Summary data on the mean number of ICDAS codes for permanent tooth surfaces are presented by sociodemographic characteristics and group in Table 3.6.

Table 3.6 Mean number of primary dentition surfaces in each ICDAS caries category, by sociodemographic characteristics (SD)

	ICDAS 0 Sound	ICDAS 1 White spot	ICDAS 2 Brown spot	ICDAS 3 Enamel cavitated	ICDAS 4 Grey shadow	ICDAS 5 Dentine cavitated	ICDAS 6 Large cavitation
Total	15.5 (17.3)	5.9 (7.1)	0.8 (1.5)	0.1 (0.5)	0.2 (0.5)	0.1 (0.4)	0.1 (1.2)
	13.3 (17.3)	3.9 (7.1)	0.6 (1.5)	0.1 (0.3)	0.2 (0.3)	0.1 (0.4)	0.1 (1.2)
Sex	160(174)	( 0 (7 0)	0.0 (1.5)	0.2 (0.6)	0.2 (0.6)	0.1 (0.4)	0.2 (1.7)
Male	16.2 (17.4)	6.0 (7.0)	0.8 (1.5)	0.2 (0.6)	0.2 (0.6)	0.1 (0.4)	0.2 (1.7)
Female	14.9 (17.3)	5.8 (7.2)	0.7(1.4)	0.1 (0.4)	0.2(0.5)	0.0(0.2)	0.0(0.2)
Age							
10-11	14.5 (16.0)	5.6 (6.7)	$0.9 (1.6)^{a}$	$0.2 (0.6)^{a}$	$0.3 (0.6)^a$	$0.1 (0.4)^{a}$	0.2 (1.5)
12-13	17.5 (19.5)	6.4 (7.8)	0.5 (1.1)	0.0 (0.1)	0.1 (0.3)	0.0 (0.4)	0.0 (0.1)
Ethnicity	` ,	, ,	` '	` ,	` ,	, ,	` ,
NonMāori	16.0 (16.6)	5.6 (6.1)	1.0 (1.6) <sup>a</sup>	$0.3 (0.8)^a$	0.3 (0.6)	$0.1 (0.5)^{a}$	0.1 (0.5)
Māori	15.3 (17.7)	6.1 (7.6)	0.7(1.4)	0.0(0.2)	0.2(0.5)	0.0(0.2)	0.1 (1.4)
NZDEP13							
High	15.6 (17.3)	6.2 (7.5)	0.8 (1.5)	0.1 (0.5)	0.2 (0.6)	0.1 (0.3)	0.1 (1.3)
Medium	15.6 (17.6)	5.0 (5.5)	0.6 (1.3)	0.1 (0.3)	0.1 (0.3)	0.0 (0.2)	0.2 (0.9)
Low	12.2 (12.6)	6.4 (6.7)	0.8 (1.3)	0.3 (0.9)	0.2 (0.6)	0.0(0.0)	0.0(0.0)
Group							
Control	9.1 (13.0) <sup>a</sup>	4.8 (7.3) <sup>a</sup>	0.7 (1.4)	$0.2 (0.6)^{a}$	0.2 (0.5)	0.1 (0.3)	0.2 (1.5)
Intervention	22.7 (18.7)	7.2 (6.7)	0.8 (1.5)	0.1 (0.3)	0.2 (0.5)	0.1 (0.3)	0.1 (0.6)

 $<sup>\</sup>frac{a}{p} < 0.05$ 

There was a significantly higher mean number of surfaces in the 10- and 11-year-old children scoring ICDAS 2, 3, 4 and 5 than in the older age group. There was a statistically significantly higher mean ICDAS score for ICDAS 2, 3 and 5 for NonMāori children.

Summary data on the mean number of permanent dentition surfaces for each ICDAS restoration category are presented by sociodemographic characteristics and group in Table 3.7.

Table 3.7 Mean number of permanent dentition surfaces in each ICDAS restoration category, by sociodemographic characteristics (SD)

	Partial Sealant	Full Sealant	White restoration	Amalgam	Stainless steel crown	Other crown/lost filling/temp filling
						mmig
Total	0.3 (0.8)	0.5 (1.2)	0.8 (2.2)	0.0 (0.2)	0.6 (3.4)	0.0 (0.1)
Sex						
Male	0.4(0.9)	0.4 (1.0)	1.0 (2.7)	0.0(0.0)	1.0 (4.3)	0.0(0.1)
Female	0.3 (0.7)	0.6 (1.5)	0.7 (1.7)	0.0(0.2)	0.3 (2.1)	0.0(0.1)
Age						
10-11	0.3(0.8)	$0.3(1.0)^{a}$	$1.2 (2.6)^{a}$	0.0(0.1)	$1.0 (4.1)^a$	0.0(0.2)
12-13	0.4(0.7)	0.8 (1.7)	0.2(0.8)	0.0(0.2)	0.0(0.0)	0.0(0.0)
Ethnicity						
NonMāori	$0.2 (0.5)^{a}$	0.3 (1.0)	$1.7 (3.4)^a$	0.0(0.2)	1.1 (4.7)	0.0(0.1)
Māori	0.4(0.9)	0.6 (1.4)	0.4 (1.1)	0.0(0.1)	0.4 (2.4)	0.0(0.1)
NZDep13						
High	0.4(0.8)	0.0(0.0)	0.8 (2.1)	0.0(0.1)	0.7 (3.6)	0.0(0.1)
Medium	0.3 (0.8)	0.5 (1.5)	0.8 (1.9)	0.0(0.0)	0.6 (3.1)	0.0(0.0)
Low	0.0(0.0)	0.5 (1.3)	2.1 (5.7)	0.2 (0.6)	0.0(0.0)	0.0(0.0)
Group						
Control	$0.2(0.6)^{a}$	$0.3(1.2)^{a}$	0.9 (2.7)	0.1 (0.2)	$0.2 (1.8)^a$	0.0(0.1)
Intervention	0.5 (0.9)	0.6 (1.4)	0.7 (1.6)	0.0 (0.2)	1.1 (4.5)	0.0(0.0)

a p < 0.05

The 10-11-year-old children had a higher number of white restorations and stainless steel crowns placed in their primary teeth than the 12-13-year-old group. The NonMāori children had fewer sealants and more white restorations than Māori children. There were more white restorations in Dargaville Intermediate children.

# 3.1.3.1. Decayed, missing and filled surfaces (conventional dmfs/DMFS)

The decayed missing and filled surface data were calculated based on an ICDAS 3 or higher being 'decayed'. The data were adjusted using PBW radiographs. Table 3.8 shows caries severity (dmf/DMF) and prevalence data (1 or more carious lesion) by sociodemographic characteristics and group.

Table 3.8 Prevalence and severity of dental caries by sociodemographic characteristics and intervention group

	DMFS	dmfs (SD)	DMFT (SD)	dmft (SD)	Permanent dentition caries prevalence N (%)	Primary dentition caries prevalence N (%)
Total	2.1 (3.9)	2.4 (5.5)	1.1 (1.6)	1.3 (2.5)	202 (60.3)	120 (35.3)
Sex	(= 1.2 )	(= 1-)	( , , ,	( , ,	( ( )	( )
Male	2.4 (4.8)	$3.1(6.7)^a$	1.1 (1.5)	1.5 (2.9)	100 (61.7)	59 (36.4)
Female	1.9 (2.7)	1.7 (4.1)	1.1 (1.6)	1.1 (2.1)	102 (59.0)	61 (35.3)
Age	, ,	, ,	` ,	, ,	, ,	,
10-11	2.0 (4.2)	$3.4 (6.5)^a$	$1.0(1.6)^{a}$	1.8 (2.9)	130 (59.1)	98 (44.5) <sup>a</sup>
12-13	2.3 (3.2)	0.5 (1.5)	1.2 (1.5)	0.4(1.1)	72 (62.6)	22 (19.1)
Ethnicity						
NonMāori	1.9 (3.2)	$4.3 (7.5)^{a}$	1.0 (1.4)	$2.2(3.5)^{a}$	63 (55.8) <sup>a</sup>	51 (45.1) <sup>a</sup>
Māori	2.2 (4.2)	1.5 (3.9)	1.1 (1.6)	0.9 (1.7)	139 (62.6)	69 (31.)
NZDEP13	, ,	, ,	, ,	, ,	, ,	, ,
High	2.2 (3.8)	2.5 (5.7)	1.2 (1.6)	1.3 (3.3)	162 (63.0)	91 (35.4)
Medium	2.1 (4.4)	2.0 (4.9)	0.9 (1.5)	1.1 (2.3)	32 (51.6)	21 (33.9)
Low	0.6 (0.7)	3.0 (7.1)	0.4 (0.7)	1.8 (3.8)	5 (50.0)	4 (40.0)
Group	, ,	, ,	•	` '	, ,	• • •
Control	1.9 (3.7)	2.2 (5.3)	1.0 (1.4)	1.2 (2.8)	105 (59.7)	51 (29.0) <sup>a</sup>
Intervention	2.4 (4.1)	2.6 (5.6)	1.2 (1.8)	1.4 (2.2)	97 (61.0)	69 (43.4)

a p < 0.05

Children in the younger age group had a lower caries experience in their permanent teeth than older children. The younger children had higher caries prevalence in their primary teeth than the older group. NonMāori children had a lower severity and prevalence of caries in their permanent teeth, but a higher caries severity and prevalence in their primary teeth, than Māori children. The control group had a significantly lower caries prevalence and severity in their primary dentition.

# 3.1.4. Self-reported oral hygiene questions

Six self-reported oral hygiene questions were asked at baseline, five of which had dichotomous responses, and one with a multiple response option. The dichotomous question responses are displayed in Table 3.9 by sociodemographic characteristics and intervention group.

Table 3.9 Self-reported oral hygiene practices by sociodemographic characteristics and intervention group

	Do you have a tooth brush at home?		Do you know what dental floss is?		•	Do you have dental floss at home?		Do you use dental floss at home?		Do you think that brushing your teeth keeps you healthy?	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	
Total	309 (92.5)	25 (7.5)	283 (85.0)	50 (15.0)	158 (47.6)	174 (52.4)	127 (38.4)	204 (61.6)	319 (95.5)	5 (1.5)	
Sex	` ,	, ,	` ,	, ,	, ,	, ,	` ,	, ,	` ,	` ,	
Male	162 (93.6)	11 (6.4)	159 (91.9)	14 (8.1)	89 (51.7)	83 (48.3)	71 (41.5)	100 (58.5)	154 (98.7)	2 (1.3)	
Female	147 (91.3)	14 (8.7)	124 (77.5)	36 (22.5)	69 (43.1)	91 (56.9)	56 (35.0)	104 (65.0)	116 (98.2)	3 (1.8)	
Age											
10 and 11	203 (92.3)	17 (7.7)	183 (83.9)	35 (16.1)	118 (54.1) <sup>a</sup>	100 (45.9)	94 (43.3) <sup>a</sup>	123 (56.7)	211 (99.1)	2(0.9)	
12 and 13	106 (93.0)	8 (7.0)	100 (87.0)	15 (13.0)	40 (35.1)	74 (64.9)	33 (28.9)	81 (71.1)	109 (97.3)	3 (2.7)	
Ethnicity											
NonMāori	111 (98.2)	2 (1.8)	101 (90.2)	11 (9.8)	69 (61.6) <sup>a</sup>	43 (38.4)	55 (49.1) <sup>a</sup>	57 (50.9)	112 (100.0)	0(0.0)	
Māori	198 (89.6)	23 (10.4)	182 (82.4)	39 (17.6)	89 (40.5)	131 (59.5)	72 (32.9)	147 (67.1)	208 (97.7)	5 (2.3)	
NZDEP13											
High	229 (91.6)	21 (8.4)	209 (83.3)	42 (16.7)	110 (43.8)	141 (56.2)	89 (35.5)	162 (64.5)	239 (98.4)	4 (1.7)	
Medium	59 (96.7)	2 (3.3)	54 (88.5)	7 (11.5)	33 (55.0)	27 (45.0)	28 (46.7)	32 (53.3)	59 (98.3)	1 (1.7)	
Low	10 (100.0)	0(0.0)	10 (100.0)	0 (0.0)	7 (70.0)	3 (30.0)	4 (40.0)	6 (60.0)	10 (100.0)	0(0.0)	
Group	,			•	, ,		•	, ,			
Control	157 (89.7)	18 (10.3)	142 (81.1)	33 (18.9)	77 (44.0)	98 (56.0)	64 (36.6)	111 (63.4)	171 (98.3)	3 (1.7)	
Intervention	152 (95.6)	7 (4.4)	141 (89.2)	17 (10.8)	81 (51.6)	76 (48.4)	63 (40.4)	93 (59.6)	149 (98.7)	2 (1.3)	

a p < 0.05

Nearly all of the children reported having a tooth brush at home (92.5%). Fewer Māori participants reported having a brush at home. One-fifth of girls reported they did not know what floss was and almost twice as many Māori reported not knowing what it was. Approximately half of the children reported having floss at home. There was a significant difference in use and availability of floss at home, with younger children and NonMāori reporting having it and using it at home. Most felt that brushing your teeth keeps them healthy. The 5 children who did not feel that brushing teeth keeps you healthy were Māori and resided in deprived communities. The responses to the multi-response item are summarised in Table 3.10, by sociodemographic characteristics and intervention group.

Table 3.10 Self-reported tooth brushing frequency by sociodemographic characteristics and intervention group

	Never	One time per	One time per day	Twice or more
	N (%)	week	N (%)	each day
		N (%)		N (%)
Total	15 (4.5)	28 (8.4)	116 (34.6)	175 (52.2)
Sex				
Male	8 (4.7)	14 (8.1)	51 (29.7)	99 (57.6)
Female	7 (4.3)	14 (8.6)	65 (40.1)	76 (46.9)
Age				
10 and 11	10 (4.5)	17 (7.7)	77 (35.0)	116 (52.7)
12 and 13	5 (4.4)	11 (9.6)	39 (34.2)	59 (51.8)
Ethnicity				
NonMāori	1 (0.9)	3 (2.7)	29 (25.7)	$80 (70.8)^{a}$
Māori	14 (6.3)	25 (11.3)	87 (39.4)	95 (43.0)
NZDep13				
High	15 (6.0)	25 (9.9)	90 (35.7)	122 (48.4)
Medium	0(0.0)	3 (4.8)	16 (25.8)	43 (69.4)
Low	0(0.0)	0(0.0)	4 (40.0)	6 (60.0)
Group				
Control	14 (8.0)	15 (8.6)	60 (34.3)	86 (49.1)
Intervention	1 (0.6)	13 (8.2)	56 (35.2)	89 (56.0)

a p < 0.05

Most participants (86.8%) reported brushing their teeth at least once daily, and this was higher among NonMāori.

## 3.1.5. Oral health-related quality of life

The short-form 16-item impact Child Perception's Questionnaire (CPQ<sub>11-14</sub>-ISF) has two domains containing 8 items each. These are termed the symptoms and well-being domains.

Cronbach's alpha values were 0.80, 0.62 and 0.75 for the  $CPQ_{11-14}$ -ISF, symptoms and well-being domains, respectively. There was substantial internal consistency reliability for the total  $CPQ_{11-14}$ -ISF, although the symptoms domain was not as high as the well-being domain (but still within an acceptable range).

The mean  $CPQ_{11-14}$  and domain scores are presented by global oral health questions in Table 3.11.

Table 3.11 Mean CPQ<sub>11-14</sub> and domain scores by global items (SD)

	CPQ <sub>11-14</sub>	Symptoms	Well-being
Self-rated oral health			_
Excellent/Very good	10.2 (7.7)	5.8 (4.3)	4.4 (4.6)
Good	13.7 (7.5)	7.5 (3.8)	6.2 (4.7)
Poor/Fair	16.3 (7.8)	8.5 (4.0)	7.7 (4.9)
Total	13.1 (8.0)	7.2 (4.1)	6.0 (4.9)
Impact on quality of life			
Global oral health			
Not at all	9.3 (6.4)	5.7 (3.8)	3.7 (3.8)
Very little	13.3 (6.9)	7.0 (3.5)	6.2 (4.5)
Some/ A lot/Very much	18.1 (8.4)	9.5 (4.4)	8.6 (5.1)
Total	13.1 (8.0)	7.2 (4.1)	6.0 (4.9)

<sup>&</sup>lt;sup>a</sup> p < 0.05 Kruskal-Wallis/Mann-Whitney

There was a distinct gradient in mean  $CPQ_{11-14}$  (and domain) scores across the categories of self-rated oral health, whereby those who rated their oral health as 'poor'/'fair' had the highest score, and those with excellent self-rated oral health the lowest. There was a similar gradient in mean  $CPQ_{11-14}$  (and domain) scores across the categories of global oral health.

The mean CPQ<sub>11-14</sub> scores are presented by sociodemographic characteristics and intervention group in Table 3.12.

Table 3.12 Mean  $CPQ_{11-14}$  and domain scores by sociodemographic characteristics and intervention group (SD)

Characteristic	CPQ <sub>11-14</sub>	Symptoms	Well-being
Total	13.1 (8.0)	7.2 (4.1)	6.0 (4.9)
Sex			
Male	12.8 (8.1)	7.0 (4.2)	5.9 (5.0)
Female	13.4 (7.8)	7.3 (4.1)	6.1 (4.8)
Age			
10-11	13.0 (8.1)	7.2 (4.3)	5.8 (4.8)
12-13	13.3 (7.7)	7.2 (3.7)	6.2 (5.0)
Ethnicity			
NonMāori	12.6 (7.9)	7.1 (4.2)	5.5 (4.8)
Māori	13.4 (8.0)	7.2 (4.1)	6.2 (4.9)
NZDEP13			
High	13.1 (8.0)	7.2 (4.2)	6.0 (4.9)
Medium	13.3 (7.6)	7.2 (3.9)	6.0 (4.6)
Low	12.1 (7.1)	6.5 (3.1)	5.6 (4.9)
Group			
Control	12.7 (8.6)	7.0 (4.3)	5.7 (5.2)
Intervention	13.6 (7.2)	7.4 (3.9)	6.2 (4.4)

There were no statistically significantly differences in CPQ scores at baseline. Repeat test reliability was undertaken on 38 questionnaires. The internal consistency was 0.84.

# 3.2. Follow-up

In this section, follow-up data collected in November and December of 2015 will be reported on.

## 3.2.1. Participation

Follow-up data were collected 9 months after the baseline data. A summary of the children who were followed up is presented in Table 3.13.

**Table 3.13 Summary of Participation** 

Group	Baseline	Follow-up (%)
Control	176	130 (73.9)
Intervention	159	110 (69.2)
Total	335	240 (71.6)

The follow-up participation rate for the study was 71.6%.

## 3.2.2. Attrition analysis

Of the 335 children who were examined at baseline, there were 95 who did not have follow-up examinations. The most common reason for children not being followed up was them leaving school: this accounted for 52 (54.7%) children. There were 39 (41.1%) children who were absent on all of the examination days, although were still enrolled with the school. There were 4 (4.2%) children in the 'other' category, 2 of whom were suspended from school, while one was unlikely to return due to long-term illness (brain tumour) and another was missing for an unknown reason. Table 3.14 compares the sociodemographic characteristics of children followed up and lost to follow-up.

Table 3.14 Attrition analysis: comparison of the sociodemographic characteristics of children followed and not followed up

	Baseline (%)	Followed up (%)	Not followed up (%)
Total	335 (100.0)	240 (71.6)	95 (28.4)
Sex			
Male	162 (48.4)	116 (48.3)	46 (48.4)
Female	173 (51.6)	124 (51.7)	49 (51.6)
Age			
10 and 11	220 (65.7)	157 (65.4)	63 (66.3)
12 and 13	115 (34.3)	83 (34.6)	32 (33.7)
Ethnicity			
NonMāori	113 (33.7)	91 (37.9)	22 (23.2)
Māori	222 (66.3)	149 (62.1)	73 (76.8) <sup>a</sup>
NZDep13			
High	253 (77.8)	172 (74.8)	76 (83.5)
Medium	62 (19.1)	49 (21.3)	15 (16.5)
Low	1 (3.1)	9 (3.9)	0(0.0)
Group	` ,	, ,	` ,
Control	176 (52.5)	130 (54.2)	46 (48.4)
Intervention	159 (47.5)	110 (45.8)	49 (51.6)

a p < 0.05

There were significantly more Māori children who were not followed up. Of the children who were not followed up, about half were in the intervention group and half were in the control group.

The baseline dental caries experience of those lost and those followed-up is presented in Table 3.15.

Table 3.15 Baseline caries experience by follow-up status

	Baseline	Followed up	Not followed up
Primary dentition			
Caries prevalence (%)	120 (35.8)	71 (29.6)	49 (51.6) <sup>a</sup>
Mean dmfs (SD)	2.4 (5.5)	1.8 (4.5)	4.0 (7.3) <sup>a</sup>
Permanent dentition			
Caries prevalence	202 (60.3)	151 (62.9)	51 (53.7)
Mean DMFS (SD)	2.1 (3.9)	2.3 (3.7)	1.7 (4.3)
Combined			
DMFS mean (SD)	4.5 (6.7)	4.1 (6.0)	5.7 (8.1) <sup>b</sup>

 $<sup>\</sup>begin{array}{c} \hline ^{a} \ p < 0.001 \\ ^{b} \ p < 0.05 \\ \end{array}$ 

The children who were lost to follow-up had significantly greater primary caries severity and prevalence at baseline than those who were followed up. The children who were not followed up had a higher combined (primary and permanent) DMFS overall at baseline.

The CPQ<sub>11-14</sub> scores for children who were followed up and lost to follow-up are displayed in Table 3.16.

Table 3.16 Baseline CPQ<sub>11-14</sub> scores by follow-up status

	Baseline (%)	Followed up (%)	Not followed up (%)
CPQ <sub>11-14</sub>	13.1 (8.0)	12.2 (7.6)	15.4 (8.4) <sup>a</sup>
Symptoms	7.2 (4.1)	6.9 (4.0)	$8.0 (4.2)^a$
Well-being	6.0 (4.9)	5.4 (4.6)	7.5 (5.2) <sup>a</sup>

a p < 0.05

The group who were not followed up had significantly poorer OHRQoL in both domains and CPQ<sub>11-14</sub> overall. Cronbach's alpha values were 0.82, 0.59 and 0.68 for the CPQ<sub>11-14</sub>-ISF, symptoms and well-being domains, respectively. There was substantial internal consistency reliability for the total CPQ<sub>11-14</sub>-ISF, although the symptoms domain was not as high as the well-being domain.

## 3.2.3. Changes in dental caries

The change in dental caries was considered by comparing baseline and follow-up status at surface level. Repeat clinical examinations were conducted on 9 children. The intra-examiner reliability was 0.91.

Data on net caries increment (with ICDAS 'demineralisation criteria') and traditional net caries (using 'DMFS criteria') are presented Table 3.17.

Table 3.17 Dental caries increment and incidence

	Intervention	Control	Significance
Inclusion of demineralisation			
(ICDAS 1 & 2)			
DMFS increment (SD)	-11.7 (10.1)	8.6 (12.1)	P<0.001
DMFS incidence (%)	8 (7.3)	93 (71.5)	P<0.001
Traditional DMFS (Sound = ICDAS 0, 1 & 2)			
DMFS increment (SD)	-1.0 (3.1)	-0.2 (3.1)	P<0.05
DMFS incidence (%)	15 (13.6)	36 (27.7)	P<0.05
Surfaces Smooth Surface caries only			
DMFS increment (SD)	-9.8 (9.2)	8.2 (11.7)	P<0.001
DMFS incidence (%)	8 (7.3)	93 (71.5)	P<0.001
Pit and Fissure caries only			
DMFS increment (SD)	-1.8 (2.4)	0.4(2.4)	P<0.001
DMFS incidence (%)	15 (13.6)	63 (48.5)	P<0.001
Proximal surfaces			
DMFS increment (SD)	-1.8 (3.1)	5.0 (6.7)	P<0.001
DMFS incidence (%)	26 (23.6)	95 (73.1)	P<0.001
Facial surfaces			
DMFS increment (SD)	-8.1 (7.4)	3.1 (7.2)	P<0.001
DMFS incidence (%)	7 (6.4)	79 (60.8)	P<0.001

The difference in DMFS increment and incidence between the control and intervention group is highly significant both overall and for each of the tooth surfaces. When considering traditional DMFS criteria (ICDAS 0, 1 and 2 as sound) the differences between the control and intervention group surfaces for both caries increment and incidence were statistically significant. The intervention group had less surface lesions that progressed, and more reversals, than the control group.

The net caries increment data are also presented in Figure 9 and the caries incidence data is presented in Figure 10.

Figure 9. Net caries increment by group and by type of lesion

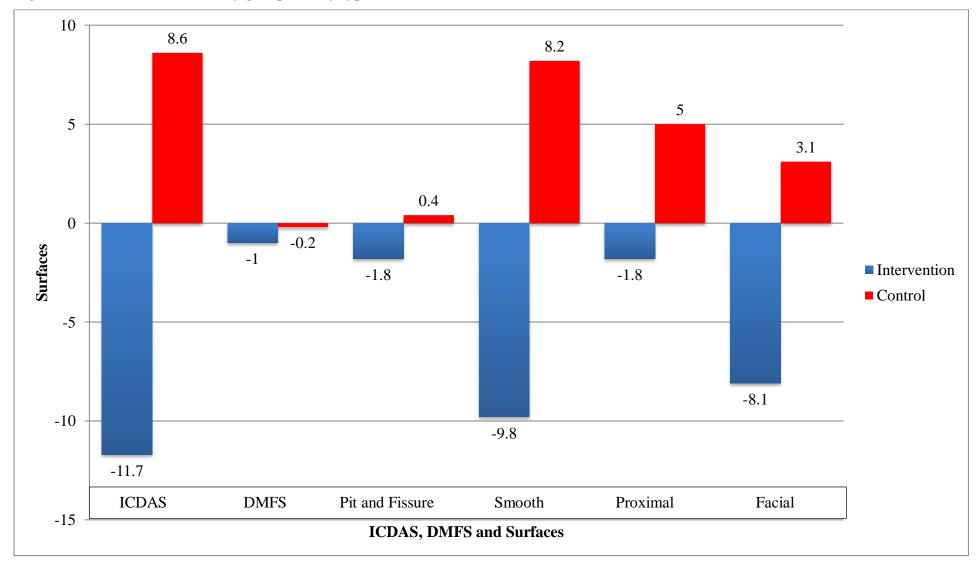
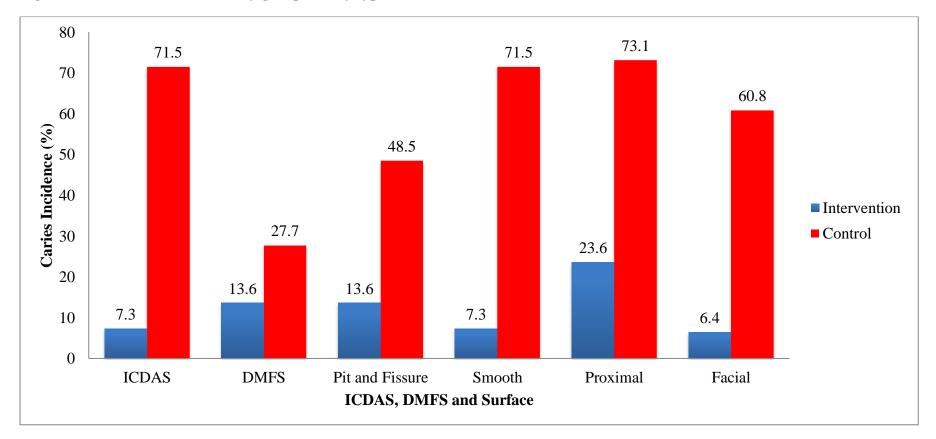


Figure 10. Caries incidence (%) by group and by type of lesion



# 3.2.4. Changes in OHRQoL

The change in  $CPQ_{11-14}$  (for each domain and overall) with range and effect size, for the intervention group and control groups are presented in Table 3.18.

Table 3.18 Mean overall and domain scores by group at baseline and follow-up, with effect sizes.

		Baseline Mean score (SD)	Range (no. scoring 0)	Follow-up Mean score (SD)	Range (no. scoring 0)	Change in score (SD)	Effect size	Effect size description
						_		
All	CPQ	12.2 (7.6)	0-36	10.0 (7.1)	0-37	2.1 <sup>a</sup>	0.3	Small
	Symptoms	6.9 (4.0)	0-24	5.9 (3.9)	0-20	1.1 <sup>a</sup>	0.3	Small
	Wellbeing	5.4 (4.6)	0-21	4.2 (4.3)	0-22	1.1 <sup>b</sup>	0.2	Small
Control	CPQ	11.8 (8.0)	0-34	10.6 (7.4)	0-32	1.3	0.2	Small
	Symptoms	6.8 (4.1)	0-19	6.3 (4.1)	0-20	0.6	0.2	Small
	Wellbeing	5.1 (4.9)	0-21	4.4 (4.6)	0-22	0.7	0.1	Small
Intervention	CPQ	12.7 (7.3)	1-36	9.4 (6.8)	0-32	3.2 a	0.4	Moderate
	Symptoms	7.0 (3.9)	0-24	5.4 (3.7)	0-17	1.6 <sup>a</sup>	0.4	Moderate
	Wellbeing	5.7 (4.3)	0-19	4.1 (4.0)	0-16	1.5 <sup>a</sup>	0.4	Moderate

<sup>&</sup>lt;sup>a</sup> P<0.001 Paired t-test <sup>b</sup> P<0.05 Paired t-test

Overall the change in  $CPQ_{11-14}$  scores from baseline to follow-up for all children was substantially significant.

Changes in CPQ<sub>11-14</sub> total and subscale scores are summarised in Table 3.19. Numbers may not sum exactly because of rounding.

Table 3.19 Mean CPQ and domain change scores by socio-demographic characteristics and intervention group

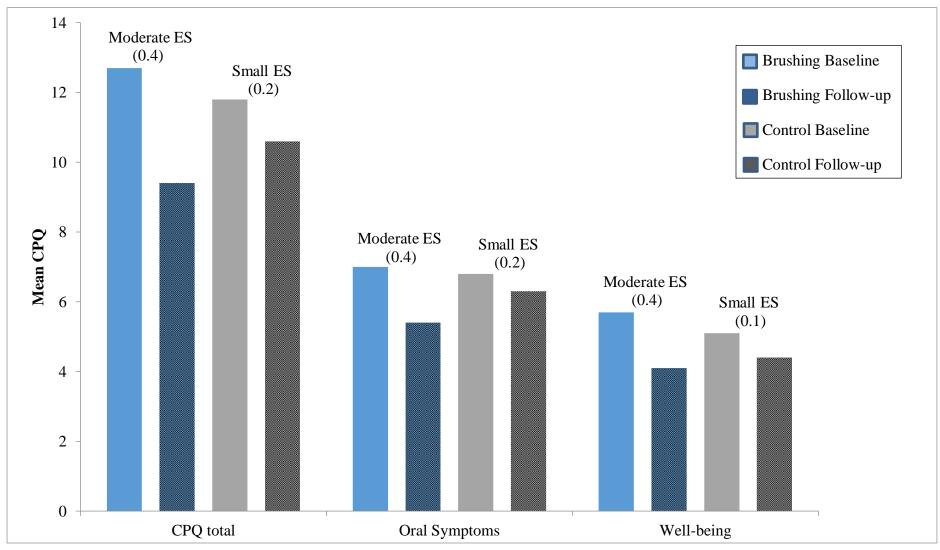
	Change in CPQ (SD)	Effect size	Change in Symptoms Domain (SD)	Effect Size	Change in Wellbeing Domain (SD)	Effect Size
Sex						
Male	2.4 (7.7)	0.3	1.3 (4.1)	0.3	1.2 (5.0)	0.3
Female	1.9 (7.9)	0.3	0.9 (4.5)	0.2	0.9 (4.8)	0.2
Age						
10 and 11	2.1 (8.2)	0.3	1.0 (4.5)	0.2	1.0 (5.0)	0.2
12 and 13	2.3 (7.0)	0.3	1.1 (4.1)	0.3	1.3 (4.7)	0.3
Ethnicity						
NonMāori	1.2 (7.8)	0.2	0.4 (4.3) <sup>a</sup>	0.1	0.9 (5.1)	0.2
Māori	2.7 (7.8)	0.4	1.5 (4.3)	0.4	1.2 (4.8)	0.3
NZDEP13	, ,		, ,		, ,	
Low	-3.3 (11.1)	0.5	0.9 (5.9)	0.4	-2.4 (5.4)	0.5
Medium	2.1 (7.6)	0.3	0.8 (4.0)	0.2	1.1 (5.2)	0.2
High	2.3 (7.6)	0.3	1.2 (4.4)	0.3	1.2 (4.8)	0.3
Group						
Control	1.3 (8.6) <sup>a</sup>	0.2	0.6 (4.5)	0.2	0.7 (5.5)	0.1
Intervention	3.2 (6.7)	0.4	1.6 (4.0)	0.4	1.5 (4.1)	0.4

<sup>&</sup>lt;sup>a</sup> P<0.05

OHRQoL improved for all groups with the exception of those in the low deprivation group. There were 9 children in the low deprivation group with follow-up responses; they had a lower OHRQoL at follow-up and the effect size was moderate. Māori children and those in the highly-deprived group had an improvement in OHRQoL across both domains and in the overall CPQ<sub>11-14</sub>.

The children in the tooth brushing group had the greatest improvement in OHRQoL. The effect size changes are displayed in Figure 11.

Figure 11. Mean CPQ total and domain scores at baseline and follow-up for intervention groups



Domain/ CPQ Total

Children in the tooth brushing group had higher OHRQoL scores across all domains at baseline (poorer OHRQoL). At follow-up, all had lower scores than those in the control group. The overall OHRQoL improved for all groups, but the largest improvement was for those in the tooth brushing group which had a moderate effect size.

At follow-up repeat test reliability was undertaken on 28 questionnaires, the internal consistency calculation was 0.90.

#### 3.2.5. Multivariate analysis

In the multivariate linear regression model, the only significant predictor of net caries increment (using the ICDAS codes) was the intervention group (p< 0.001). When modeling with the traditional DMFS categories, no predictor variable was detected as statistically significant. The group variable was almost significant, at p = 0.053.

The binary logistic model indicated that the only significant predictor of improved net caries increment was the intervention group (p < 0.001).

#### Chapter 4

#### 4. Discussion

In this section, the overall findings and what they demonstrate will be discussed, along with the weaknesses, strengths and limitations of the study.

#### 4.1. Overview of findings

This quasi-experimental study has demonstrated that a tooth brushing programme can be successfully implemented in a Northland Intermediate school. The study has shown that, over a one-year period, OHRQoL improved more for children who took part in a supervised tooth brushing programme than for those who did not. Māori children had a large improvement in OHRQoL. The children who took part in the brushing programme had improvements in oral health, with more caries reversals and a lower prevalence of new carious lesions than those in the control group. Membership of the brushing group was the only statistically significant predictor of a lower net caries increment. Tooth brushing at school reduced oral health inequalities.

#### 4.2. Weaknesses, strengths and limitations of the study

There were many weaknesses in this study which must not be overlooked when assessing the findings and drawing the overall conclusions. These are discussed in the following paragraphs.

The first issue is the make-up of the control and intervention groups. The control group had younger children and more NonMāori children. Ideally, the intervention and control groups would not differ systematically by any of their sociodemographic or oral health characteristics; such a situation would have been achievable through randomised allocation of children to those groups, but it is not practical to use a randomized controlled design with school tooth brushing, so a quasi-experimental design was used. This resulted in the groups not being identical.

The study did not have participation from every child who could have taken part in the study; both parental consent and child assent were required for every child to join the study. Not all consent forms issued were returned. Evaluation feedback from the supervisor showed that there were issues with filling in the lengthy consent form. This may have been the primary reason for some children not returning forms and taking part in the study. Some of the children were also absent on the days when the data were collected. The research team attempted to minimise

this by having multiple days of data collection at each school; however, some children were absent from school on all days allocated to data collection. Long-term absence was controlled for in the intervention school because the research supervisor took note of whether any children were away from school for more than one month, and they were excluded from the study. This did not happen in the control group schools; it was assumed that, if a child was absent from school, his/her home oral hygiene habits would remain the same.

The study's targeting of highly deprived schools has meant that a comparison by deprivation was limited. The sample included very few children in the medium and low deprivation groups, and so no statistically significant differences were detected by deprivation. This may mean that the study's findings are not generalisable to other children in Northland or other regions of New Zealand.

This study did not use blinding. The children who were participating in the tooth brushing programme knew they were in the intervention group, and those in the control group (who were not involved in daily brushing) were aware of that. The examiner was not blinded to which children were allocated to the intervention and control group. The latter could have led to examiner bias when recording the clinical data. This would have affected ICDAS demineralisation scores predominantly on anterior teeth, and on the buccal, lingual and occlusal surfaces of posterior teeth. Since bitewing radiographs were used to adjust caries data for the other surfaces—and the radiograph reader was unaware of the child's group (control or intervention) at the time of radiograph reading—these would not have differed.

All data were recorded manually, then transferred to an Excel spreadsheet. This double handling of data could have led to some transfer of information errors on the spread sheet. If data were missing from the data-set, a second research assistant checked the record manually and reentered data, to minimise errors. Accordingly, the risk of error from data mishandling is likely to have been very low.

Many of the children who were in the sample presented in the mixed dentition. Since some primary teeth exfoliated between baseline and follow-up, the eruption of new sound permanent teeth and the exfoliation of primary teeth may have resulted in some apparent improvements in dental caries outcomes that would not have been due to the intervention. This could create an incorrect change in caries data collected. The control group had younger participants with

more primary teeth at baseline, than the intervention group, which would mean the 'exfoliation effect' is more likely to have affected the control group, giving them an untrue 'improvement' in their caries data over the time of the study. However, this would have applied only to the cross-sectional comparison at follow-up; the surface-level determination of caries increment between baseline and follow-up was limited to teeth in the same dentition, and so this is unlikely to have been an issue in the final analysis.

There are some identifiable strengths which need to be acknowledged; these are discussed in the following paragraphs.

A particular strength of this study was the comprehensive nature of the data collected. The clinical and survey data allowed an in-depth analysis of all aspects of the running of a supervised tooth brushing programme in New Zealand, including the clinical efficacy and cost-effectiveness of the programme, along with its impact on OHRQoL.

An additional strength was that there was only one examiner involved in collecting the data. This means there was no need for inter-examiner calibration, and errors arising from using more than one examiner were eliminated.

A power calculation confirmed that the study required a sample size of 104 children, with 52 in each group. The number of children finally recruited and who participated at baseline was nearly three times this original number and so there was ample statistical power.

The follow-up rate of 72% after one year is a strength. It is comparable to those in other longitudinal studies investigating supervised tooth brushing programmes (Rong *et al*, 2003; Jackson *et al*, 2005; Sitthisettapong *et al*, 2012). Rong *et al* had a two-year tooth brushing study with preschool children in China with a follow-up rate of 70% (Rong *et al*, 2003). In a 20-month tooth brushing trial for primary school children in London, a follow-up rate of 72% was obtained (Jackson *et al*, 2005), and a tooth brushing trial with Thai preschoolers had a follow-up rate of 77% after one year (Sitthisettapong *et al*, 2012). In an ideal situation, there would have been a full baseline cohort available at follow-up. People who are from high deprived communities frequently change residences and are more prone to high attrition rates when included in studies (Bjerkeset *et al*, 2009; Tambs *et al*, 2009; Gustavon *et al*, 2012). The attrition analysis showed that the children who were lost to follow-up had poorer oral health

and OHRQoL. The loss to follow-up affected both groups equally, with a similar number lost from the control group (N = 46) and the intervention group (N = 49).

The use of the ICDAS caries detection index was another strength of the study. Although time-consuming to use in the field, the index allowed a more sensitive analysis of caries status change, which meant that a smaller number of participants were required to detect any change. The traditional World Health Organization caries approach using a DMF index is acceptable for studies conducted over a longer period, but a relatively short 1-year follow-up study of an anti-caries agent requires a system which is much more sensitive to change.

Baseline and follow-up repeat clinical examinations showed excellent intra-examiner reliability (0.85 and 0.91 respectively) which is more than acceptable when undertaking ICDAS scoring. A German study involving preschool children using ICDAS considered an intra-examiner reliability score of 0.86 to be 'near perfect' (Winter *et al*, 2016).

A main limitation of this study was that it only showed a short snapshot (albeit longitudinal) of a sample of children with a high caries experience in a non-fluoridated, highly deprived region, which cannot be generalised to the rest of New Zealand. A larger sample with good representation of all sociodemographic and ethnic groups with some exposure to community water fluoridation would allow generalisability to other regions around New Zealand.

#### 4.3. The study findings

#### 4.3.1. Sociodemographic characteristics

The final baseline sample consisted of 335 children from 5 Northland Intermediate schools. The sample's representativeness is important when assessing the quality of this study. There were approximately similar numbers of males and females in the control and intervention groups. The children's ages ranged between 10 and 13 years old, which is the standard age expected for those school year groups. Two-thirds were Māori children. Census data from 2013 reported that the overall Māori population for young people in Northland was approximately one-third (34.6%). The study sample had nearly two times the proportion of Māori children, indicating that they were significantly over-represented in the sample. Moreover, the latest Census statistics for the Northland population show that 63.0% reside in areas of high deprivation. The study sample had more than three-quarters (77.8%) of children living in areas of high deprivation. This again indicates that the sample over-represented the most highly-

deprived areas<sup>7</sup>. Since schools chosen for the programme were in Kaitaia, Kaikohe, Dargaville, Bream Bay and Raurimu, the sample would be expected to have more Māori children and those who were living in areas of high deprivation.

The control group and the intervention group were similar in terms of sex, but the control group had a significantly larger proportion of younger children than in the intervention group, because only year 7 children were recruited from Dargaville Intermediate for the study.

#### 4.3.2. Dental caries

The study findings show statistically significantly improved caries outcomes after one year for children involved in a supervised tooth brushing programme. It is the first New Zealand study to demonstrate such a difference. It also reinforces findings from overseas studies which show improved caries outcomes following supervised tooth brushing programmes (Curnow *et al*, 2002; Twetman *et al*, 2003; Rong *et al*, 2003; Jackson *et al*, 2005; Al-Jundi *et al*, 2006; Macpherson *et al*, 2013; de Silva *et al*, 2016; Wolff *et al*, 2016).

It is difficult to compare the specific caries findings (whether ICDAS or DMF) from this study to those from other studies. There are no New Zealand studies to date (the author is aware of) that have reported caries data at the ICDAS level, or which have examined a tooth brushing intervention using any caries index. International tooth brushing studies predominantly include younger children with very different SES and caries experience profiles. They have also used substantially different methods, measures and analyses. The two measures used (ICDAS and DMF) to measure changes in caries, will be discussed in the following sections.

#### 4.3.2.1. ICDAS

The ICDAS index was a suitable index for this intervention study. The index has provided the sensitivity necessary to detect any important changes in caries in the children's dentition. The ICDAS has the ability to distinguish the continuum of disease at the non-cavitated level; it represents lesion progression stages in enamel, not relying on surface cavitation before caries can be diagnosed. It has been thoroughly tested and shown to be valid, reliable and predictable (ICDAS Co-ordinating Committee, 2009; Banting *et al*, 2012).

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<sup>&</sup>lt;sup>7</sup>www.stats.govt.nz

At baseline, the control group children had significantly more permanent tooth surfaces categorised as sound or with a demineralised lesion than did the intervention group. Net caries increment was used because this gives the true surface-by-surface comparison of baseline and follow-up data minus any reversals which can compensate for the effect of the examiner (Hawkins *et al*, 1997; Broadbent and Thomson, 2005). Caries incidence uses 1 or more newly affected surfaces to define an incident case. It allows for a simple broad picture and is reported as a percentage. However, it does not distinguish between individuals who experience only one caries event and those who experience multiple events (Broadbent and Thomson, 2005). Used together, the measures increment and incidence provide a useful overall picture of dental caries experience over a given period.

Caries data collected at follow-up showed a highly significant improvement in caries increment and incidence, both overall and for all surfaces in the children who were tooth brushing when the ICDAS criteria (demineralisation; ICDAS 1 and 2) were used. The children in the tooth brushing group had a mean 11.7 surfaces which improved, while the children who were not brushing had a mean 8.6 surfaces which deteriorated over the year. Thus, the net mean difference between the groups was 20.3 surfaces. The greatest improvement was seen in smooth surfaces and facial surfaces, which are the surfaces with which the toothbrush and paste come in to contact, and so this would be expected. It is likely that the magnitude of these differences would have been under-estimated had the ICDAS index not been used in this study. It also enabled more nuanced documentation of enamel changes and accounting for the many reversals seen in the tooth brushing group, such as a ICDAS 1 or 2 reversing to an ICDAS 0 (sound surface). Nearly three-quarters (71.5%) of the control children experienced new carious lesions. This was significantly greater than the 7.3% observed in the tooth brushing group. Thus, both the increment and incidence of dental caries were considerably greater among those who were not in the tooth brushing group.

Overall, data from international tooth brushing studies show an improvement in dental caries experience for children (Curnow *et al*, 2002; Rong *et al*, 2003; Twetman *et al*, 2003; Jackson *et al*, 2005; Al-Jundi *et al*, 2006; Macpherson *et al*, 2013; de Silva *et al*, 2016; Wolff *et al*, 2016). The caries increment data from tooth brushing studies using the ICDAS are hard to compare because these studies have different samples, with different caries experience and different methods. The few studies that have been conducted using ICDAS with preventive interventions have shown mixed findings (Hilgert *et al*, 2015). There has been only one study

of a supervised tooth brushing programme which used the ICDAS as the index for caries measurement. It was investigated whether there was any benefit of using a 10% CPP-ACP paste for 296 high caries-risk preschoolers in a non-fluoridated area near Bangkok, Thailand. It found that, after one year, there was no benefit on top of the supervised tooth brushing of applying the 10% CPP-ACP paste. All children had an increase in enamel and dentine lesions (ICDAS criteria) and dmfs, with a mean increment of approximately 4 surfaces. The mean baseline dmfs of these children was 9.1, reinforcing that a tooth brushing intervention with fluoride toothpaste in this very high caries group of children did not improve their oral health. However, the level of supervision of the brushing was questionable, and this may have affected the findings (Sitthisettapong *et al*, 2012).

In the current study, the multivariate analysis showed that the only significant predictor of net caries increment was whether the child was in the control or intervention group. By undertaking a simple tooth brushing programme daily at school, the effect of common sociodemographic characteristics (ethnicity and deprivation) that are associated with greater caries experience appeared to have been removed. It is noteworthy that lower inequalities have also been observed in New Zealand children with access to community water fluoridation. Communities with community water fluoridation have a 40% lower dental caries experience than nonfluoridated areas (Ministry of Health, 2010). In the current study, children with higher experience of caries at baseline had the same net caries increment (improvement) as those who were NonMāori or who live in low deprivation areas, but only if they were in the tooth brushing group. This means that the tooth brushing intervention appeared to reduce inequalities, which is one of the main objectives of current Ministry of Health Policy, as seen in the New Zealand Health Strategy.

The ICDAS index data were also able to be collapsed into traditional DMFS and DMFT measures. A surface classified as an ICDAS 3 (micro-cavitated) was considered to be a D surface. This made it consistent with the existing literature (ICDAS Co-ordinating Committee, 2009). The DMFS and DMFT indices are more frequently used to measure and report dental caries experience in clinical and epidemiological studies (World Health Organization, 2013). They allow comparison of the current study's findings with other international literature on tooth brushing programmes.

#### 4.3.2.2. Decayed, missing and filled

The caries data after one year showed a significantly lower DMFS increment for the tooth brushing group (a mean of 1.0 surfaces) than in the control group (a mean of 0.2 surfaces) showing that one year of supervised tooth brushing had a positive effect on DMFS scores. That is the effect was even detectable using the conventional DMF approach.

These findings are similar to those from other studies with an improvement in DMF/dmf following a supervised tooth brushing programme. In one such programme in a group of high caries-risk Dundee children, the 2-year mean DMFS caries increment on first permanent molars was 0.8, but was 1.2 for children who were not brushing. The authors concluded that high-caries-risk children in their supervised tooth brushing programme with fluoridated toothpaste had significantly lower caries experience after 2 years (Curnow *et al*, 2002). A tooth brushing programme over 2 years with 3,706 preschool children in Thailand found dmfs increments of 0.4 and 0.3 (respectively) in the control and intervention schools (Petersen *et al*, 2015). These studies did not use a paid supervisor in schools to carry out the tooth brushing with students every day. Instead, school staff were relied upon to deliver the tooth brushing programme, and so it may have meant that brushing was intermittent or did not occur every day, with a smaller difference observed between the groups.

The multivariate analysis showed that group (control or intervention) was almost significant for net caries increment for DMFS categories (p=0.053) with no other variables predicting DMFS increment. Even when using an index that is less sensitive than the ICDAS, a near significant finding was found with the tooth brushing programme for a reduction in net caries increment.

In the current study, the intervention and control groups both had an apparent lower DMFS at follow-up. This overall improvement could be attributed to the fact that primary teeth were exfoliating over the year and being replaced with new permanent teeth, which are caries-free. Because the control group were younger (and had more primary teeth at baseline), this 'exfoliation effect' is likely to have contributed to an apparent improvement in DMFS in the control children to a greater extent than the intervention group. This would have favoured the null hypothesis (that is, reduced the difference between the groups).

The DMFS incidence data are particularly interesting, and meaningful. At the point of cavitation, a traditional 'treatment' intervention is required for a surface. The control group had twice as many children (27.7%) presenting with a new case of caries at the cavitated stage (1+DMFS). A cost-benefit analysis would aid in converting these numbers into an associated cost to treat, to assess the cost benefit of a tooth brushing intervention, versus treating these teeth (and the future burden of restorative treatment). Such analysis is beyond the scope of this thesis but is planned. Internationally, large-scale brushing programmes have found a considerable cost-benefit ratio in providing supervised tooth brushing on a large scale (Anopa *et al*, 2015).

#### 4.3.3. Oral health-related quality of life

This is the first study to show that an overall improvement in OHRQoL can occur in children who take part in a supervised tooth brushing programme. This reinforces the need for policy to consider other approaches to improve children's oral health in communities that experience high caries and poor oral health.

The CPQ<sub>11-14</sub> measure is an index for measuring OHRQoL in 11-14-year-old children which has been validated and tested for reliability (Jokovic *et al*, 2006; Foster Page *et al*, 2008). It was used in this study to determine whether a supervised tooth brushing programme also improved OHRQoL. The short-form CPQ<sub>11-14</sub> was used which has been validated in this age group in New Zealand before (Foster Page *et al*, 2005; Foster Page *et al*, 2008; Foster Page *et al*, 2010; Foster Page *et al*, 2011; Foster Page *et al*, 2013; Foster Page *et al*, 2014; Thomson *et al*, 2016), and the measure has previously performed well in a predominantly Māori Northland population with high caries experience (Foster Page *et al*, 2011).

Confirmatory factor analysis of the CPQ<sub>11-14</sub> in an international collaboration involving multiple studies has shown that there appear to be two main factors, with the four domains falling into two underlying factors (constructs): the 'symptoms/function' subscale and the 'well-being' subscale. That secondary cross-sectional analysis of the CPQ<sub>11-14</sub> using data from Australia, New Zealand, Brunei, Cambodia, Hong Kong, Malaysia, England, Thailand, Germany, Mexico and Brazil found that the measure performed well, with robust and mostly consistent psychometric characteristics (Thomson *et al*, 2016). Accordingly, the analysis for the current study involved two domains, rather than the four conventional domains.

The two-factor CPQ measure was found to be valid when assessing the CPQ<sub>11-14</sub> domains against the global measures in the current study. The overall CPQ and domains had higher mean scores in those who reported poorer oral health. Overall mean scale score differences were the same for impact on quality of life and self-rated oral health. The measure was found to be reliable, with baseline Cronbach's alpha values of 0.80, 0.62 and 0.75 for the CPQ<sub>11-14</sub>, symptoms and well-being constructs, respectively, and, at follow-up they were 0.82, 0.59 and 0.68, respectively. This confirmed the substantial internal consistency reliability of the overall CPQ<sub>11-14</sub>, although the symptoms domain was not as high as the well-being domain. These values fall within an acceptable range, with a value of 0.70 being considered acceptable in most studies (Tavakol and Dennick, 2011). Test-retest reliability was undertaken on over 10% of the sample at baseline and follow-up. The intra-class correlation coefficient was found to be 0.84 and 0.90 at baseline and follow up respectively, indicating excellent reliability and showing that the measure yielded similar values under the same conditions in the same individuals.

There have been many cross-sectional studies confirming the psychometric properties of the short-form CPQ internationally investigating different oral health conditions (Jokovic *et al*, 2002; Marshman *et al*, 2005; Li *et al*, 2008; Foster Page *et al*, 2013; Nunez *et al*, 2015; Kumar *et al*, 2016; Healey *et al*, 2016; Feldens *et al*, 2016). This study has also contributed to this work with the mean baseline CPQ<sub>11-14</sub> score of 13.1 from this study higher, but consistent with other New Zealand studies. A Northland study of 187 12-to-13-year-old children in 2008 found the children to have a mean CPQ<sub>11-14</sub> score of 11.5 (Foster Page *et al*, 2011). An earlier study involving Taranaki adolescents (age 13) had a CPQ<sub>11-14</sub> total of 9.6 (Foster Page *et al*, 2010). These samples included older children which may have reflected why they reported a lower score. Other studies have reported lower overall mean scores in younger children as it appears that scores may reduce slightly with age, given that a study using the CPQ<sub>11-14</sub> measure with 6 to 9-year-old Dunedin children had a mean CPQ total of 11.7 (Foster Page *et al*, 2014).

To date, there have been few studies reporting on the CPQ's evaluative properties, and none investigating whether a supervised tooth brushing programme impacts on children's OHRQoL. The CPQ is responsive to change with significant improvements seen in OHRQoL following comprehensive dental treatment under general anaesthetic, the parental-caregiver CPQ was used in these studies as children were too young to respond on their own (Malden *et al*, 2007; Jankauskiene *et al*, 2014; *Rane et al* 2017). An overall large effect size (0.9) was seen in OHRQoL in Wellington children following general anaesthetic dental care (Malden *et al*,

2007). Basic dental treatment in Cambodian children has also been shown to improve OHRQoL, with a small effect size found following care (Turton *et al*, 2014).

This study showed an overall improvement in mean CPQ and domain scores for all of the children. The change was greatest for those in the intervention group (moderate effect size vs small). Māori children reported a larger improvement in CPQ<sub>11-14</sub> overall, and had a greater improvement in the 'symptoms' domain than NonMāori. Children in the low deprivation group were the only ones to have mean OHRQoL deteriorate from baseline to follow-up. The effect size was moderate, but, due to the small sample size (only 9 in the group), the difference was not statistically significant. The CPQ was found to be a responsive measure and was able to detect a change from a tooth brushing intervention. It showed that children's OHRQoL improved significantly with a simple 2-minute supervised brushing programme at school.

There was also an improvement in OHRQoL in the control group. This could be attributed to the Hawthorne effect; that is, children who knew they were part of a study could have altered their responses due to their awareness of being in it. The attrition analysis also showed that children with poorer oral health dropped out of the study, and this would have contributed somewhat to the apparent improvement in quality of life overall for both the control group and the intervention group.

#### 4.3.4. Self-reported oral hygiene

The self-reported oral hygiene questions demonstrated that there were no significant differences between groups (control and intervention) reported at baseline for owning a tooth brush and flossing related questions. Younger children and NonMāori children reported that they had dental floss at home and used it more frequently than older children and Māori children. More NonMāori children reported brushing their teeth twice per day. The number of children who reported brushing their teeth twice per day (52.2%) is lower than the 2009 New Zealand National Oral Health Survey, which found that 63.5% of children and adolescents aged 2–17 years brushed their teeth at least twice per day (Ministry of Health, 2010). Because the sample of children in this study are from one of the most deprived areas of New Zealand, with a higher-than-average burden of disease, it would be expected (as found) that the proportion of children brushing their teeth twice per day was below the national average.

Other national surveys have reported different responses to brushing frequency, with 80.7% of 12-year-old Hong Kong children reporting that they brush their teeth twice per day (Department of Oral Health, 2011), while, in China, only 44.4% of the respondents brushed their teeth at least twice a day with only 17% using fluoridated toothpaste (Zhu *et al*, 2003). The most recent Australian National Child Oral Health Survey reported similar findings to New Zealand with on average 67.8% of 11 and 12-year-old children who brush their teeth twice per day with toothpaste. Of those brushing a difference between Indigenous and NonIndigenous children was found with only 44.8% of Indigenous children and 69.3% of NonIndigenous children reporting brushing their teeth twice per day (Do and Spencer, 2016). This is not to dissimilar to the findings in the current study, in which showed 70.8% of NonMāori and only 43.0% of Māori children reported brushing their teeth twice or more per day. This highlights the need to focus on improving brushing frequency among indigenous children, regardless of country.

#### 4.3.5. Evaluation and sustainability of the tooth brushing programme

Overall, the supervised tooth brushing programme was a success. Tooth brushing for 2 minutes each day became a part of the school routine. Teachers appreciated the assistance from the supervisor, and commented that it often brought the children back in from break times and was an activity to get their minds back on task. The feedback from the evaluation forms was that the research supervisor was happy with the way the programme was running. Brushing was going well in class and the children were rinsing their brushes with the water fountains after they had finished cleaning their teeth. The research supervisor requested more frequent changes of brushes, because they were going mouldy during the school holidays, so these were replaced every term (four times per school year). The research supervisor also requested additional oral hygiene instruction and support onsite from a registered dental therapist. Since education sessions were not part of the intervention, this was unable to be provided outside of the regular visits made by a dental therapist on site. School teaching staff were all very positive about the way the programme was running. Tooth brushing was reported not to impact on learning time in the classroom. Minor changes were constantly made to ensure the trial was running smoothly.

A key issue found with previous tooth brushing programmes and pilot projects has been their sustainability. The earlier attempts in Northland reported a high level of school and classroom drop-out rate, with associated sustainability issues (Ali and Dones, 2013; Gowda, 2011). In the

current study, there was funding available for the tooth brushing supervisor to conduct sessions on a daily basis, there was no issue with the programme ceasing due to a lack of enthusiasm. Tooth brushing became a part of the daily school routine. Supplies (such as tooth paste, brushes and paper towels) were readily accessible. There was also no reliance on commercial sponsorship or gifting of supplies. The supervisor maintained close contact with both staff at the school and researchers so that the programme continued, and stock was ordered in a timely fashion. These were crucial factors which substantially contributed to the success and sustainability of this programme.

#### 4.4. Future research

The data from this longitudinal study of a snapshot of a Northland tooth brushing trial are an important contribution, both internationally and to New Zealand. A full cost-benefit analysis has not yet been completed but will be undertaken in the future to ascertain whether a supervised tooth brushing intervention in schools outweighs the cost and burden of treating carious lesions.

Data from the second year of this trial will require analysis in a similar fashion to determine whether two years of brushing has an additive effect on the prevention of dental caries and improvement has in OHRQoL. Further tooth brushing studies in high caries groups in different regions of New Zealand would be beneficial to add weight to the evidence for improving oral health, from such interventions.

#### 4.5. Conclusion

The aim of this study—to improve the oral health of Northland children—has been successfully achieved with a supervised tooth brushing programme. This programme has been the first large-scale, fully evaluated tooth brushing programme to be set up and run successfully in New Zealand. The sample of children chosen to take part in the study are some of those who experience the greatest burden of disease in the country, and they have shown improved oral health. The OHRQoL and clinical caries data show that there has been a significant improvement in the children who participated in the tooth brushing programme; thus, even if the programme is not continued, it would have made a difference to children who were able to participate. The sample is generalisable to some populations of New Zealand children in deprived areas, and so the data and methods can be used to implement similar programmes.

The aims have kept in line with key policy documents to reduce inequalities in highly deprived communities. The outcome (demonstrated by the caries data and OHRQoL data) is consistent with the main goals of current Ministry of Health Policy, in which the reduction of inequalities is a main focus (The New Zealand Health Strategy: Future Direction, 2016). The data from this study will be able to be used by policy-makers and health service stakeholders to implement oral health programmes that are able to improve health outcomes and reduce inequalities. This is the first study to show an improvement in OHRQoL for children participating in a one-year tooth brushing intervention. Further analysis of the data and future studies will contribute to the collection of international data available on large scale interventions to improve oral health for children.

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## **APPENDICES**

#### **Appendix I: Regional Ethical Approval**



#### Locality Assessment by Northland District Health Board

Locality Assessment No: 2014-29

#### Locality Assessment Sign Off

All research conducted in the Northland DHB must be conducted with the knowledge of the Northland DHB, and must meet all the requirements of the Health & Disability Ethics Committees (HDECs), though not all research will require HDEC review.

A locality assessment must be undertaken to review all research conducted at Northland District Health Board. Locality Assessments will consider resource implications, suitability of the local researcher and research environment, and cultural issues.

Part One: General

Full project title: Supervised toothbrushing trial in Northland intermediate schools

Short project title: Supervised toothbrushing trial in Northland intermediate schools

Locality to be assessed: Northland

Brief outline of study:

thland

There are still clear inequalities in the oral health of New Zealanders, with Māori and low socio-economic families experiencing a high proportion of oral disease, mainly dental decay. The Northland population has high proportions of Māori and low socioeconomic status people; dental disease rates in children in Northland, which has no fluoridated water supply, are the highest in the country. Tooth brushing with fluoride toothpaste reduces the incidence of dental decay significantly. Moreover, calcium compounds and arginine added to toothpaste are more effective than toothpaste with fluoride alone. Studies supervising children to brush in schools have shown measurable improvements in oral health, including a pilot study in Northland. A larger scale study is needed to reach more children and to examine the feasibility of tooth brushing interventions throughout New Zealand.

The proposed research is a supervised tooth brushing trial of Intermediate-aged school children in Northland with high caries experience. All children will undergo routine dental examinations at the beginning of the study. Children will be allocated to two different toothpaste treatments (1450ppm fluoride toothpaste alone, or arginine, calcium and 1450ppm fluoride toothpaste) and have a supervised brushing session each school day. Examinations will be repeated annually until they complete Intermediate school. Data will be collected to analyse oral health outcomes, and the relative cost of this programme against the current model of treating dental disease. Data will also show which treatment is more effective for a population suffering from high levels of dental disease.

Principal investigator (for this locality):

Dr Ellen Clark, Community Dentist

# NORTHLAND DISTRICT HEALTH BOARD Te Poari Hauora & Rohe O Te Tul Tokerau





Contact details:			Oral Health Services, Northland District Health Board Email: ellen.johnson@northlanddhb.org.nz Tel: 021 816938					
Other local investigators (list all at this site):			Dr Lyndie Foster Page, Senior Lecturer Professor Murray Thomson, Professor of Dental Epidemiology Shareen Ali, Oral Health Promotion Advisor					
Contact details:			(See application)					
Part	t Two: Loc	cality Issues						
Iden	tify any loca	l issues and specify how t	hese issues will be addressed.					
1,	Suitability of local researcher							
	For example, are all roles for the investigator(s) at the local site appropriate  (for example, has any conflict the investigator might have between her or his local roles in research and in patient care been adequately resolved)?							
2.	Suitability of the local research environment							
	Are all the resources (other than funding that is conditional on ethical approval) and/or facilities that the study requires appropriate and available (for example, is staffing adequate? Is this site accessible for mobility-impaired people where necessary)?							
		ve all potentially affected cords or laboratory manag	managers of resources such as ci ers been notified?	inical	Yes	No		
3.		ave issues such as cultural issues specific to this locality or to eople being recruited at this locality been addressed?						
4.	Have the local investigator contact details and other important ves No							
Part	Three: De	eclaration by locality	organisation					
locati	ty approval		val on behalf of this locality organ cerns arise. I agree to advise the					
			demnity insurance to compensate Rehabilitation and Compensatio		for harm that does not qual	fy for		
Signa	ture:	M. Koe	Js.	Date:	11/9/14			
Name	к	Dr Michael Roberts		Position:	Chief Medical Officer			
Conta	ct details:	ct details: Northland District Health Board, Private Bag 9742, Whangarei 0148						
N D-H	0 Locali	ty Assessment			7.11	12		

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12 September 2014

To Whom It May Concern

Re: Short Project Title:

Supervised tooth brushing trial in Northland intermediate schools

This letter is to confirm the Kaunihera Kaumatua have expressed approval through the Locality Assessment process for the above study.

This study was approved on 12 September 2014 under Reference No. 2014-29

Yours faithfully

PP Kim A Tito Cenaral Margor Marin Meath

# Appendix II: Parent Information, consent form and child assent for intervention participant

## **Participant Information Sheet - Parent**



Study title: Northland Tooth brushing Project

Locality: Northland District Health Board Ethics committee ref.:

Investigator: Ellen Clark Contact phone number: 021 816938

You and your child are invited to take part in a study about tooth brushing in school. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care your child receives. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you and your child decide if you'd like to take part. It sets out why we are doing the study, what your joining in would involve, and answers any questions you may have. You do not have to decide today whether or not you will take part in this study. Before you decide you may want to talk about the study with other people, such as family, friends, or your dental therapist. Feel free to do this.

If you and your child agree to take part in this study, you will be asked to sign the Consent Form on the second last page of this document, and your child will be asked to complete the assent form on the last page of this document. A copy of both the Participant Information Sheet and the Consent Form will be kept in your child's file and you can read this again at any time.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

#### WHAT IS THE PURPOSE OF THE STUDY?

Tooth decay is a really common problem. Tooth brushing with fluoride toothpaste is the most effective activity we can do to prevent tooth decay. If decay is prevented, there is less need for fillings or for your child to experience pain from their teeth.

This study will measure how effective an in school tooth brushing program can be, we will be using two types of toothpaste for your child to use.

We aim to have about 300 Intermediate school children from two different schools involved in the study. These children will have a dental check-up with x-ray pictures taken as usual, at their regular yearly appointments, through the Northland District Health Board. There are questionnaires for the children to fill-in to help us understand how dental health and dental care impacts on them. All children in the study will still receive their normal dental care (including check ups, x-rays, prevention and any other treatment needed) from the dental clinic as usual.

#### WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Your child will start by answering a questionnaire, which takes about 10 minutes, as we want your child to tell us how your child's teeth affect them. They will then have their teeth checked with x-rays at the school dental clinic like a normal dental check-up.

If you and your child are happy to participate in the study, your child will be placed into a toothpaste group (red or green). One group will be given toothpaste with 1450ppm fluoride toothpaste alone and the other group with arginine, calcium and 1450ppm fluoride toothpaste respectively. These two different toothpastes are available at the supermarket and are both very effective at preventing tooth decay. Your child will be given a tube of toothpaste to take home, and one to use at school and two toothbrushes, one for at home and one for at school. The toothbrush to be used at school will have a cap to place over the top of it between uses.

Your child will take part in tooth brushing each day at school, the time this happens will be decided by your child's classroom teacher. There will be a supervisor who will help to assist the teacher with the tooth brushing sessions in class.

We want to see your child again each year for their dental check ups. You may get reminders about this. We will also get your child to answer a questionnaire about how they feel about their teeth. We will need to know if you move schools or homes because we need to stay in touch with you. You or your child can ask us questions at any time. One of the research team can help your child with the questionnaire if needed.

If you are happy to take part then you will fill out a consent form, and if your child is happy to take part they will fill out the assent form. You will be given a copy of the form you fill in to keep.

#### WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

This study will help to show clearly how well tooth brushing in schools prevents tooth decay.

In all dental care there is a risk that things used in the mouth may be accidentally swallowed or breathed in, and this risk is lowered as we have a trained supervisor who will help in class to supervise the tooth brushing.

Children will still get the same dental care in all other ways, including preventive care and advice, x-ray pictures, check-ups, and emergency care visits.

#### WHO PAYS FOR THE STUDY?

This study is being paid for by a grant from The Ministry of Health Dental Research fund. The Northland District Health Board are providing the staff and clinics for the dental care.

#### WHAT ARE MY RIGHTS?

You and your child don't have to take part in the study if you do not want to, and if you choose not to take part your child will still have the dental care you usually do. You can

change your mind at any time. If you are worried about anything, please call in to the dental clinic or phone us for a talk. An interpreter can help if needed.

Any information you give us will be only seen by the dentists and the researchers, and information will be stored carefully by the researchers for 10 years. Study findings will be shared in talks and findings will be written in papers for sharing in scientific journals, but noone will be told which children and their caregivers took part. If you would like a copy of the findings please tell us. The researchers will inform participant's GPs of their involvement in the study.

#### **Ethical Approval**

This study is approved by the Northern B Ethics Committee.

#### WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can

contact: Dr Ellen Clark, Community Dentist

**Community Dentist** 

Northland District Health Board

Tel: 021 816 938

Email: ellen.johnson@northlanddhb.org.nz

or

Dr Lyndie Foster Page,

Specialist in Community Dentistry,

University of Otago Tel: 03 479 5853

Email: lyndie.fosterpage@otago.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050

Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@hdc.org.nz

For Māori health support please contact:

Linda Grennell at 0800 377 766.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS Email: hdecs@moh.govt.nz

## **Consent Form**



## If you need an INTERPRETER, please tell us.

## Please tick to indicate you consent to the following

I understand that taking part in this study is voluntary (my choice) and that I may come out of the study at any time without this affecting my medical care.	Yes □	No □						
I consent to the research staff collecting and processing my information, including information about my child's health.	Yes □	No □						
If I decide to withdraw from the study, I agree that the information collected about me and my child up to the point when I withdraw may still be used	Yes □	No □						
I understand that my joining in this study is confidential and that no material, which could identify me or my child personally, will be used in any reports on this study.	Yes □	No □						
I know whom to contact if I have any questions about the study in general.	Yes □	No □						
I wish to receive a summary of the results from the study.	Yes □	No □						
I wish my General Medical Practitioner to receive information.	Yes □	No □						
Please advise us the name and address of your General	Medical	Practitioner						
Parent/Caregiver Consent	4141							
I hereby consent to take part in this study. I have read and understood the information sheet and have had time to decide if I want to take part, and to ask any questions and have had these answered. If I decide to withdraw from the study I know I can do so at any time.								
Child Participant's name:								
Parent/Caregiver name:								
Parent/caregiver signature: Date	<b>)</b> :							

## Child Assent

## **Northland Tooth brushing Study**

arginine and calcium.

eth

the toothpaste you can buy from the supermarket. One g toothpaste with 1450 parts per million fluoride and the the paste with the same amount of fluoride in it as well as

We know both of the toothpastes work, but we don't know which one is better than the other, which is why we are asking you to help by joining in a project to test which toothpaste is better. We are excited about our Northland children having healthy teeth.



If it is an easy way to prevent tooth decay why have we not tried it before? We have run small tooth brushing projects in Northland schools before, but we have not previously had someone to help come into classrooms, and we have not run the project for very long.

## Joining in our study

Will you join in?

If you join in our study then you will brush your teeth at school each day with your classmates. You will be asked what you thought about it and what you think about your teeth, you will also have your normal dental check each year. Do you have any questions about it? You can ask the dentist or helper any questions. You don't have to join in if you don't want to.

, 3			
If you want to join in please tick the box below	and then write your full name here:		
Yes I would like to be a part of the study			
No I don't want to be a part of the study			
Declaration by member of research team:			
have given a verbal explanation of the research project to the participant, and have answered ne participant's questions about it.			
I believe that the participant understands the participate.	study and has given informed consent to		
Researcher's name:			
Signature:	Date:		

### Appendix III: Parent Information, consent form and child assent for control participant

### Participant Information Sheet - Parent



Study title: Northland Oral Health Project

Locality: Northland District Health Board Ethics committee ref.:

Investigator: Ellen Clark Contact phone number: 021 816938

You and your child are invited to take part in a study about how your child feels about their teeth, and if dental education in schools works to prevent tooth decay. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care your child receives. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you and your child decide if you'd like to take part. It sets out why we are doing the study, what your joining in would involve, and answers any questions you may have. You do not have to decide today whether or not you will take part in this study. Before you decide you may want to talk about the study with other people, such as family, friends, or your dental therapist. Feel free to do this.

If you and your child agree to take part in this study, you will be asked to sign the Consent Form on the second last page of this document, and your child will be asked to complete the assent form on the last page of this document. A copy of both the Participant Information Sheet and the Consent Form will be kept in your child's file and you can read this again at any time.

This document is 5 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

#### WHAT IS THE PURPOSE OF THE STUDY?

Tooth decay is a really common problem. There are lots of ways to prevent tooth decay, and tooth brushing with fluoride toothpaste is the most effective activity we can do to prevent tooth decay. If decay is prevented, there is less need for fillings or for your child to experience pain from their teeth. We want to find out how much your child brushes their teeth, and if what we are currently doing now in Northland makes any difference to their teeth.

We aim to have about 125 Intermediate school children from your child's school involved in the study. These children will have a dental check-up with x-ray pictures taken as usual, at their regular yearly appointments, through the Northland District Health Board. There are questionnaires for the children to fill-in to help us understand how their teeth and dental care impacts on them. All children in this study will still receive routine dental care (check ups, x-rays, prevention and any other treatment needed) from the dental clinic as usual.

#### WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Your child will start by answering a questionnaire, which takes about 10 minutes, as we want your child to tell us how your child's teeth affect them. They will then have their teeth checked with x-rays at the school dental clinic like a normal dental check-up.

If you and your child are happy to participate in the study, your child will have their check up, and fill in the questionnaire. They will also receive a toothbrush and toothpaste to take home to brush with.

We want to see your child again each year for their dental check ups. You may get reminders about this. We will also get your child to answer another questionnaire about how they feel about their teeth. We will need to know if you move schools or homes because we need to stay in touch with you. You or your child can ask us questions at any time. One of the research team can help your child with the questionnaires if needed.

If you are happy to take part then you will fill out a consent form, and if your child is happy to take part they will fill out the assent form. You will be given a copy of the form you fill in to keep.

#### WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

This study will help to show how oral health affects children's teeth. We want to know if what we are currently doing in Northland is enough to keep your child's teeth healthy.

Children will still get the same dental care in all other ways, including preventive care, advice, x-ray pictures, check-ups, and emergency care visits.

#### WHO PAYS FOR THE STUDY?

This study is being paid for by a grant from The Ministry of Health Dental Research fund. The Northland District Health Board are providing the staff and clinics for the dental care.

#### WHAT ARE MY RIGHTS?

You and your child don't have to take part in the study if you do not want to, and if you choose not to take part your child will still have the dental care you usually do. You can change your mind at any time. If you are worried about anything, please call in to the dental clinic or phone us for a talk. An interpreter can help if needed.

Any information you give us will be only seen by the dentists and the researchers, and information will be stored carefully by the researchers for 10 years. Study findings will be shared in talks and findings will be written in papers for sharing in scientific journals, but no-

one will be told which children and their caregivers took part. If you would like a copy of the findings please tell us. The researchers will inform participant's GPs of their involvement in the study.

### **Ethical Approval**

This study is approved by the Northern B Ethics Committee.

### WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can

contact: Dr Ellen Clark, Community Dentist

Community Dentist

Northland District Health Board

Tel: 021 816 938

Email: ellen.johnson@northlanddhb.org.nz

or

Dr Lyndie Foster Page,

Specialist in Community Dentistry,

University of Otago Tel: 03 479 5853

Email: lyndie.fosterpage@otago.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050

Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@hdc.org.nz

For Māori health support please contact:

Linda Grennell at 0800 377 766.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS Email: hdecs@moh.govt.nz

## **Consent Form**



### If you need an INTERPRETER, please tell us.

Please tick to indicate you consent to the following		
I understand that taking part in this study is voluntary (my choice) and that I may come out of the study at any time without this affecting my medical care.	Yes □	No □
I consent to the research staff collecting and processing my information, including information about my child's health.	Yes □	No □
If I decide to withdraw from the study, I agree that the information collected about me and my child up to the point when I withdraw may still be used	Yes □	No □
I understand that my joining in this study is confidential and that no material, which could identify me or my child personally, will be used in any reports on this study.	Yes □	No □
I know whom to contact if I have any questions about the study in general.	Yes □	No □
I wish to receive a summary of the results from the study.	Yes □	No □
I wish my General Medical Practitioner to receive information.	Yes □	No □
Please advise us the name and address of your General	Medical	Practitioner
Parent/Caregiver Consent		
I hereby consent to take part in this study. I have read and unders sheet and have had time to decide if I want to take part, and to as have had these answered. If I decide to withdraw from the study any time.	sk any qu	estions and
Child Participant's name:		
Parent/Caregiver name:		
Parent/caregiver signature: Dat	e:	

### **Child Assent**

Lots of children in New Zealand get sick teeth because of tooth decay.

We want to find out if what we are doing in Northland now is enough?



We want to find out about how you feel about your teeth and how important they are.

### If you join our study

You will also have your normal dental check each year and fill in some questions asking you about your teeth.

Do you have any questions about it? You can ask the dentist or helper your questions. You don't have to join in if you don't want to

Will you join in?	
If you want to join in plea	ase tick the box below and then write your full name here
Yes I would like to be a p	art of the study
Declaration by member o	f research team
I have given a verbal expla answered the participant's	nation of the research project to the participant, and have questions about it.
I believe that the participan participate.	t understands the study and has given informed consent to
Researcher's name:	
Signature:	Date:

### Appendix IV: ICDAS score sheet

ID Number	
Examiner	

### **ICDAS** examination record

Φ	Upp	er Ri	ght											ι	Jpper	Left
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#### Restoration and Sealant Codes **Caries Codes** 0 = Not sealed or restored Q\_= Sound tooth surface 1 = Sealant, partial 2 = Sealant, full 1,= First visual change in enamel 2 .= Distinct visual change in enamel 3 = Tooth coloured restoration 3 = Enamel breakdown, no dentine visible 4 = Dentinal shadow (not cavitated into dentine) 4 = Amalgam restoration 5 = Stainless steel crown 5.= Distinct cavity with visible dentine 6 = Porcelain, gold, PFM crown or veneer 6 = Extensive distinct cavity with visible dentine 7 = Lost or broken restoration 8 = Temporary restoration Missing Teeth 96 = unable to be scored A 2-digit code should 97 = Extracted due to caries 98 = Missing for other reason be used 99 = Unerupted

### Appendix V: Radiograph score sheet

ID Number	
Examiner	Radiographic record

o)	Upp	er Ri	ght											ι	Jpper	Left
Surface				55	54	53	52	51	61	62	63	64	65			
งั	18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
М																
0						Ĭ	Ĭ	Ĭ	Ţ	Ĭ	Ţ					
D																
В																
L																
<b>©</b>																

ø	Low	er Ri	ght											L	.ower	Left
Surface				85	84	83	82	81	71	72	73	74	75			
Ö	48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38
М																
0						Ţ	Ţ	T	Ţ	Ţ	Ĭ					
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### P scores

- 0, = Sound tooth surface

- 1 = Radiolucency to outer half of enamel
  2 = Radiolucency to inner half of enamel
  3 = Radiolucency extends <0.5mm into dentine
  4 = Radiolucency extends >0.5mm into dentine
- 5 = Radiolucency extends into inner half of Hi dentine

96 = unable to be scored -overlap

97 = SSC present

98 = Missing for other reason

99 = Unerupted

A P code should be used on posterior surfaces

### Appendix VI: Supervisor and staff evaluation form

# Questionnaire for tooth brushing supervisor and staff (6 months, 12months 24 months)

1. Have you enjoyed being part of the project so far?	Yes	No
2. Do you feel you have gained valuable experience from being a part of the project?	Yes	No
Do you think the kids are enjoying being a part of the project?	Yes	No
3. Has the equipment supplied been efficient to carry out daily tooth brushing with the children?	Yes	No
4. Have you had enough education and support to carry out tooth brushing daily with the children?	Yes	No
5. Have you been able to contact the researchers and resolve any issues that have arisen?	Yes	No
6. Are there any changes you would like to see made to help the tooth brushing so run more smoothly?	essions	S
If yes, please explain:		
7. In your opinion is there anything we could do to increase uptake/enthusiasm of students at school to participate?	f the	
If yes, please explain:		
8. Are there any other comments or suggestions you would like to make?		

### Appendix VII: Questionnaire

Questionnaire	Date		Number	
Hello!				
Thank you for helping children feel about the	· · · · · · · · · · · · · · · · · · ·	_	is study to better	understand how
Name				
Class				
School				
Please read carefully e past 3 months regardin We want to know how	ng your teeth, mout			-
Some things to keep in anyone about the questyourself:		•	•	
Does this happen beca describes you in the pa	-	outh, and face?	Choose the ansv	ver that best
1. Do you have a tooth	brush at home?		☐ Yes	□No
2. How often do you b	rush your teeth at h	ome?		
☐ Never ☐ One tin	ne per week 🔲 (	One time per da	y 🔲 Twice or r	more each day
In the past 3 months, I	how often have you	ı had:		
3. Sores in your mouth	?			
☐ Never ☐ Once o	rtwice 🗆 Sometir	mes 🗌 Often	☐ Every day or	almost every day
4. Bad Breath?				
☐ Never ☐ Once o	rtwice 🗆 Sometir	mes 🗆 Often	☐ Every day or	almost every day
5. Food stuck in betwe	en your teeth?			
□ Never □ Once o	rtwice $\square$ Sometin	mes 🗆 Often	☐ Every day or	almost every day

6. Difficulty biting or chewing food like apples, corn on the cob or steak?
$\square$ Never $\square$ Once or twice $\square$ Sometimes $\square$ Often $\square$ Every day or almost every day
7. Difficult to drink or eat hot or cold foods?
$\square$ Never $\square$ Once or twice $\square$ Sometimes $\square$ Often $\square$ Every day or almost every day
8. Difficulty saying any words?
$\square$ Never $\square$ Once or twice $\square$ Sometimes $\square$ Often $\square$ Every day or almost every day
9. Pain in your teeth, lips, jaws or mouth?
$\square$ Never $\square$ Once or twice $\square$ Sometimes $\square$ Often $\square$ Every day or almost every day
10. Taken longer than others to eat a meal?
$\square$ Never $\square$ Once or twice $\square$ Sometimes $\square$ Often $\square$ Every day or almost every day
11. Felt irritable or frustrated?
$\square$ Never $\square$ Once or twice $\square$ Sometimes $\square$ Often $\square$ Every day or almost every day
12. Felt shy or embarrassed?
$\square$ Never $\square$ Once or twice $\square$ Sometimes $\square$ Often $\square$ Every day or almost every day
13. Been upset?
$\square$ Never $\square$ Once or twice $\square$ Sometimes $\square$ Often $\square$ Every day or almost every day
14. Been concerned what other people think about your teeth, lips, mouth or jaws?
$\square$ Never $\square$ Once or twice $\square$ Sometimes $\square$ Often $\square$ Every day or almost every day
15. Avoided smiling or laughing when around other children?
$\square$ Never $\square$ Once or twice $\square$ Sometimes $\square$ Often $\square$ Every day or almost every day
16. Other children teased you or called you names?
$\square$ Never $\square$ Once or twice $\square$ Sometimes $\square$ Often $\square$ Every day or almost every day
17. Had other children ask you questions about your teeth, lips, jaws or mouth?
$\square$ Never $\square$ Once or twice $\square$ Sometimes $\square$ Often $\square$ Every day or almost every day
18. Argued with other children or your family?

□ Never □	Once or tw	rice $\square$	Sometim	nes 🗌 Of	ten [	☐ Every	day or almost every day
19. Would you	say the <u>hea</u>	alth of y	our teeth	, lips, jaws	and r	nouth is:	
☐ Excellent	□ Very G	ood [	Good	☐ Fair		Poor	
20. How much	does the co	ondition	of your t	eeth, lips, j	jaws c	or mouth	affect your <u>life overall?</u>
☐ Not at all	□ Very li	ttle 🗆	Some	☐ A lot		Very mu	ch
21. Do you kno	ow what der	ntal floss	s is?			☐ Yes	□ No
22. Do you hav	ve dental flo	ss at ho	me?			☐ Yes	□ No
23. Do you use	e dental flos	s at hon	ne?			☐ Yes	□ No
24. How much	do your tee	eth hurt	you?				
☐ Not at all	☐ A bit	□ Ald	ot				
25. Do your te	eth make it	hard to	eat some	foods?			
☐ Not at all	☐ A bit	□ Ald	ot				
26. Do you hav	e to eat on	one side	e of your	mouth bed	cause	of your t	eeth?
☐ Not at all	☐ A bit	□ Ald	ot				
27. Do you get	food stuck	in your	teeth?				
☐ Not at all	☐ A bit		ot				
28. How much	do you get	kept aw	ake by yo	our teeth?			
☐ Not at all	☐ A bit		ot				
29. How much	do your tee	eth anno	y you?				
☐ Not at all	☐ A bit	□ Ald	ot				
30. Have vou t	aken medic	ine beca	use of vo	our teeth?			

Ш	Not at all	☐ A bit	□ A lot	
31.	How much	do your tee	th hurt when you brush them?	
	Not at all	☐ A bit	☐ A lot	
32.	Do you hav	e to eat mo	re carefully because of your teeth?	
	Not at all	☐ A bit	☐ A lot	
33.	Do you hav	e to eat mo	re slowly because of your teeth?	
	Not at all	☐ A bit	☐ A lot	
34.	Do you fee	l cross beca	use of your teeth?	
	Not at all	☐ A bit	☐ A lot	
35.	How much	have you cı	ied because of your teeth?	
	Not at all	☐ A bit	☐ A lot	
36.	Do you thir	nk your fron	t teeth look brown or black?	
	Not at all	☐ A bit	☐ A lot	
37.	Do your tee	eth make it	hard to do your school work?	
	Not at all	☐ A bit	☐ A lot	
38.	Do you fee	l tired beca	use of your teeth?	
	Not at all	☐ A bit	☐ A lot	
39.	Do you thir	nk that brus	ning your teeth keeps you healthy?	
In t	the past 3 m	onths, how	often have you:	
40.	Had pain in	your teeth	/toothache?	
	Never $\square$	l Almost Ne	ever $\square$ Sometimes $\square$ Fairly Often $\square$ Almost all the ti	me
41.	Had crooke	ed teeth or s	paces between your teeth?	
	Never $\square$	Almost Ne	ever $\square$ Sometimes $\square$ Fairly Often $\square$ Almost all the ti	me
42.	Had discolo	ored teeth o	r spots on your teeth?	

☐ Never	☐ Almost Never	☐ Sometimes	☐ Fairly Often	☐ Almost all the time
43. Had bad	d breath?			
☐ Never	☐ Almost Never	☐ Sometimes	☐ Fairly Often	☐ Almost all the time
44. Had ble	eding gums?			
☐ Never	☐ Almost Never	☐ Sometimes	☐ Fairly Often	☐ Almost all the time
45. Been ui	nhappy or sad becau	se of your teeth, r	mouth, or face?	
☐ Never	☐ Almost Never	☐ Sometimes	☐ Fairly Often	☐ Almost all the time
46. Missed	school for any reaso	n because of your	teeth, mouth, or	face?
☐ Never	☐ Almost Never	☐ Sometimes	☐ Fairly Often	☐ Almost all the time
47. Been co	onfident because of y	our teeth, mouth	, or face?	
☐ Never	☐ Almost Never	☐ Sometimes	☐ Fairly Often	☐ Almost all the time
48. Had dif	ficulty eating foods y	ou would like to b	pecause of your tee	eth, mouth, or face?
☐ Never	☐ Almost Never	☐ Sometimes	☐ Fairly Often	☐ Almost all the time
49. Felt wo	rried or anxious beca	ause of your teeth	, mouth, or face?	
☐ Never	☐ Almost Never	☐ Sometimes	☐ Fairly Often	☐ Almost all the time
50. Not wa	nted to speak/read o	out loud in class?		
☐ Never	☐ Almost Never	☐ Sometimes	☐ Fairly Often	☐ Almost all the time
51. Avoided	d smiling or laughing	with other childre	en because of your	teeth, mouth or face?
☐ Never	☐ Almost Never	☐ Sometimes	☐ Fairly Often	☐ Almost all the time
52. Had tro	uble sleeping becaus	se of your teeth, n	nouth, or face?	
☐ Never	☐ Almost Never	☐ Sometimes	☐ Fairly Often	☐ Almost all the time
53. Been te	eased, bullied or calle	ed names by other	children because	of your teeth, mouth or
☐ Never	☐ Almost Never	☐ Sometimes	☐ Fairly Often	☐ Almost all the time

54. F	elt that	t you were attractiv	e (good looking) b	ecause of	your tee	eth, mouth, or face?
□ r	Never	☐ Almost Never	☐ Sometimes	☐ Fairly	y Often	☐ Almost all the time
55. F	elt that	t you look different	because of your m	nouth, tee	th, or fac	ce?
□ r	Never	☐ Almost Never	☐ Sometimes	☐ Fairly	y Often	☐ Almost all the time
56. H	Had diff	iculty saying certair	words?			
	Never	☐ Almost Never	☐ Sometimes	☐ Fairly	y Often	☐ Almost all the time
57. H	Had diff	iculty keeping your	teeth clean?			
□ r	Never	☐ Almost Never	☐ Sometimes	☐ Fairly	y Often	☐ Almost all the time
58. E	Been wo	orried about what o	ther people think	about you	ır teeth,	mouth or face?
	Never	☐ Almost Never	☐ Sometimes	☐ Fairly	y Often	☐ Almost all the time
59. (	Overall,	please rate your or	al health:			
	Poor	☐ Fair	☐ Average	□G	ood	☐ Excellent
	-	tions ask about how	,	•	•	stion, read all the
	ves and	decide which one i	s most like now yo		Sad	
00. \		: : feel worried today		01. □		feel sad today
						-
Ш	I feel a	a little bit worried to	oday		I feel a	little bit sad today
	I feel a	a bit worried today			I feel a	bit sad today
	I feel o	quite worried today			I feel q	uite sad today
	I feel v	very worried today			I feel ve	ery sad today
62. F	Pain			63. Tired	l	

$\square$ I don't have any pain today	☐ I don't feel tired today
$\square$ I have a little bit of pain today	☐ I feel a little bit tired today
☐ I have a bit of pain today	☐ I feel a bit tired today
☐ I have quite a lot of pain today	☐ I feel quite tired today
☐ I have a lot of pain today	☐ I feel very tired today
64. Annoyed	65. Sleep
☐ I don't feel annoyed today	☐ Last night I had no problems sleeping
☐ I feel a little bit annoyed today	☐ Last night I had a few problems sleeping
☐ I feel a bit annoyed today	☐ Last night I had some problems sleeping
☐ I feel quite annoyed today	☐ Last night I had many problems sleeping
☐ I feel very annoyed today	☐ Last night I couldn't sleep at all
66. School Work/Homework (such as	roading writing doing lossons)
☐ I have no problems with my scho	olwork/homework today
☐ I have a few problems with my so	:hoolwork/homework today
$\square$ I have some problems with my so	:hoolwork/homework today
☐ I have many problems with my se	choolwork/homework today
☐ I can't do my schoolwork/homev	vork today

67.	Daily routine (things like eating, having a bath/shower, getting dressed)
	I have no problems with my daily routine today
	I have a few problems with my daily routine today
	I have some problems with my daily routine today
	I have many problems with my daily routine today
	I can't do my daily routine today
68.	Able to join in activities (things like playing out with their friends, doing sports, joining in
thin	
thin	
thin	ngs)
thin	gs) I can join in with any activities today
thin	I can join in with any activities today  I can join in with most activities today

### Thank you for completing the questionnaire

Oral Hygiene questions: 1-2, 21-23, 39

CPQ: 3-20

Caries Impacts and Experiences Questionnaire for Children: 24-38

COHIP: 40-59 CHU9D: 60-68