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Effectiveness of bi-annual application of 38% silver diamine fluoride and 5% sodium fluoride varnish on primary teeth of children, in a rural setting near Port Moresby, Papua New Guinea - A randomised clinical trial

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Abstract

Aim: To assess the effectiveness of 38% silver diamine fluoride (SDF) solution and 5% sodium fluoride (NaF) varnish applied bi-annually in arresting carious lesions in primary teeth of children and to assess child and parent acceptability of the treatments.

Methods: Children aged 2-5 years with at least one carious lesion were randomly allocated into 2 groups as follows: Group 1 received 38% SDF (Riva star SDI Ltd) solution and Group 2 received 5% NaF varnish (Duraphat®), applied at baseline and again at 6 months. Lesion progress or arrest was assessed by visual and tactile examination at 6 months and 12 months. Parental and child satisfaction were assessed with self-reports at 6 months and 12 months.

Results: One hundred and four children were recruited. Baseline mean dmfs scores were 10.8 and 11.7 for Group 1 and 2 respectively. At 12 months, 86.5% (90) participants remained in the study. The caries arrest rate in SDF group, was higher than that of NaF group, 97.2% vs 71.5 % ($p < 0.001$). Logistic regression analysis showed that 38% SDF was more effective than the 5% NaF varnish (OR: 7.7, 95% CI=3.14 -19.09) in arresting carious lesions. There were no differences in parental and child satisfaction between the groups.

Conclusion: At 12 months, both 38% SDF and 5% NaF were effective in arresting dental carious lesions, however 38% SDF was superior to 5% NaF. Parents and children were accepting of the treatment provided.

Key words: Silver diamine fluoride, fluoride varnish, early childhood caries, dental caries, children.

Acknowledgments

Dedication

I would like to dedicate this thesis to the children of Enga province in Papua New Guinea who have inspired me to take this journey.

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List of Abbreviations:

AAPD   American Academy of Paediatric Dentistry

ADA   American Dental Association

ANOVA   Analysis of Variance

APEC   Asia Pacific Economic Conference

CI   Confidence Interval

CPP- ACP   Casein phosphopeptide – amorphous calcium phosphate

dmfs   decay, missing, filled surfaces in primary teeth

ECC   Early Childhood caries

FDA   Food and Drug Administration

GEE   Generalised Estimating Equation

HECS   Heath Education and Clinical Sciences

ICDAS   International Caries Detection and Assessment System

ID   Identification

KI   Potassium iodide

LED   Light emitting diode

MDP   Mobile Dental Photography

MMDI   Medical Device and Diagnostic Industry Global Company

MOH   Ministry of Health

n   number

NaF	Sodium fluoride
NSO	National Statistics Office
OHI	Oral health instructions
OR	Odds Ratio
PNG	Papua New Guinea
ppm	parts per million
pufa	pulp, ulceration, fistula, abscess in primary dentition
PUFA	Pulp, Ulceration, Fistula, Abscess in permanent dentition
SDF	Silver diamine fluoride
SDI	Southern Dental Industries
SSB	Sugar Sweetened Beverages
SPSS	Statistical Package for the Social Sciences
SMHS	School of Medicine and Health Science
TB	Tuberculosis
UPNG	University of Papua New Guinea
USA	United States of America
vs	Versus
WHO	World Health Organisation

Introduction

Dental caries is the most prevalent chronic bacterial infection in children and adults. The World Health Organization estimates that 530 million children are affected by dental caries (WHO, 2019). It is the most common cause of dental pain and infection in children. Not only does dental caries affect the teeth, it may lead to widespread health problems including pain, infections, difficulty in chewing, malnutrition, gastrointestinal disorders and sleeping difficulties. Dental caries can have long term effects on both primary and permanent dentitions and early tooth loss may impact eating and speech and can cause malocclusion (Weir, 2002).

Early childhood caries (ECC) is defined as the presence of one or more decayed (non-cavitated or cavitated lesions), missing (due to caries) and filled tooth surfaces in any primary tooth of a child aged 71 months or younger. Severe ECC is any sign of smooth surface caries in a child younger than the age of three; or in a child from three to five years, one or more cavitated, missing (due to caries), or filled smooth surfaces in primary maxillary anterior teeth or decayed, missing or filled score of greater than or equal to four (age 3), greater than or equal to five (age 4), or greater than or equal to six (age 5) (AAPD, 2017; Drury et al., 1999).

Dental caries in young children has been described using various terminologies such as nursing bottle caries, nursing caries, rampant caries, baby bottle caries, milk bottle syndrome and prolonged nursing habit caries (WHO, 2019). Researchers have reported that ECC is a multifactorial disease with causative factors including cariogenic microorganisms, exposure to fermentable carbohydrates through inappropriate feeding practices and a range of social variables (Anil & Anand, 2017; Borutta et al., 2010). ECC prevalence is increasing in many developing countries and has become a significant

health burden especially in socially disadvantaged populations (Anil & Anand, 2017; WHO, 2019).

Untreated ECC can lead to pain, spread of infection, poor weight gain and growth due to inability to eat, difficulty in sleeping and poor general health (Acs et al., 1992; Acs et al., 1999; Sheiham, 2006). However, management of dental caries is complex for children considering their age and limited ability to cope with definite or invasive dental procedures. Access to care may be limited by a parent's inability to bring a child for regular dental care. This may be due to perceived cost, absence from work, lack of health awareness, neglect and abuse, lack of awareness and a lower socio-economic status (Weir, 2002).

Prevention of dental caries, particularly in high caries risk populations, is challenging (Scotland, 2014; Twetman, 2009). Fluoride has been used for prevention of dental caries through home-based and/or clinic-based application under professional guidance, and through community water fluoridation. Many western societies including areas in the United States, Australia and New Zealand with established water supplies have implemented water fluoridation to enable a population-wide measure to prevent dental caries. For rural communities which do not have reticulated water supplies or access to quality and affordable dental care, other methods such application of topical fluorides and atraumatic restorative techniques have been employed (Lo et al., 2014; Monse et al., 2012). These are likely to be community and school-based programs aimed at prevention of dental caries within the population.

Recent reviews of clinical trials investigating application of SDF on primary and permanent dentition for arresting and preventing dental caries concluded that SDF could

benefit many patients (Contreras et al., 2017; Seifo et al., 2019). The authors confirmed the effectiveness of SDF as a caries arresting agent for primary and permanent teeth and also its ease of use, low costs and relative safety. While there is still low evidence of the preventive effect of SDF, it has been recommended as an alternative procedure for tertiary intervention to reduce the negative effect of a carious cavitated tooth. These negative effects include loss of function, pain and disease-related complications. SDF regimes have been demonstrated to improve the quality of life of children with ECC (Phantumvanit et al., 2018).

Chapter 1 Literature Review

The management of multiple carious lesions in a child's mouth is challenging for dental practitioners. Epidemiological studies (Castro et al., 2015; Hicks et al., 2004; Wang et al., 2012) have helped the understanding of the biological and multifactorial factors affecting the process of dental caries in children. The prevention of dental caries needs to be approached at an individual and community level.

Dental caries

In 2010, untreated caries in permanent teeth was the most prevalent condition worldwide, affecting 2.4 billion people, and untreated caries in primary teeth was 10th most prevalent condition, affecting 621 million children worldwide (Kassebaum et al., 2015).. The disease affects both adults and children, especially those whose teeth are frequently exposed to high sugar foods, have poor oral hygiene habits and come from a disadvantaged or low socio-economic background (WHO, 2019). Dental caries in children can lead to undesirable effects in growth and development, oral health and general health and wellbeing. Dental caries in children can lead to pain and infection causing sleepless nights, poor nutrition due to difficulty in eating and unwarranted hospital stays (AAPD, 2017; Sheiham, 2006). It can also have undesirable effects on the developing permanent dentition, adding to the cost burden of dental treatment at both an individual and at community level (AAPD, 2017).

Aetiology of Dental Caries

Understanding the disease process of dental caries is prerequisite for identifying opportunities to reduce the disease burden in a community. The aetiology of dental caries at a biological level has improved the clinical understanding of the disease progress,

thereby identifying specific target ages for intervention in order to prevent development of disease, rather than controlling the severity of the established disease (Phantumvanit et al., 2018).

In recent years, dental plaque has been identified as a biofilm. Microbial biofilms are complex bacterial communities in humans. The nature of the biofilm enhances the component bacterial resistance to both the host defense systems and antimicrobials so that if not removed regularly by daily oral hygiene practices, will undergo maturation resulting in pathogenic bacterial complex (Gurenlian, 2007). Bacterial plaque in the biofilm metabolizes fermentable carbohydrates consumed by the host producing harmful acidic bi-products that cause disease in the oral cavity, such as dental caries, gingivitis and periodontitis. Furthermore, dental biofilm has been associated with various systemic diseases including cardiovascular disease, diabetes mellitus and adverse pregnancy outcomes in patients with subgingival plaque. This is the essential rationale for the removal of dental plaque (Gurenlian, 2007).

As the enamel is porous when the tooth erupts into the oral cavity it is at increased susceptibility to dental caries (Lynch, 2013). Plaque bacteria metabolize fermentable carbohydrates such as sucrose, fructose, glucose or cooked starch, and produce acid. *Mutans streptococci* and *Lactobacilli* are bacteria that are commonly associated with dental caries (Liu et al., 2019; van Houte, 1993). The acids produced reduce the pH environment in the oral cavity, and force calcium and phosphate ions to diffuse out of the dental enamel hydroxyapatite into solution (Featherstone, 2008). This process is known as demineralisation and results in white spot lesions referred to as initial dental caries. The enamel continues to demineralize if the environment remains acidic and dental plaque is not removed. However, the acids may be neutralised by increasing the

pH level within the oral cavity allowing remineralisation of the tooth structure by redeposition of minerals lost from the enamel hydroxyapatite, or by deposition of mineral ions derived from the saliva. The process of demineralisation and remineralisation is dependent on the interplay of the buffering capacity of saliva, the saturation level of enamel apatite in dental plaque and the presence of fluoride, calcium and phosphate ions. An unfavorable imbalance between the demineralization and remineralisation process results in cavitation (Featherstone, 2000; Featherstone, 2008).

The association between these three factors involved in caries process, dental plaque, the tooth and diet were initially described by Keyes and Jordan (1963) using a diagram displayed in Figure 1.
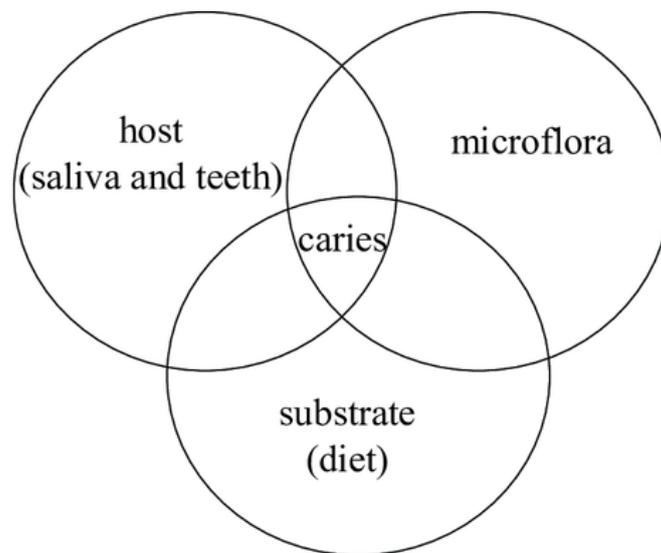
Figure 1 Keyes' Triad Initial depiction of the caries process involving the teeth, bacteria and substrate (Heijnsbroek et al., 2006).

Keyes' depiction of dental caries, is at the tooth level and does not consider the impact of the oral environment and personal factors. Understanding of the links and broader consideration of the environment that surrounds the individual allows for broader consideration of prevention as is illustrated in Figure 2 (Selwitz et al., 2007). A preventive programme has to fit with the community's needs and the realities of the caries experienced in that community. For example, there may be little gain in placing fissure seals in a community where smooth surface caries is a massive problem.
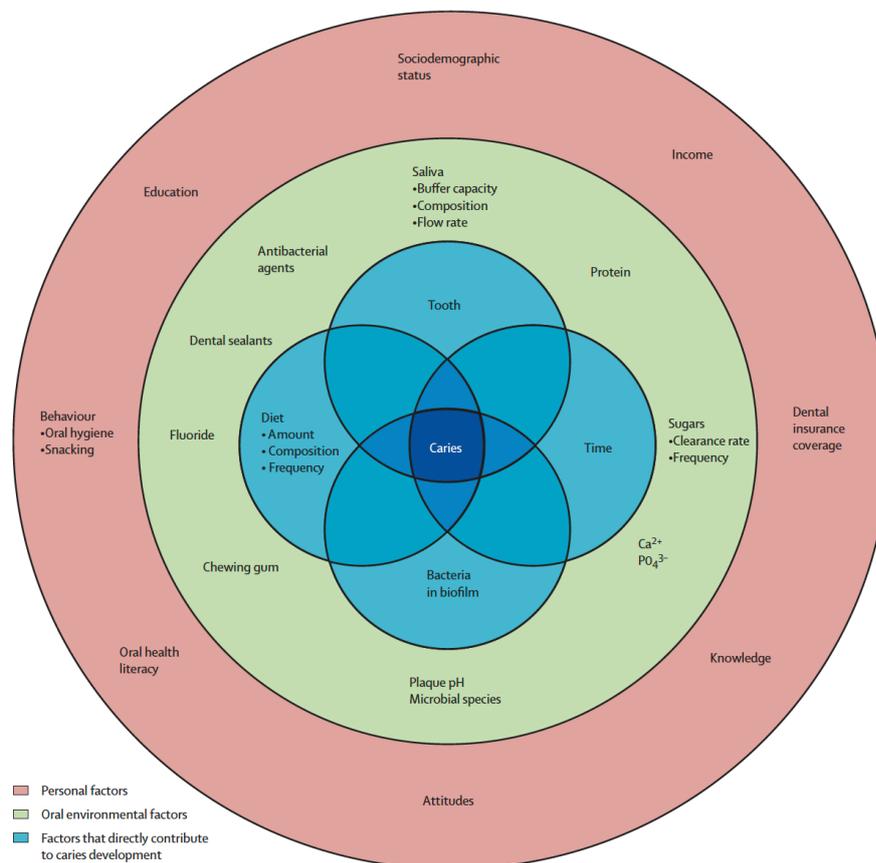
Figure 2. Diagrammatic representation of the risk factors and confounding factors in dental caries (Selwitz et al., 2007)

Aetiology of Early Childhood Caries

ECC is a multifactorial disease due to cariogenic bacteria, dietary factors, host factors and influences from the environment and socioeconomic status. An ecological shift in the oral microbiome resulting in a decrease in pH within the oral cavity promotes the development of dental carious lesions (Anderson et al., 2018).

Microorganisms that play a key role in early stage development of dental caries are the mutans streptococci which include *Streptococcus mutans* and *Streptococcus sobrinus* (Leong et al., 2013; Takahashi & Nyvad, 2011). Other bacterial species such as lactobacilli, non-mutans streptococci, actinomyces, bifidobacterium, and veillonella are involved in the later stages of the caries process (van Houte, 1993). Recent advances in the understanding of the caries process have shown that a much more complex biofilm is involved in dental caries than previously understood and that the biofilm as a whole undergoes a shift in its characteristics in that it enhances its survival strategies and enhanced pathogenicity to result in dental caries (Gurenlian, 2007; Tanner et al., 2011).

The origins of the micro-organisms that cause caries in a child's mouth have been debated. Vertical transmission, also known as mother to child transmission, is the transmission of infection from caregiver to child. It has been suggested that the major reservoir from which an infant acquires mutans streptococci is its mother (Berkowitz, 2003; Çolak et al., 2013). Horizontal transmission, between other family members or children in day care can also occur (Berkowitz, 2003). Li et al (2005) found a relationship between incidence of dental caries in infants and toddlers according to the method of delivery at birth. The study involved children born by caesarian or vaginal delivery (Li et al., 2005). *S. Mutans* was detectable in children born by caesarian section 11 months after birth and up to 22 months in infants born by vaginal delivery. Children born by

vaginal delivery developed dental caries later than infants who were born by caesarian section to mothers who were of low socioeconomic background and had high levels of *S. Mutans* in the oral cavity. They hypothesised that may be because children born by vaginal delivery were exposed to bacteria from their mother and developed some immunity against the bacteria for a period of time (Li et al., 2005). Another study (Brandquist et al., 2017) however concluded that there was not enough evidence to support the association between children born by caesarian section and caries incidence being earlier than children born by vaginal delivery. However, the environment that allows cariogenic micro-organisms to flourish or not may be more important than the source of the colonisation.

Consumption of fermentable carbohydrates is associated with the development of dental caries. The frequency, amount and timing of intake of starchy and sugary foods play an important role in increasing the risk for caries progression (Featherstone, 2000; Harris et al., 2004), and a positive correlation between sugar intake and the incidence of dental caries was found in children without access to optimally fluoridated drinking water, and whose dental hygiene was poor (Gao et al., 2014; Mishra et al., 2017). Children with long term medical conditions, who may be taking medications in the form of sugar-containing syrups and those who are immunocompromised from disease or therapy are also considered at high risk of caries (Foster & Fitzgerald, 2005).

Poor hygiene habits have been associated with development of ECC in children (Anil & Anand, 2017). Children under the age of six years may have limited manual dexterity skills and are unable to remove plaque adequately from their teeth without assistance. Habibian et al. (2001) conducted a study on dietary habits and dental health over the first 18 months of life of pre-school children. Dental assessments of visible plaque were made

at 6 months interval over 18 months. Children who brushed their own teeth had much higher visible plaque than children who had their teeth brushed by a parent or guardian (Habibian et al., 2001).

A number of studies have reported on the dental status of children who live in poverty or in poor economic conditions (Caufield et al., 2012; Davies et al., 2001); belong to minor ethnic and racial groups (Ramos-Gomez et al., 1999); were born to single parents (Quinonez et al., 2001); whose parents have low educational level especially those of uneducated mothers (Dini et al., 2000). Some studies have investigated the relation between the above social factors and ECC (Davies et al., 2001; Horowitz, 1996; Patel et al., 2018).

Children born to mothers who experienced prenatal and perinatal malnutrition or undernourishment have an increased risk of enamel hypoplasia (Seow & Perham, 1990). Hypoplasia of enamel has been shown to be associated with dental caries (Broadbent et al., 2005).

Prevalence of Early Childhood Caries

There was a decline in dental caries in children between the years 1973 and 1993, largely attributed due to widespread use of fluoride in toothpaste (Lagerweij & van Loveren, 2015; Mishra et al., 2017). However, more recently, the improvement has been at a slower rate, and in some instances ECC is again a growing problem. Dental caries remains a significant problem in both developed and developing nations (Anil & Anand, 2017; Colak et al., 2013; WHO, 2017). ECC prevalence varies widely according to race, culture and ethnicity, socioeconomic status, lifestyle, dietary pattern and oral hygiene practices. It further varies from country to country and from area to area (Andersen &

Davidson, 1997; Petersen, 2003; Shiboski et al., 2003). The global prevalence of dental

caries is listed in Table 1.

Table 1. Global Prevalence of Dental Caries

Country	Prevalence by Ethnicity (%)	Prevalence by Age [3-6 yrs] (%)	Total Prevalence (%)	Reference
Developed countries			1-12	WHO, 2017
Under developed			85	WHO, 2017
Asia	35-45			WHO, 2017
Africa	38-45			WHO, 2017
Middle East	21-61			WHO, 2017
Australia			< 35	WHO, 2019
Mexico			70	WHO, 2019
Scandinavia			35	WHO, 2019
Cambodia		90		Duangthip et al., 2017
England		23.3		Public Health England 2017
India		35-69		WHO, 2019
New Zealand		40.3		MOH, 2018
		35-69		WHO, 2019
USA		40		WHO, 2017
		35 -69		Javed et al., 2016

Clinical features of Early Childhood Caries

The pattern of caries in ECC follows a specific pattern. The initial lesions appear to as white spots on the smooth surfaces of enamel, at the gingival margins on the labial surfaces of upper central incisors (Chu, 2000; Mishra et al., 2017). As lesions progress, the white spots become discoloured and spread laterally and coronally, ultimately resulting in dentinal as well as enamel destruction and loss of the coronal structure of the teeth leaving root stumps (Anil & Anand, 2017; Chu, 2000). Carious lesions on the maxillary molars may begin simultaneously in the pits and fissures and on smooth surfaces at the gingival margins of the buccal surface. In severe cases, maxillary teeth and the mandibular molars also become carious. The maxillary incisors appear to be more severely affected as they erupt earlier than the posterior teeth and therefore have the longest exposure to cariogenic attack from the high sugary liquid in infant nursing fluids (Ripa, 1988; Tinanoff & O'Sullivan, 1997). As dental caries progresses, the pulpal tissues eventually become exposed to oral bacteria which infiltrate the root canals, with infection spreading to involve the whole dento-alveolar complex. The soft tissue effects observed are fistula, abscess and in cases of retained root fragments, ulceration (Monse et al., 2010). The mandibular incisors are more resistant to cariogenic insult, which may be due to their proximity to salivary secretions of the submandibular glands (Kawashita et al., 2011). The tongue also has a self-cleansing action and extends forward to form an oral seal over the mandibular incisors during sucking, preventing the cariogenic insults at the mandibular incisors.

Consequences of untreated caries in children

The healthy primary dentition is required for proper mastication, aesthetics, phonetics, and space maintenance (Anil & Anand, 2017). Untreated progressive dental caries can impact on the quality of life of children and their families and cause detrimental effects to the oral health as well as the general health of the child (Abanto et al., 2011; Filstrup et al., 2002; Naidu et al., 2016). Carious lesions may cause pain, and therefore, the ability to eat normally becomes affected and eventually a child may be unable to eat well, and can become poorly nourished and struggle to gain weight. Acs et al. (1992) conducted a study to assess effect of dental rehabilitation on the body weight of children with ECC. The study consisted of participants who had ECC compared to those who were caries free. Percentile weight categories of the children in both study groups were assessed before oral rehabilitation of children with ECC under general anesthesia. It was noted that 18% of children with ECC weighed less than 80% of their ideal weight. After comprehensive dental treatment, the participants were followed up to two and a half years. There was no longer a difference between weights of participants in children who had ECC and the control group (Acs et al., 1992). Jackson et al. (2011) also conducted a study to determine the relationship between children's oral health status and school attendance and performance by examining the number of school days missed for routine care versus the dental pain or infection. They found children who had poorer oral health status were more likely to miss school days due to dental pain and have difficulty concentrating in class thus reducing their ability to perform well in school (Jackson et al., 2011). With the child being disturbed at night, parents often also miss hours or days of work causing loss of income. This negatively impacts the quality of life of the child and his/her family (Jackson et al., 2011; Park et al., 2018).

It has been suggested that hospitalisation of young children due to facial swelling and odontogenic infections due to dental caries may indicate signs of further neglect and abuse to the child (Nuzzolese et al., 2009; Schlabe et al., 2018).

The premature loss of primary teeth due to dental caries and infection will lead to issues of space loss leading to future crowding of the permanent dentition and a need for orthodontic treatment (Bhujel et al., 2016). Early loss of teeth can also cause problems with phonetics and delayed speech (Kalia et al., 2018).

ECC is associated with caries in the permanent dentition. Broadbent et al. (2005) studied 663 children as part of the Dunedin Multidisciplinary Health and Development longstanding prospective cohort study. Study participants were examined at age five and later examined three months before their ninth birthday. Only the primary and permanent maxillary central and lateral incisors were assessed in this study. It was found that if caries affected the primary incisor, the permanent successor was twice as likely to have demarcated enamel defects and in the case of early loss of tooth due to trauma or abscess due to caries, the permanent tooth was five times more likely to develop a demarcated defect. In a further study the presence of enamel defects in the permanent dentition was found to increase susceptibility of tooth tissue to acid breakdown overtime (Abou Neel, 2016).

Management of Early Childhood Caries

A healthy primary dentition is important for the overall well-being of a child. While primary and secondary prevention of dental caries is the main goal of child dental care, treatment is often still required. It is often difficult to successfully implement caries prevention due to the multifactorial nature and pervasiveness of the disease in many

communities. Dental treatment in children is often challenging due to their age and their ability to cope with invasive procedures. For children who are not able to cope with treatment in the dental chair, advanced behavior techniques such as sedation and general anesthesia are needed to facilitate dental treatment (Chu, 2000). These procedures are costly.

Prevention of Early Childhood Caries

Biology Approach

There is evidence suggesting that a biological approach rather than surgical invention is the better way to manage primary tooth dental caries (Maguire et al., 2020).

Early caries diagnosis, risk assessment and individualised caries prevention plans will help control progression of dental caries. Grigalauskienė et al., (2015, p102) stated "…*the most important thing is not to treat the consequences of the disease - cavities - but be aware of the dental caries as a biological phenomenon"* (Grigalauskienė et al., 2015)

Biological methods include using sealants to isolate the infected dental tissues from the oral environment, selective and stepwise caries removal procedures, and the Hall technique in which dental caries in primary molar teeth is sealed under stainless steel crowns (Schwendicke et al., 2018).

Filling **C**hildren's **T**eeth: **I**ndicated **O**r **N**ot? -FiCTION- A trial by Maguire et al. (2020) conducted over three years in dental practices in Scotland, England and Wales, compared the difference between filling, sealing in decay and preventive treatment. There was no difference in children's experience of pain or infection, quality of life or dental anxiety between the groups. All three regimes were acceptable to children, parents and dental

professionals. Sealing, along with preventive treatment was considered the most cost-effective method (Maguire et al., 2020).

Community water fluoridation

Community water fluoridation was first introduced in the late 20th Century and has led to a reduced incidence of dental caries. However, there were concerns of fluorosis occurring in the water fluoridated areas. Each country has developed specific water fluoridation guidelines to suit the fluoride exposure level. The accepted level of fluoride in the USA is 0.7 to 1.2 ppm (Health & Human Services Federal Panel on Community Water, 2015). However, a consensus has been reached for the optimum level to remain at 0.7 ppm. In Australia the level of fluoride in water is within 0.6 to 1.1 ppm (Do & Health, 2020) and in New Zealand the target fluoride range is between 0.7 to 1 ppm (MOH, 2009). The effectiveness of water fluoridation in reducing the dental caries burden was reported in the USA as 35% in primary teeth with an increase of 15% shown in the number of children presenting caries free (Rugg-Gunn et al., 2016). It has been suggested that water fluoridation reduces inequalities or disparities in dental health across social classes, however a Cochrane review (Iheozor-Ejiofor et al., 2015) has argued that there is insufficient evidence to determine the effect of water fluoridation on caries reduction. Fluorosis is an adverse sequel of increased fluoride intake. It is related to high levels of fluoride up to 5 ppm (Rugg-Gunn et al., 2016). The authors of a population study using parental questionnaires and oral epidemiology assessments concluded that early life exposure to fluoridated water reduced the potential carcinogenicity of sustained breast feeding (Ha et al., 2019).

Sugar Taxes

Sugar and sugar sweetened beverages are a major contributor to non-communicable diseases such as obesity, diabetes and dental caries. Reducing sugar consumption may have an impact on reducing the worldwide burden of these diseases. Taxation on sugar-sweetened beverages (SSB) is increasingly being investigated in the recognition that they are have no nutritional value. In Mexico, two years after the introduction of a tax on sugary drinks, households with the fewest resources reduced their purchases of sugary drinks by 11.7%, compared to 7.6% for the general population (Colchero, 2017). A systematic review of sugar-sweetened beverage taxes concluded that SSB taxes have been effective in reducing SSB purchases and dietary intake in many countries. SSB taxes have been reported to be cost-effective with the added benefit that resources that can be invested back into health and obesity prevention (Teng et al., 2019).

Regular dental visits

Regular dental visits once or twice a year are recommended for early detection of risk of dental caries and to enable early intervention. Topical fluorides including fluoride varnish and SDF have been proven anti-cariogenic effects and have been approved by FDA for professional use (Horst et al., 2016). NaF varnish is effective in reducing dental caries in children, adolescents, and adults. It is effective for prevention of coronal caries on all surfaces of teeth and prevention of root caries. NaF varnish is professionally applied to teeth up to four times yearly on primary or permanent dentition of patients with an elevated risk of dental caries (Chu & Lo, 2006). A high concentrate fluoride solution, SDF, can arrest enamel and dentinal caries in the primary dentition. SDF when applied twice a year arrests caries activity and prevents further progression and development of new lesions (Chu et al., 2002; Fung et al., 2018; Llodra et al., 2005). The American Dental Association (ADA, 2019) has approved the use of silver diamine fluoride "off

label" for management of dental caries and studies have reported its use in high caries risk populations who have limited access to quality dental care (Chu et al., 2002; Duangthip et al., 2016; Horst et al., 2016; Llodra et al., 2005; Lo et al., 2001).

Pit and fissure sealants

Use of pit and fissure sealants is an evidence-based method of reducing caries incidence in occlusal surfaces in permanent teeth. Ahovuo-Saloranta and colleagues reported from their systematic review on the of use of pits and fissure sealants for prevention of dental decay in permanent teeth in children, showing moderate to quality evidence that resin-based sealant is more effective than no sealants for preventing tooth decay. Children who received resin-based sealant had 11-51% lower caries incidence than in children without sealant over a 24 month follow period (Ahovuo-Saloranta et al., 2017). While there is limited evidence for benefits of pit and fissure sealants in primary teeth, it is highly recommended that primary teeth also receive it (Feigal & Donly, 2006). Indications for the application of pit and fissure sealants in primary dentition include high caries risk individuals, at risk pits and fissures, preventive purposes or as a seal on questionable lesions (Feigal & Donly, 2006). Pit and fissure sealants must be regularly monitored and maintained to ensure effective prevention of dental caries. It has been suggested that sealants are an important dental caries prevention technology, ideally used in combination with patient education, effective personal oral hygiene, fluorides and regular dental visits (Tai et al., 2009). Different dental materials are available for fissure sealing and include glass ionomer cements, and filled and unfilled composite resins. Flowable composite material has also been suggested to have higher retention and better caries preventive effect compared to GIC or other fissure sealant materials (Kühnisch et al., 2012; Lam et al., 2020)

Antimicrobial intervention

Antimicrobial interventions and treatments have been shown to temporarily reduce bacterial levels and produce sustainable effects on cariogenic microbial reduction (Featherstone, 1999). Topical antimicrobials have also been indicated for reduction of antimicrobial load in infants throughout their growth and development (Lopez et al., 2002). It has been shown that application of topical chlorhexidine twice yearly prevented the occurrence of caries lesion in erupting deciduous teeth of infants and toddlers. Povidone iodine has also been proven to reduce bacterial counts in young children temporarily but does not improve the overall effect on cariogenic bacterial reduction. Lopez and co-authors (Lopez et al., 2002) applied povidone iodine in 83 infants every two months for a year and observed an increase in disease-free children. Adverse effects associated with use of topical antimicrobials, chlorhexidine and povidone include discoloration of restorations on teeth and bad taste.

Dental Health Education

Increased awareness and education regarding the negative effects of cariogenic feeding habits or cariogenic diets has been shown to improve the oral hygiene of parents and caregivers. Frequent consumption of highly fermentable sugars such as sucrose, lactose and fructose has been regarded as the main cause of dental caries (Gupta et al., 2013) and is also linked to overweight and obesity (WHO 2003). Sucrose has been reported to be the main form of sugar to induce acidogenic bacteria. Parents and caregivers should be educated about the effects of cariogenic dietary habits and advised vigorous homebased care (Horst et al., 2018). Research has shown that maternal awareness of healthy oral health habits during pregnancy and house visits by community dental nurses to mothers of newborn babies improved the oral hygiene of the parents and reduced caries incidence in their infants and toddlers (Kowash et al., 2000). Oral hygiene habits developed at a

young age become a habit that is likely to be taken through into adult life hence greatly increasing their chances of full permanent dentition in adulthood (Sheiham, 2006).

Home-based care

Toothbrushing with a fluoride toothpaste is the best way to effectively prevent development of dental caries in children. It is suggested that toothbrushing under the supervision of a parent or caregiver two times daily significantly increases its effectiveness (AAPD, 2017). Home-based care also involves use of other products such as fluoridated toothpastes and tooth- mousse chemically known as casein phosphopeptide – amorphous calcium (CPP-ACP). Tooth-mousse was shown in a clinical study to be highly effective in reversing the caries process (Morgan et al., 2008) . However, another study (Evans, 2013) involving mothers and infants in Logan, Queensland assessed the effectiveness of tooth mousse after toothbrushing versus application of chlorhexidine gel and a control group who only did toothbrushing. At 24 months, there was higher evidence of caries arrest for infants who had only done toothbrushing and had chlorhexidine gel applied compared to infants who had tooth mousse applied on their teeth after tooth brushing. It was suggested that there was not enough evidence to suggest the used of tooth mousse for prevention of dental caries in children. Chlorhexidine mouth rinses are suggested for used to reduce the carious bacteria *mutans streptococci* and *lactobacilli* levels in young children. While reducing some bacterial levels it did not penetrate dental plaque (Featherstone, 2006).

Silver Diamine Fluoride

SDF is a clear aqueous solution composed of silver and fluoride ions that have special antimicrobial effects against dental caries. It is being used in countries such as the USA (Horst et al., 2016) and China (Chu et al., 2002; Duangthip et al., 2014; Lo et al., 2001;

Zhi et al., 2012) for treatment of dental caries and dentine hypersensitivity. SDF has been recommended for managing dental caries in the community and school dental outreach programs where conventional dental treatment is not an option or available. In such cases, the child may not possess the ability to cope with conventional treatment or in rural areas that are not accessible by roads and have no electricity for provision of quality dental care. The use of SDF is less expensive and unlike conventional methods for treating dental caries does not require costly equipment and materials.

SDF (38%) solution contains silver, ammonia, and fluoride. Silver nitrate was first shown to arrest dental caries in 1891 (Stebbins 1891 as cited in Peng et al. 2012 page 532). In 1917, Percy Howe reported the use of silver nitrate to sterilize prepared cavities (Howe, 1917) and disinfect root canals (Howe, 1920) and by the 1950s the solution was known as 'Howes Solution'. It was reported that the use of silver nitrate became popular in the 1960s as scientists looked for ways to reduce infection while limiting use of antibiotics (Peng et al., 2012). It became useful in dental public health programmes in regions that lack access to quality dental care as caries removal was not necessary and did not require expensive sophisticated dental equipment (Gao et al., 2016; Llodra et al., 2005).

Two important components of this solution are silver and fluoride which create a plug into the dentine tubules upon application. Silver has antimicrobial properties while fluoride facilitates remineralisation of tooth tissue (Peng et al., 2012). Laboratory studies (Knight et al., 2008; Knight et al., 2006; Mei et al., 2013; Mei et al., 2012) explained that, application of SDF results in formation of a physical barrier of silver phosphate which acts as a reservoir for phosphate ions and calcium fluoride which generally becomes available in the oral cavity to facilitate continuous remineralisation during acid attacks (Vinod et al., 2020).

SDF has been studied in varying concentrations (Dos Santos et al., 2012; Gao et al., 2016; Mei et al., 2012; Yee et al., 2009). Most studies (Chu et al., 2002; Llodra et al., 2005; Lo et al., 2001; Yee et al., 2009; Zhi et al., 2012) accepted 38% SDF as the most effective concentration in arresting dentine caries and there have been no reports of toxicity at 44,800 ppm (Chu et al., 2002).SDF (38%) solution has only been recently approved by the United States Food and Drug Administration (FDA) for treatment of dentine hypersensitivity (Horst et al., 2016). SDF (38%) has FDA approval for treatment of dentine hypersensitivity and has been permitted by the ADA to be used "off-label" by dental clinicians for management of dental caries (ADA, 2019).

Effectiveness of 38% Silver Diamine Fluoride

Research studies (Chu et al., 2002; Liu et al., 2012; Llodra et al., 2005; Lo et al., 2001; Yee et al., 2009; Zhi et al., 2012) have shown that 38% SDF solution besides arresting dental caries could also prevent further development of new caries lesions. It has been shown that 38% SDF is more effective than 5% NaF varnish in arresting dental caries in primary teeth (Duangthip et al., 2014; Lo et al., 2001). Effectiveness of 38% SDF solution versus glass ionomer cement (GIC) in arresting and preventing new lesions has also been investigated. Zhi et al. (2012) performed a clinical trial involving 212 children aged 3-4 years. The study assessed the effectiveness of annual application of 38% SDF, semi-annual application of 38% SDF and annual application of high fluoride releasing GIC in arresting dental caries in primary teeth. Children were divided into three treatment groups; group one receiving 38% SDF, group two received semi-annual 38% SDF and group three received annual high fluoride releasing GIC. After 24 months, caries arrest rate of group one, two and three were 79%, 91% and 82 % respectively. It was concluded that both SDF and GIC were able to arrest dental caries though application of SDF semi-annually had the highest effect on caries arrest (Zhi et al., 2012).

Dos Santos and colleagues (Dos Santos et al., 2012) found from their randomized controlled trial that after one-year, SDF performed better in arresting caries in primary teeth than interim restorative treatment with GIC. They concluded that SDF use in disadvantaged communities would help reduce oral health disparities. There have been *in vivo* and *in vitro* studies on the mechanism of action and effectiveness of SDF in arresting dental caries (Knight et al., 2008; Mei et al., 2013). Clinical studies have shown high caries arrest following topical application of 38% SDF solution annually (Yee et al., 2009; Zhi et al., 2012), bi-annually (Llodra et al., 2005; Zhi et al., 2012) and three times a year for two to two and-a- half years. The effect of bi-annual application for two years showed significant caries arrest in children (Chu et al., 2002; Llodra et al., 2005; Zhi et al., 2012).

SDF (38%) was approved for use in the USA by FDA in 2014 (Horst et al., 2016) for treatment of dentine hypersensitivity but has been used in the USA, Japan, China, Brazil, Cuba, Argentina and Australia for management of dental caries.

Adverse effects of 38% SDF in management of ECC in Children

There are no reports of adverse systemic outcomes or severe side effects of SDF as a topical medicament. This is confirmed by clinical trial conducted by Duangthip and colleagues in 2018 (Duangthip et al., 2018). The aim of the study was to compare the adverse effects and parental satisfaction of four regimens of SDF among preschool children. Overall they reported minor adverse reactions following application SDF in terms of tooth and gum pain, gum swelling and gum bleaching as 6.6%, 2.8% and 4.7% respectively. Black staining of the teeth occurs after topical application of SDF solution. Parental satisfaction of their child's appearance regarding blackening of teeth ranged

from 61-70.8% (Duangthip et al., 2018). The black staining can be slightly reduced by application of potassium iodide following SDF (Knight et al., 2006; Patel et al., 2018).

There have been concerns about the possibility of toxicity from the use of 38% SDF due to its high fluoride content (44,800 ppm); however, there are no reports to substantiate such claims at present (Chu et al., 2002). It has been estimated that one topical application of 38% SDF solution only contains 0.2mg fluoride (Chu et al., 2002) which is far below the toxic dosage of 5mg/kg (Whitford, 1987). The low dosage of fluoride in 38% SDF is unlikely to cause any systemic health effects and the study treatment method should be very safe for use in children under the age of five living in non-fluoridated areas and with no access to fluoride containing toothpaste.

Acceptability of 38% Silver Diamine Fluoride

SDF (38%) is indicated for management of patients who are also high risk of developing dental caries, do not have access to quality dental care services, including children who may have dental anxiety or have limited ability to cope with traditional cavity preparation (Horst et al., 2016). Systematic reviews (Contreras et al., 2017; Gao et al., 2016; Rosenblatt et al., 2009) have suggested that 38% SDF is a minimally invasive therapy that is inexpensive, does not require caries removal, is easy to apply, and poses minimal risk to patients. However, the most common adverse effect of this treatment is tooth discoloration, a black staining which indicated that the caries has been halted. In many western and modern societies, parents are aware of the unaesthetic effect of staining due to caries on the anterior teeth and therefore having SDF placed on the front teeth may be undesirable (Alshammari et al., 2019; Clemens et al., 2018; Crystal et al., 2017; Gordon, 2018; Hu et al., 2020; Nelson et al., 2016). A study in the USA (Crystal et al., 2017) has shown that parents were more affected when their child with staining on the child's front

teeth however evidence suggested that parents preferred the use of SDF to advanced behavioral techniques such as sedation and general anesthesia. Parents showed less concern when the black staining appeared on the posterior teeth (Clemens et al., 2018; Crystal et al., 2017; Gordon, 2018; Hu et al., 2020). As the child's behavior became more apprehensive so was the parent's level of acceptance with the use of 38% SDF (Crystal et al., 2017). A report of USA Paediatric dental programs (Nelson et al., 2016) in which parents were surveyed by questionnaire further supported the use and acceptability of SDF by parents.

Sodium Fluoride

NaF varnish and SDF solution are both topical fluoride agents that have been widely investigated since the 1960s. A study by Chu and Lo (2008) showed that fluoride varnish (Duraphat®, Colgate-Palmolive Ltd, New York, USA) was widely accepted (Chu & Lo, 2008). This is a natural resin of a neutral colophonium base, containing 5% sodium fluoride (2.26% Fluoride) dissolved in ethanol (Strohmenger & Brambilla, 2001). It has the ability to adhere to tooth surfaces thereby prolonging the effects of fluoride and increasing the uptake of fluoride by enamel and allowing a reservoir in the oral cavity for the continuous process of remineralisation.

Effectiveness of 5% NaF varnish in management of ECC

The effectiveness of 5% NaF varnish in the prevention of dental caries in primary dentition has been extensively studied (Clark, 1982; Seppa, 2004; Strohmenger & Brambilla, 2001). It was shown that topical application of 5% NaF varnish resulted in caries reduction of up to 44% when the varnish was applied two to three times a year over 2 to 3 years (Holm, 1979). It was believed that the uptake of fluoride by the teeth was more effective after dental prophylaxis. However, Seppä in 1983 found from an *in*

vivo study of 55 adolescents that no significant difference in fluoride uptake was found between the cleaned and uncleaned teeth (Seppä, 1983). Application of 5% sodium fluoride varnish is painless, quick and easy to manipulate in apprehensive children as well as growing children with limited coping skills. Additionally, there is minimal toxicity potential. Topical application of 5% NaF varnish has been recommended for preschool children and the risk of fluorosis is minimal (Chu & Lo, 2008). The simplicity of its application makes it a very suitable and practical for use in dental clinics and outreach dental services, especially in young children and in other special needs groups (Chu & Lo, 2008). It has been available and widely used in most European countries, USA, Australia, Middle East and Asian Countries but not routinely for caries prevention in Papua New Guinea (PNG).

Significance of research

PNG is a developing country. Many issues affect dental services in PNG and they include:

- Inadequate manpower at primary health care level, general and specialist level

- Insufficient funding

- Scarce and substandard resources and equipment

- Limited or no qualitative and quantitative assessment of treatment protocols and their cost effectiveness

- Inconsistent and non-standard recording systems, and

- Unsatisfactory establishment of a referral system exist within the health system.

The majority of the population of PNG are from disadvantaged socioeconomic backgrounds. Many young children below the age of six presenting to public dental clinics with late stage dental caries and accompanying pain and facial swelling. These children are given antibiotics and sent home. Many do not return for follow up care after the swelling and pain has subsided. Although dental treatment for children under the age of six is free, the cost of transportation is not covered by the government and this is often the reason for not returning for care. The children's caries experience becomes a strong predictor of future caries (Fontana & Zero, 2006; Li & Wang, 2002) and the risk for development of caries in erupting permanent teeth gradually increases the burden of oral disease within the country.

38% SDF has been proven to arrest dental caries and prevent development of new caries lesions. While 5% sodium fluoride varnish has a greater effect in caries prevention, studies have indicated that its ability to arrest dental caries is lower than 38% SDF

(Duangthip et al., 2016; Lo et al., 2001). SDF is an FDA approved agent for reducing tooth sensitivity and its "off label" anti-cariogenic properties. To date it has not been used in PNG.

It is possible (and our hope) that this intervention study will help change the management of dental caries in young children in PNG. Caring for a child's dental health at primary health care level may lead to a wider appreciation of the benefits of improved oral health. As more people become aware of their dental health needs, the nation's dental profession must also evolve to meet the unique challenges this will present in caring for the diverse population of PNG. We hope this study is one small step to achieving both of those objectives.

Aims and Null Hypothesis

Aims

The aims of the study were:

To compare the effectiveness of topical application of 38% SDF solution and 5% sodium fluoride varnish in arresting dental caries in children from PNG.

To assess the parent and child acceptability of treating dental caries in primary teeth with either 38% SDF solution or with 5% NaF varnish.

Null Hypothesis

The null hypothesis to be tested was that, there would be no differences in the effectiveness of bi- annual application of 38% SDF and 5% NaF in arresting dental caries and preventing development of new carious lesions in primary teeth of children. In addition, there will be no differences in parent and child satisfaction between the two medicaments.

Chapter 2 Methodology

Study site

Pari village

This randomized clinical trial (RCT) was carried out in Pari village, a thirty-minute drive from the capital city Port Moresby.

Figure 3. Pari village homes on stilts

According to the National Statistics Office of PNG, the population of Pari village was 3424 following report of the National Census 2011.The reported growth rate of PNG is about 3.1% annually (PNG NSO Census 2011) therefore over these past nine years the

population may have increased by almost 1000. The native people of this area are the Motuan people. They speak the Hiri Motu, an oral language, similar to languages of the New Zealand Maori and other Polynesian countries - Tonga, Tahiti and Samoa (Lynch, 1998). The Motuans believe they are in a never-ending spiritual warfare. According to folklore, Koiari and Goilala people (mountain people) of the Central province who live near the Owen Stanley ranges, the spine of PNG, practice powerful black magic which has drove the Motuans toward the coastline. Motuan villages along the coast of Port Moresby have houses built on stilts over seawater (Figure 3). This elevation prevents the mountain sorcerers' spells from causing them harm.

Pari villagers live in houses without partitions. They live in extended families and everyone shares the same space for sleeping at night; parents, their children, husbands and wives and their grandchildren and great grandchildren live in the same building. This poses a risk to health especially to airborne diseases and contagious infections like, cold and flu virus, tuberculosis (TB) and measles.

Pari village comprises the native people, Motuans, and other settlers from all four other regions of the country- Southern region, Momase region, Highlands and Islands region. Some children have Asian and Caucasian features. Many do not know who their fathers are as they were expatriates who worked in the city. Many young women, due to the hardships and obligations to family, make a living by becoming escorts to expatriates based in Port Moresby. Due to cultural influences especially the male superiority within PNG society, many women refuse or do not seek birth control methods even during the time spent with an expatriate. Women are not accepted by men if they are known to be using birth control. As a consequence, a number of children are born with mixed Caucasian and Asian ethnicity.

Any person living in the Pari village would speak the native language Hiri Motu as it is the only means of communication with other people living in the area. English is also spoken and understood by the villagers and the settlers. Although PNG has well over 800 languages, Tok Pisin, a Melanesian form of Pidgin English is the main language for communication amongst Papua New Guineans.

As the children who participated in the study only communicated and responded in Motu, the parents interpreted the researcher instructions for the children and responded to the researchers in either English or Tok Pisin.

Prior to the 2018 Asia Pacific Economic Conference (APEC) Meeting in PNG, Pari village was difficult to access by the highway connected to Port Moresby and other suburban areas of the city. The road was not sealed and with the weather changes, the road rapidly deteriorated. People were often accosted and robbed when travelling in and out of the village. This has changed. The road is now sealed and villagers have access to privately owned buses for transport to Port Moresby. Figure 4 indicates the pickup point of researchers, the Papua Guinea's School of Medicine and Health Sciences and the distance and direction travelled with the escorts to and from the Pari village daily. Interestingly not all villagers - have travelled to Port Moresby, as they are fearful of "sorcery" and the petty crime that occurs in the city.
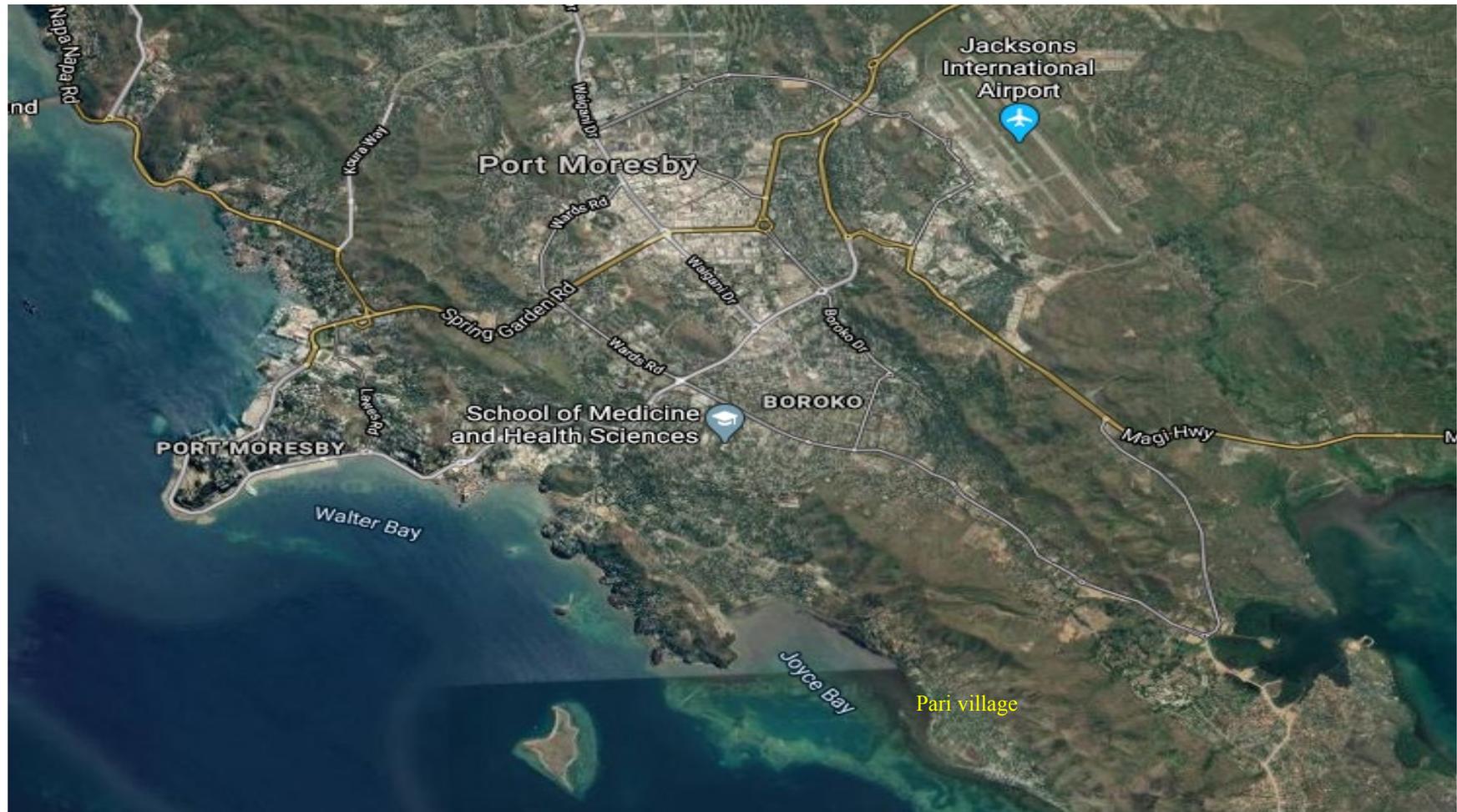
Figure 4. Satellite image of Port Moresby region *(adapted from Google Maps)*

Population sample

The target sample of 104 children was based on the results of a previous study (Lo et al., 2001). This sample size allowed a standard deviation of 2.45 and a 20% dropout rate. A sample size of 52 participants per group was required to detect a mean difference of 1.49 between the two treatment arms, with a power of 80% and a significance level of 5% (Lo et al., 2001).

Ethics

Ethics approval was obtained from the University of Otago Human and Ethics Committee (Appendix I) and the University of Papua New Guinea, School of Medicine and Health Sciences Research Ethics Committee (Appendix II).

We liaised with very highly educated and influential public servants from Pari village. These included a physician and cardiac specialist at the School of Medicine and Health Sciences and the assistant secretary to the Governor of National Capital District. After preliminary discussion, the research team travelled to the village together to speak to the Pari United church elders. While Pari village had a village chief, it was highly recommended that the team liaise with the Pari United Church council elders. As the church congregation comprised the largest number of people in the village, announcements would spread rapidly to other villagers. The church took care of community utilities like village community hall and power supply. They also owned a truck which could assist us by transporting chairs and tables from one village site to another.

Prior to the start of the clinical trial, the primary research supervisor from University of Otago travelled with the field researchers to Pari village to assess the study site.

The lead researcher was also invited to attend the church's Sunday service to describe the research to congregation and to invite participation. The support of the Church was recognised with *"emu harehare gaunia ba henia"* (gift in Motu).

Funding

Study design

This study is a RCT with two parallel groups. In this study, the individual participants serve as a unit of randomization. The Consolidated Standards for Reporting Trials (CONSORT) 2010 Statement (Schulz et al., 2010) was followed. Figure 5 shows the flow diagram of the proposed RCT.
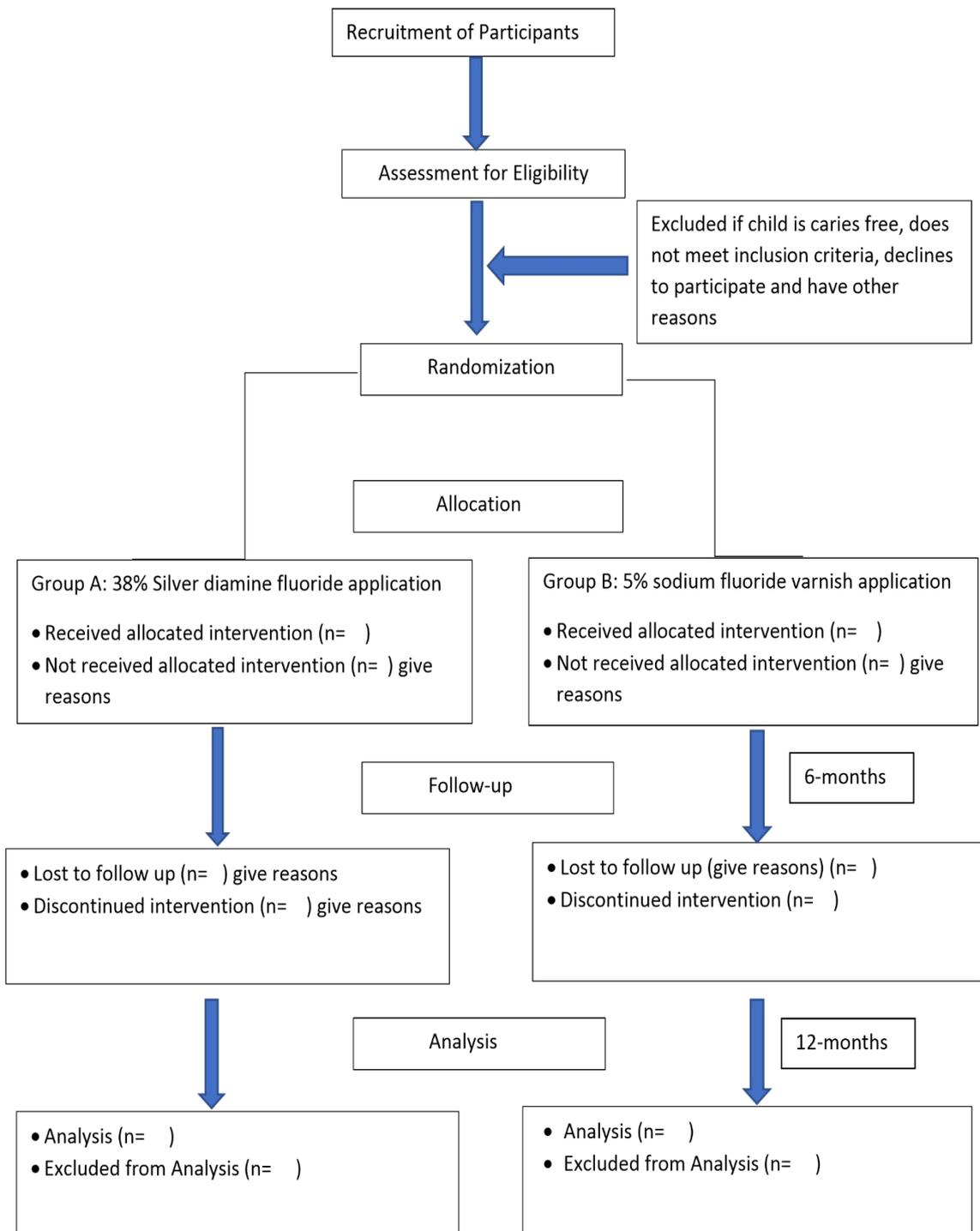
Figure 5. Flow diagram of the randomized controlled trial.

Phase One

Recruitment of participants

Children aged 18 months to 14-years-old presented to the team for an initial dental check. Dental screening was completed for 302 children. If the child was not in the age range of 2-5 years old, the child was given oral hygiene instructions (Appendix VIII), an oral hygiene kit containing a child toothbrush and an adult tooth brush and toothpaste sachet (Colgate Palmolive (PNG) Ltd) and was dismissed. Parents/caregivers of children in the age range 2-5 years of age were asked about past and current illnesses and completed a dental examination by calibrated examiners using a standard protocol. If a child fulfilled the inclusion criteria, the child and parent were invited to participate in the clinical trial. If they consented, the research was explained and when agreed verbally, written informed consent obtained. The child was then asked to pick a sealed opaque envelope from a box. Each envelope contained a randomly assign number that indicated the child's assigned group (5% NaF or 38% SDF).

Inclusion criteria

The inclusion criteria encompassed:

- Heathy children with one or more carious teeth.

- Children with a history of infectious conditions including TB who had completed treatment.

- Children who had a medical history of unknown fever and who had been admitted to hospital for up to two days with fluids and antibiotics in the last 12 months. These children were examined to rule out dental infection before inclusion in the study.

Exclusion criteria

Exclusion criteria involved:

- Any child with a long-term medical condition and who was on prolonged medication.

- Any child who had a history of allergies and the parent had limited knowledge of the cause.

- Any child with current or previous abscess, ulceration, fistula or an exposed pulp.

- Any child without consent from a parent or a guardian.

Field researchers

Dental personnel including a male dentist and four female dentists, two male students and one female dental assistant were invited via email and phone contact to participate in this project. The four female dentists and dental assistant were able to join the project.

The field researchers comprised the lead researcher, the four other dentists and dental assistant. Except the lead researcher who travelled from New Zealand to conduct the trial, all other members of the research team lived and worked in Port Moresby. At the time of the trial the lead researcher, also a postgraduate student at the University of Otago and the dental assistant were staff at the Division of Dentistry at University of Papua New Guinea. One dentist worked in a private dental clinic and three others were public servants at the Port Moresby Dental Clinics.

Researcher calibration

Calibration of field researchers

Calibration of field researchers was overseen by the primary supervisor, a specialist paediatric dentist and a senior lecturer at the University of Otago. She travelled from Dunedin, New Zealand to Port Moresby a week prior to the start of the initial phase to calibrate all field researchers.

The week-long calibration and training involved:

- Successive completions of oral examinations on dental models using the WHO dmfs (decay, missing, filled, surfaces) Oral Health Survey form for children.
- Coding of information. As part of demography, ethnicity and provinces were given codes to enter during data collection in the field.
- Oral health advice and hygiene instruction.
- Intra oral photography.
- Field set up.
- Designing safety protocols for field research.

Calibration at initial phase

All participating field researchers were calibrated prior to the start of the initial phase. During calibration, safety protocols, examination and treatment protocols, the workflow were also established. Teams were paired up and calibrated so that both parties were able to work together. Examiner 1, the lead researcher, and dental assistant were paired and calibrated together as they were to remain together for the second and third phase. Examiner 2 and 3 were calibrated with two other general dental practitioners as

assistants/recorder. They were not involved in the second and third phase due to unavailability.

Paediatric dental models, a disposable mirror and probe the same as those used in the trial were used for calibration. A headlight was used to increase visibility. Details were recorded on a WHO form for assessment of oral health of children (WHO, 2013). The calibration process was repeated over a period of four days until the researchers were confident in the process of examination with the set-up protocol and the applications of the 38% SDF and 5% NaF.

Calibration at second and third phase

For the second and third phase, the lead researcher was calibrated in Dunedin by the primary supervisor. The assistant was calibrated over a period of two days by the lead researcher until there was intra calibration agreement with recording examination data, questionnaire data, and the trial set up procedures. Intra-examiner reliability was assessed by repeating dental examination of seven dental models after 30-minute break.

Workflow and Stations

During the initial phase there were four stations involved (Figure 6 & 7). Station one for initial screening and enrolment, station two and three were for obtaining the medical history, dental examination of potential participants and informed consent for those recruited. At the fourth station all children received oral hygiene instructions and an oral hygiene kit.

Dentists were stationed at each station. During the first phase, except for the lead researcher and her assigned recorder, all other researchers were rotated through the other stations.

Back of Hall

Back table covered with a cloth.
Personal belongs & supplies stored under

Rubbish Container

Camera

Examiner 1 Table

Examiner 2 Table

Chairs if need to wait for OHI

Chairs if need to wait for exam

Enrolment & MH Table

OHI Table

Chairs for those waiting to been seen

■ = Chair

Front of Hall
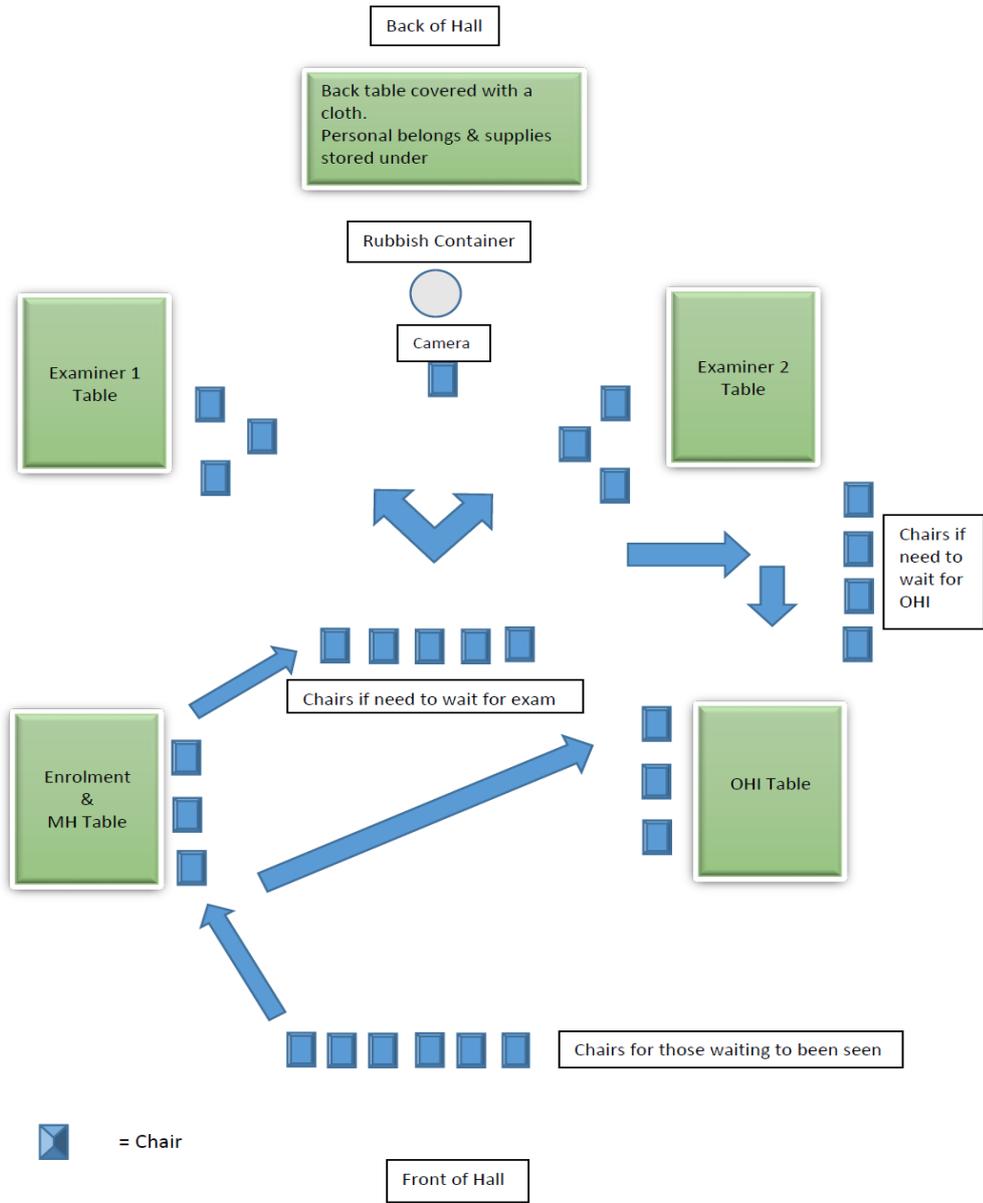
Figure 6. Pari Church hall lay-out and set-up of workstations and workflow.

Participant screening

Parents brought their children for their dental check and treatment. The enrolling dentist who was stationed in station one explained the research and process to the parent and to the child. At this station limited dental examination was carried out using a light emitting diode (LED) headlight and wooden spatula. Any child who was not within the age range of 2 to 5 years and had no visible cavities, had permanent molars at the age of five or presented with pulpally involved or abscessed teeth was excluded and directed to Station Four. Station Four was the oral health promotion table where the children and their parents received oral health education and oral hygiene advice. Posters depicting poor and good dental health and oral hygiene techniques were used. Each child received an oral hygiene kit (Colgate Palmolive (PNG) Ltd).

Figure 7. Set up of Pari village community hall for clinical trial.

Medical history

Medical history of potential candidates was obtained and recorded on the medical history form (Appendix III) during the screening phase.

The participant's parent/ guardian signed the medical history forms were checked, reviewed by the clinician at Station One (Figure 8).

Figure 8. Screening Station One

Recruitment of participants

Participants who satisfied the medical inclusion criteria and consented to participate progressed with their parents to the waiting area for Stations Two and Three

comprehensive examination. The name and age of the child was recorded, and the medical history was confirmed when the participant and parent presented to the examiners. When there were signs of dental caries and the child met the age requirement and had a clear medical history, details of the child were collected and recorded in the demography section of the WHO Oral Health Assessment form for children. A comprehensive dental examination was completed using knee to knee technique for comfort of the child and better view during examination (Figure 9), and then the child and parent/guardian were invited to participate in the study.

Figure 9. Dental examination of a child using knee to knee technique.

It took two weeks to recruit all participants. Unfortunately, the timing of the clinical trial coincided with school activities such as end of year graduations and class parties which

parents were obliged to attend with their older children. Consequently, they could only bring their younger children in the following week.

To increase recruitment, rate the Pari church elders suggested that we moved to different sections of the village – Doru (Figure 10), Gwadu and Dadarai for the convenience of the parents.
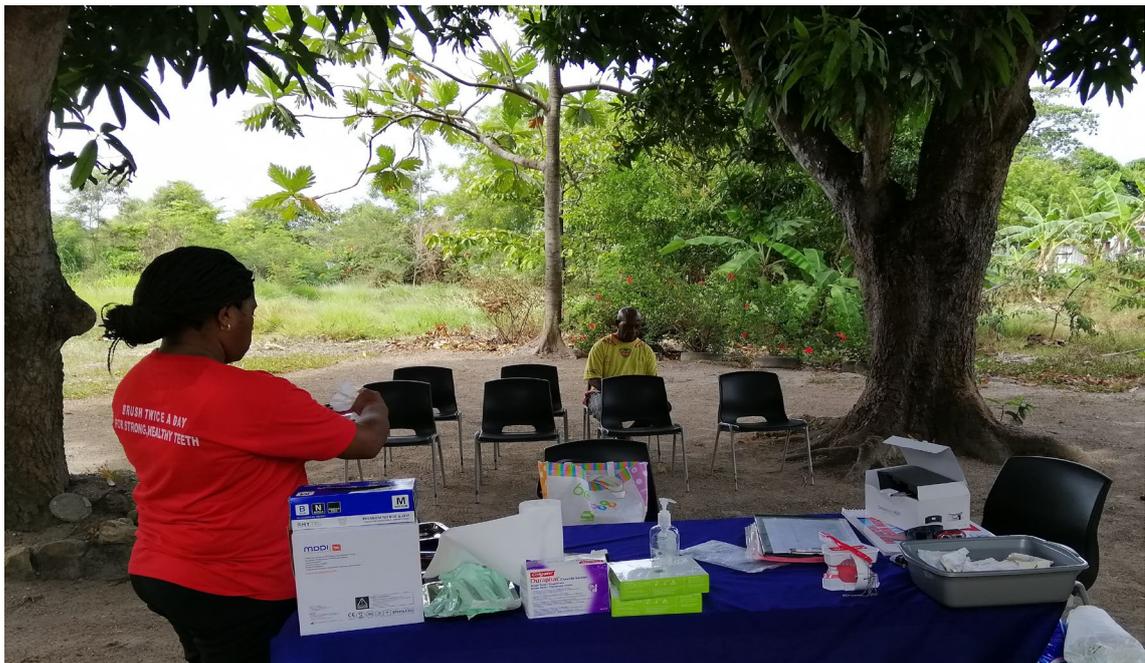
Figure 10. New set-up at Doru section in Pari village.

Comprehensive examination

At Station Two and Three the children were examined. A headlight was used to improve visibility. The examination kit comprised disposable mirror and probe (MDDI), and sterile metal tweezers placed on a disinfected metal tray (Figure 11). The disposable materials were disposed of after each patient, metal tweezers placed in a separate dirty tray and the metal tray wiped down with 70% alcohol and clean paper towel after each patient.

Figure 11. Set-up table at station two and three

A complete examination was done on the child and findings recorded on the WHO oral health survey form for children (Appendix IVa, IVb). The survey form contained participant demography, a dentition chart for primary and permanent teeth, periodontal assessment, assessment for fluorosis, dental erosion, dental trauma, oral mucosal lesions, and treatment need.

WHO Oral Health assessment form for children (Appendix IVa, IVb)

Demography

After confirmation of participation by consent, the participant's details were obtained from the parent/guardian. The child was given an identification number and an examiner number also recorded.

Each examiner was given a unique identifying code which was recorded on the baseline assessment forms. Treatment and assessments at phases two and three were completed by primary researcher examiner 1. The dental assistant paired up with examiner 1 from the baseline visit continued in second and third phase as assistant and recorder.

The participant's name, gender, date of birth and age were obtained from the participant's guardian/parent and recorded.

Papua New Guinea has twenty-two provinces with different languages and cultures hence different ethnicity groups.

Dentition Status by tooth surface

The dentition status of the child's teeth was recorded on the WHO oral health assessment from for children:

A = sound teeth

B = caries

C = filled with caries

D = filled with no caries

E = missing due to caries

A dash (-) = an unerupted tooth

Caries was assessed by visual and tactile examination. If the cavity was completely black and had hard smooth cavity surface, this was recorded as arrested. When brown, soft areas and margins were present on any lesion, then it was recorded as not arrested.

On the second phase and third phase some children had erupted permanent incisors and first permanent molars. These teeth were also recorded with codes for permanent teeth.

Periodontal Status

According to WHO, assessment of periodontal pockets is not recommended in children (WHO, 2013). Assessment of periodontal status was completed by carefully inserting the tip of the periodontal probe between the gingiva and the tooth to assess the presence or absence of bleeding response only. Absence of condition was scored 0, presence of condition or bleeding on probing was scored 1.

Teeth excluded (due to coronal breakdown of tooth due to caries) and teeth not present were recorded X.

Periodontal status of teeth was recorded as number and percentage of teeth present with bleeding, without bleeding and excluded.

Enamel hypoplasia

The WHO section as used for enamel fluorosis was used instead for enamel hypoplasia. Enamel fluorosis is a condition characterised by diffused white spots or opacities generalised on all teeth due to excessive fluoride ingestion through dietary or homecare products including professional fluoride exposure during tooth formation (DenBesten & Li, 2011). Fluorosis can also occur when there is a naturally occurring high concentration of fluoride coming from spring water or creeks used for cooking and drinking by the community (DenBesten & Li, 2011).

Fluorosis was not applicable to this population group as there is no evidence of high fluoride exposure in this population and many do not have access to fluoride tooth paste, fluoride mouthwash or professional fluoride products. Additionally, the village has a

shortage of potable water with no naturally occurring springs or creeks. Some villagers therefore have to travel to relatives living in urban and suburban areas for water. A few of the villagers have water tanks and have them refilled by water companies in town however the water supply in Port Moresby and throughout Papua New Guinea is not fluoridated.

Hypoplastic enamel is defined as a break in continuity of enamel with reduction in the layers leading to depressions or grooves. Enamel hypoplasia is a quantitative defect associated with reduced localised thickness of enamel whereas hypo mineralisation is a qualitative defect affecting enamel translucency (Garg et al., 2012).

The study adopted the definitions and coding on the WHO assessment form for children (WHO, 2013):

0 = teeth with normal enamel and a smooth, glossy and usually a pale creamy white colour.

1 = teeth with slight aberrations in the translucent normal enamel which range from white specks to occasional spots but involving less than 50% of the tooth surface on teeth

2 = teeth with enamel showing white opacities on teeth and involving more than 25% was recorded as mild

3 = teeth with enamel surfaces showing marked wear and brown staining was recorded as moderate

5 = teeth with enamel surfaces severely affected with widely spread brown stains, pitted and worn or corroded appearance affecting the general form of the tooth.

Dental erosion / attrition

Dental erosion is a type of tooth wear. It is a progressive irreversible loss of dental hard tissue that is chemically etched away from the tooth surface by dietary extrinsic and/or intrinsic acids (Taji & Seow, 2010). Erosion is often associated with other forms of tooth wear such as abrasion and attrition (Taji & Seow, 2010) from overzealous oral hygiene, frequent exposure to acidic drinks, and grinding of teeth.

Evidence of attrition and abrasion were recorded following coding system according to WHO (WHO, 2013). Severity of attrition and abrasion was recorded according to the tooth with the highest score of wear.

0 = no sign of attrition

1 = when attrition involved dentin

2 = when involved the pulp

4 = when pulp was involved

5 = missing tooth due to trauma

6 = other damage

9 = excluded tooth

Oral mucosal lesions

Oral mucosal lesions due to ulceration caused by herpetic, aphthous, traumatic, acute necrotizing ulcerative gingivitis and candidiasis were part of the examination form.

However, abscess and ulceration due to cariously infected teeth were recorded under the pufa index table.

Intervention urgency

Treatment need of the participant depended on the severity of their condition due to dental caries or tooth decay and periodontal or gum disease. Participant with a healthy mouth and not requiring treatment were excluded from the study.

1 = Children with enamel caries, dentinal caries and plaque accumulation required preventive treatment and routine care

2 = Children with extensive dental decay and formation of calculus around the teeth prompted treatment such as dental fillings or restorations and dental scaling

3 = Pain and infection due to caries prompted immediate treatment.

The research team did not have the resources to provide dental treatment. These participants continued to receive the fluoride treatment at second phase and were also advised to present to Port Moresby General Hospital for urgent dental care.

Participant enrolment

After medical history was recorded and checked the completion of a comprehensive examination and the child met inclusion criteria, the research was again explained to the child and parent/guardian and an invitation was given to participate in the study. Children who presented with a one or more dental cavities, no history of pain or soreness and no permanent molars were invited to participate in the study. Prior to the signing of consent the information for the child and the parent were explained with the opportunity to ask questions.

Children who had extensive caries already causing pain and infection were excluded and parents were advised to seek dental treatment at the Port Moresby General Hospital Dental Clinic.

Participant information

Information about the clinical trial was thoroughly explained to the parent and the child using the parent and participant information sheet (Appendix V). The information sheet contained reason for this study and why it was being undertaken in Pari village, Papua New Guinea. Details included how the treatment would be beneficial to the child, and possibility of adverse effect of both medicaments, especially of the 38% silver diamine fluoride which causes black staining of the teeth. The potassium iodide would remove some of the black staining effect in and around the cavity margins.

The information sheet also described the three phases of the trial and parents were aware that for the trial to succeed, attendance at all three phases was required.

Consent and Assent

A consent form (Appendix VI) was signed by the parent/guardian after parent and the child had fully understood the reason for this clinical trial with the potential benefits and adverse effects explained by the clinician recruiting the participant.

Any child presenting with a guardian who could not give consent for treatment was excluded. However, those who wanted treatment required consent from parent before the treatment therefore consent form and the participant information sheet were given to the carer to take home to the parents to read and to sign consent form before returning to get treatment the following day. The parents of these children travelled to the city for work.

Photography

Following consent and before treatment allocation, photographs were taken. A photograph of the demographic section of the examination form was taken to record participant details and identification. Extraoral photographs were taken prior to the intraoral photographs of maxillary and mandibular arch. Photos for the upper and lower arch were taken with the child's head toward the parent/guardian's lap. A mobile phone (Huawei nova 3i) and mobile dental photography (MDP) flashlight device (Smile Line Europe) was used to record the photographs. The mobile phone had a 12 megapixels lens on the rear and 8 megapixels on the front lens. The Smile Lite MDP, specifically designed for taking dental photographs is attached to the phone and has three groups of light emitting diodes (Figure 12).

As there were two stations (two and three) using the mobile phone and flash device for taking photos, these were set up prior to dental examinations and placed on a chair in between the two stations. The assistants, who were previously calibrated, took the photographs during the examination.

The photographs of all participants were downloaded from the mobile phone into individually named folders (ID number and full name) and stored in a password protected hard drive.

Figure 12. Smile Lite MDP Device (*https://www.aegisdentalnetwork.com/media/62800*)

Treatment allocation

The treatment was randomized by computer generated numbers by a secondary supervisor. Treatment cards were prepared by the lead researcher and given to the supervisor who recorded the treatment and concealed the cards in opaque sealed envelopes (Figure 13).

Participant Number:

Treatment Allocation:

Papamama plis tingim long halpim pikinini long brasim tit tupla time long wanpla dei

Mipla i amamas long yu na pikinini wok bing wantem mipla na i laik tok Merry Kristamas na Hepi Niu Year 2019!!!

Na lukim yupla ken klostu taim!

Figure 13. Treatment card in enveloped with participant number, treatment allocation and post-operative instructions in Tok Pisin.

The envelopes were brought to Port Moresby by primary supervisor and securely looked after by another dentist who was not part of the research team. The card contained the allocated treatment and number and postoperative instructions for parents.

After parents gave written consent, the assistant took out a box of envelopes and asked the child to pick out an envelope and opened it in front of the parent/guardian and the treating clinician who is the examiner. The treatment card revealed whether 38% SDF or 5% NaF was going to be applied. There was a randomized number on the treatment card which was recorded in the participant file. In this way, the same and correct treatment was provided at second phase

Treatment

38% SDF (Riva Star kit):

The SDI kit contained 10 grey capsules 38% SDF and 10 green capsules containing potassium iodide (KI). SDF (38%) had a fluoride composition of 48 000 ppm (Figure 14). There were 10 grey and 10 green micro-brushes ready for use. Gingival barrier pastes were also included in the kit but these were not used (Figure 14).

Figure 14. SDI Riva star kit containing 10 grey capsules of 38% SDF and 10 green capsules of potassium iodide capsules with colour matched micro-brushes

Each grey capsule contained enough SDF solution required to treat at least 5 affected teeth. The potassium iodide was mainly to remove the black staining created on the tooth after application of the 38% SDF.

While the examiner prepared the patient for treatment the dental assistant prepared the SDF kit and KI capsules.

Application of 38% SDF (Riva Star kit)[1]:

1. Dry the area to be treated with gauze

2. Isolate the teeth with cotton rolls

3. Using silver micro brush pierce the foil on silver capsule

4. In circular motion, push foil to the edge of the opening

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[1] Application instructions for 38% SDF Riva Star kit (SDI Australia) was obtained from www.sdi.com.

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5. Carefully apply solution from the capsule to the treatment area(s) only.

   (Due to very high temperatures and open exposure to light in the field, the capsule needed to be covered with gloved hands if required to apply to several teeth)

6. Immediately using green brush, pierce the foil on the green capsule

7. In circular motion, push foil to the edge of the opening

8. Apply generous amount from the green capsule to the treatment area(s) until the creamy white turns clear.

9. Blot dry with cotton pellet(s)

5% sodium fluoride varnish (Duraphat®)

The Colgate Duraphat® contained white 5% sodium fluoride varnish with fluoride composition of 26, 000 ppm (Figure 15). Single use packets were used for this research. Each packet contained a measured amount of fluoride required for full mouth application and a micro-brush inside the single unit pack.

Figure 15. Duraphat® box of 50 single units.

While the clinician prepared the patient to receive treatment, the assistant opened the packet and stirred to mix the contents before handing the micro-brush to the clinician for treatment.

Application of 5% NaF (Duraphat®)[2]:

1. Tooth surfaces were cleaned by use of cotton rolls and gauze.

2. Teeth were isolated using cotton roll/gauze

3. The varnish was applied in sweeping horizontal brush stokes across the teeth

4. The child was asked to close the mouth for varnish to set

Post- operative instructions

After receiving the fluoride treatments, participants were advised not to eat or drink or rinse for next thirty minutes so prevent dilution of the varnish and maintain the ability of the fluoride treatment to arrest the dental caries

Rewards

Stickers were given to each child after treatment and post- operative instructions were given to the child and parent. The reward was more a behaviour management technique to increase compliance in the next visit. Otherwise, also rewarded for being brave enough to participate in the research.

Oral hygiene instructions

Oral hygiene instructions included instructions as to how the child should brush their teeth, how much toothpaste a child under 6 years should use and how often toothbrushing should be done.

The children were advised to use clean water for toothbrushing and a smear layer of toothpaste on the toothbrush. They were advised to brush their teeth in a circular motion. The children were also advised to brush their tongue and cheeks and spit out excess but

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[2] Application instructions for 5% NaF Duraphat® was obtained from www.colgrateprofessional.com.au.

not rinse. Advice provided to the children was to brush teeth twice daily after breakfast and dinner however as the village had shortage of water supply, toothbrushing was highly recommended after dinner before going to bed. Parents were advised to buy a new tube of toothpaste when the sachets provided in the oral hygiene kit needed to be replaced.

Oral health education included explaining how dental caries and periodontal diseases are caused by bacterial plaque accumulation on teeth and poor oral hygiene habit (Figure 16). This was advice given to parents and they were encouraged to improve toothbrushing habit of their children.

Figure 16. Providing oral health education to parent and participant.

Parents and children were also advised to reduce consumption of sweets such as lollies and sugary drinks and high starchy diet. These were food stuffs bought daily by the villagers and many could more readily afford these less costly than healthy food from the fresh vegetable markets or supermarkets.

Oral hygiene kits

The oral hygiene kits contained a child's toothbrush, an adult toothbrush and fluoridated toothpaste sachets. This was for the child and for the guardian/ parent who presented with the child for the appointment. The adult was advised to encourage the child to join them while they brushed their teeth.

Parents were advised to apply a pea-sized or smear layer of toothpaste on the child's toothbrush before toothbrushing. The sachets of toothpaste were not going to last until the next visit in six months. Therefore, parents/guardians were advised to buy a new tube of fluoridated toothpaste when the sachets became empty.

Phase Two

Six-month follow- up

Set up and examination

During the second phase of the trial, participant names including their parent/guardian's names were printed out as recommended by the church elders and posted on notice boards around the village. Announcements were made in the Pari United Church informing the villagers of the dates and venues of the second visit. Due to experience from the first visit, village was divided into four sections – Doru, Community hall (Laurina), Gwadu and Dadarai. Most days were spent at Laurina, the main community area. The community hall was not available for use in the second and third phase as was undergoing renovations to become a teaching centre - A project funded by the Australian-Aid Fund Program.

As there was only one examiner and assistant for phase two, the table and chair arrangements were modified to accommodate for changes (Figure 11). Chairs were arranged for parents and children who had to wait for participants preceding them.

The purpose of the second visit was explained to both the guardian and the child. The procedure was explained to the child again with reference to his or her experience in the first appointment. The medical history of the participant was updated on the previous medical history form followed by parent and child acceptability of the initial treatment at phase one. An updated dental examination, using the WHO form (Appendix IVa) including the addition of an assessment of the primary teeth pufa index (Appendix IVc).

Extra supplies under table beside DA

Table covered with a cloth.
Personal belongs & supplies stored under

Data collection:
1. Medical history
2. Dental history
3. Examination
4. Photography
5. Application

Exam kits & Camera

Treatment area

OHI Kits

Chairs in wait area for exam

Rubbish container

OHI kits supply under table beside examiner
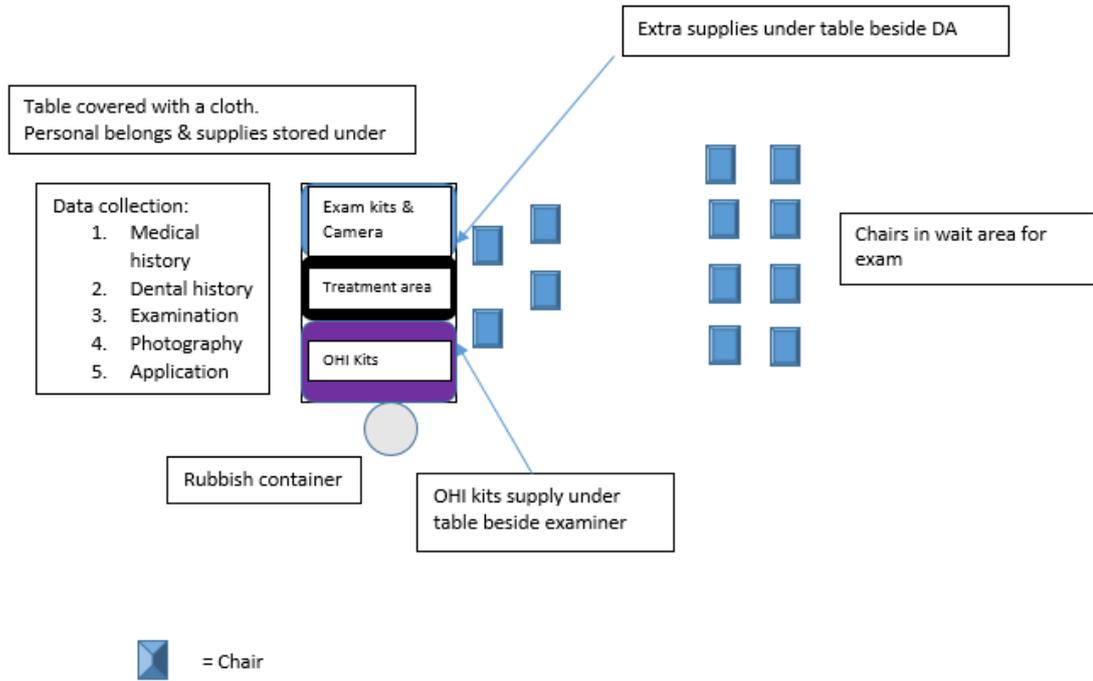
= Chair

Figure 17. Table and chair lay-out for second phase and third phase.

Assessment of Acceptability

Acceptability of treatment was assessed separately for parent and the participant. Parent assessment was done by a Likert scale questionnaire (Appendix VII). Three questions were asked to assess the parent's acceptability of the treatment. The questionnaire asked whether the parent was satisfied with the treatment given to his/her child, if this benefited the child and whether black staining of the teeth bothered the parent. Answers were given on a Likert scale from 1 to 5 where 1=strongly agree, 2= agree, 3= neutral, 4= disagree and 5= strongly disagree. The assessment was based on questions that were not validated from literature as there were no validated questionnaires available in studies to assess acceptability of treatment.

Children on the other hand were assessed with the use of visual analogue scale (Buchanan, 2005) from 5 to 1 where 5= very unhappy, 4= unhappy, 3= neutral or do not know, 2= happy and 1= unhappy. The children were asked to colour in the facial expression that depicted how they felt about the treatment (Appendix VII).

PUFA/pufa Assessment

The PUFA/pufa index is to assess the presence of oral health conditions resulting from untreated caries (Appendix IVc).

The PUFA for permanent dentition with score ranging from 0 to 32 and pufa for primary dentition with sore ranging from 0 to 20. The prevalence of PUFA/pufa is calculated as percentage of the population with a PUFA/pufa score of one or more. While the pufa experience for a population is calculated as a mean figure. This assessment was additional to the WHO assessment. It was a visual assessment only. It was included in the second and third phases.

To ensure consistent clinical judgement throughout phase two and three, the lead researcher studied the photos provided by Monse et al. (2010) for assessment of pulp, ulceration, fistula and abscess before the follow up visit (Figure 18-21).

The pufa index assesses for presence of pulpal exposure (p) of teeth, an ulceration(u) on the oral mucosa due to caries breakdown of dental tissue, fistula (f) on the buccal or lingual alveolar mucosa of carious teeth, and an (a) abscess that has developed on the side of alveolar mucosa of carious teeth (Monse et al., 2010).

This research has based pufa index calculation on primary dentition even though some children had developed permanent first molars and lower and upper central incisors by the third phase. The pufa score per person is calculated in the same cumulative way as for the dmft and represents the number of the teeth that meet the pufa diagnostic criteria.

$$\text{pufa index} = \frac{p + u + f + a}{\text{population}} \times 100$$

Figure 18. Pulpal exposure (p) 61

Figure 19. Ulceration (u) due to root fragment

Figure 20. Fistula (f) on buccal of 75

Figure 21. Abscess (a) on the buccal 64

Photography

Photographs were taken using the same protocol as for the first phase.

Treatment

The medicament was applied to the teeth of the children according to recorded treatment number and type of fluoride treatment that was given to the participant in the initial phase.

Oral Hygiene Instructions and Oral Hygiene Kits

Following treatment, an oral hygiene kit was given to each child. The kit was the same as used in phase one. Oral hygiene advice was given using the same protocol as for phase one.

Rewards

Children were again rewarded with stickers to show appreciation for their willingness

and participation. This was also aimed at increasing compliance level in the third phase.

Phase Three

12-month follow- up

The final phase of the study, participant and parent names were again printed out and taken to the village with a note for the Pari village United Church chairman to make an announcement on behalf of the research team, three consecutive Sunday church services preceding to our dental visit.

A period of two weeks was spent in the village for data collection. The set-up in the four different sections as we did in the second phase in the first week. In the following week, the set-up was mainly based at Laurina which is the main community area.

The third phase of the research was at 12 months from baseline assessment and it involved a comprehensive dental examination, pufa index assessment, assessment of acceptability of treatment by parent/guardian and the participant and photographs. The same protocol as in second phase was implemented except for the application of topical fluoride treatments. Oral hygiene kits were provided, and parents were educated to encourage toothbrushing in children ant to continue to support their child's oral health.

Parents of children who developed pulpal exposure and abscess overtime were advised to bring their child to the Port Moresby general hospital for definite dental treatment.

Emphasis was placed on use of fluoridated toothpaste and toothbrushing especially at night-time before bed.

Again, stickers were given as rewards for their bravery throughout the three phases of this study. Toys for boys and girls were also given as gifts to show appreciation to the child for their time throughout the clinical trial period.

Outcomes measures

Progression of dental caries was using clinical examination and recording of data on the WHO oral health assessment form for children (WHO, 2013). Decayed, missing and filled surface (dmfs) scores were also recorded at baseline and repeated at 6 and 12 months review. Progression of dental caries were assessed by modifying the codes for arrested carious lesions to AR and active caries remained as code B at each review. Tooth surface analysis was carried out to assess surface changes from, carious to arrested, arrested to carious, sound to carious at baseline and 12 month review.

Data Analysis

Survey and clinical data were transferred onto Windows excel spreadsheet (Microsoft Office 8.0) in a de-identified format and analysed. Statistical Package for Social Sciences (SPSS, version 26.0) for windows was used to analyse demographic data. An intention to treat analysis was undertaken. The STATA software (version 16.0) was used to complete regression analysis.

The primary outcome measures were the number of arrested caries lesions at 12 months and the mean number of new lesions that developed over time. Within-group changes in the mean dmfs at 6 and 12 months by employing repeated ANOVA. Between-group comparisons of mean of arrested caries at 12 months and mean dmfs over time was determined using t-test for independent sample test. Subsequently, multivariate linear regression analysis for surface caries analysis was conducted by negative binomial regression analysis with the generalize estimating equation model (GEE) to determine the effect of intervention (38% SDF vs 5% NaF) controlling arrested caries, tooth location (posterior and anterior), lesion site (occlusal, buccal/lingual, distal and mesial),

age and gender at baseline. The same regression model was used for increment of carious lesions and the pufa index score controlling for same variables at baseline.

The secondary outcome measures involved analysis of parent and child acceptability were further analysed and compared by the Pearson's chi- square and Fisher's exact test where suitable; the chi-square test where sample size is large and the Fisher's exact test where the sample size is small.

Chapter 3: Results

Participants

The 104 participants aged 2 to 5 years were randomly allocated into two treatment groups.

Participants response

In this study, at baseline, there were 302 prospective participants who were assessed for eligibility and 183 children were excluded as they did not meet the inclusion criteria. One parent declined participation of his child and 14 children presented with accompanying person who could not provide consent. These children went away with consent form after initial screening to get consent from parents and did not return for treatment. A total of 104 participants were recruited. At six months visits, 85 children returned for follow up examination and received dental treatment according to the protocol of their allocated group. At the 12-month visit, 90 participants returned for follow-up.

In terms of treatment groups, eight participants in SDF group, and six participants in NaF group were excluded from regression analysis as lost to follow-up. Figure 22 shows the flow of participation throughout the study.

Participants Demography

The children were from Pari village, a rural setting 30 minutes outside of Port Moresby in Papua New Guinea. The majority of the children, 83.7%, were born in Pari and the other children, 16.3%, moved to Pari from other areas of Papua New Guinea

All the participants lived in Pari village at the time of trial and were from low socioeconomic background. At baseline there 55 girls and 49 boys. At six months follow

up 49.4% of males and 50.6 % females returned for assessment and second phase treatment. At 12 months, 48.9% of males and 51.1% of female participants returned for follow up. There was no significant difference between the number of boys and girls who presented for the 6 months and 12 months follow up phases.

The age group ranged from 2 to 5 years, 44.2% were aged 2-3 years and 55.6% were aged 4-5 years and mean age was 3.69 years. Throughout the 12-month period, some of the children turned 6 years at 6 month (16.5%) and 12 months (18.9%) follow-up.

The children were divided into two treatment groups. Group one received 38% SDF and Group two received 5% NaF. At baseline, there were 52 participants in each treatment. At the 6 month 86.5% of SDF group and 76.9% of NaF group attended. At 12 months there were more children in NaF group compared to SDF group returned (Table 2).

Chi square analysis confirmed there were no significant differences of gender and age between the groups at each phase of the trial ($p > 0.05$).

Examiner calibration

Intra-examiner reproducibility and inter-examiner reproducibility in the diagnosis of caries was done by Cohen's Kappa statistic for three phases. The inter-examiner reliability between three examiners at baseline was 0.77 and intra-examiner reliability at second and third phase for the principle researcher was a good Kappa value of 0.9.

Table 2. Demographic characteristic of participants.

	Baseline N (%)	6 months N (%)	12 months N (%)
Total	104 (100)	85 (81.7)	90 (86.5)
Treatment groups			
38% SDF	52 (100)	45 (86.5)	44 (84.6)
5% NaF	52 (100)	40 (76.9)	46 (88.5)
Gender			
Male	49 (47.1)	42 (49.4)	44 (48.9)
38% SDF	22 (42.3)	19 (45.2)	19 (43.2)
5% NaF	27 (51.9)	23 (54.8)	25 (56.8)
Female	55 (52.9)	43 (50.6)	46 (51.1)
38% SDF	30 (57.7)	26 (60.5)	25 (54.3)
5% NaF	25 (48.1)	17 (39.5)	21 (45.7)
Age in years			
2	17 (16.3)	9 (10.6)	5 (5.6)
3	29 (27.9)	14 (16.5)	12 (13.3)
4	27 (26.0)	28 (32.9)	33 (36.7)
5	31 (29.8)	20 (32.9)	23 (25.6)
6		14 (16.5)	17 (18.9)
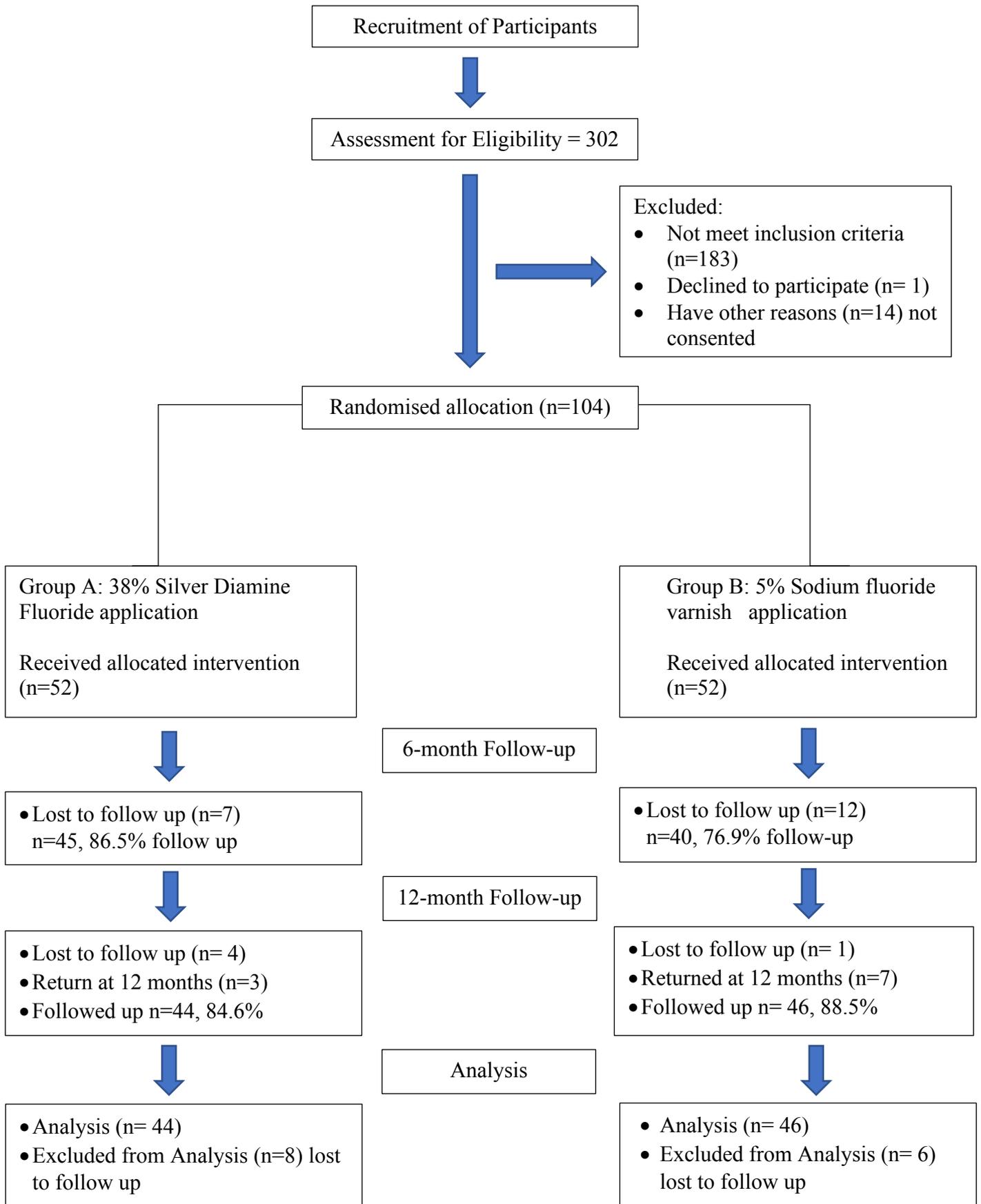
Figure 22. Flow diagram of the participation.

Caries experience by sex and treatment group

The total mean dmfs at baseline for the 104 participants was 11.28 and at 6 months (85 participants) 12 months visit (90 participants), 11.08 and 10.93 respectively. Using the independent sample t-tests to compare mean dmfs between phases 1 and 2, there was no statistical significant difference ($p > 0.005$). There was also no statistically significant difference ($p = 0.305$) in the mean dmfs changes between the treatment groups at 6 month and 12 months follow-up.

Mean dmfs was calculated for participants by treatment groups. Children who received SDF at baseline had a mean dmfs of 10.7 and those who received NaF had a mean dmfs of 11.8. The differences in dmfs values in the three phases were insignificant ($p > 0.05$).

One-way ANOVA was used to compare means of treatment group between the three intervals. There was no significant difference between the dmfs values of treatment groups at baseline ($p = 0.645$), 6 months ($p = 0.244$) and 12 months ($p = 0.794$) follow-up.

Table 3. Mean dmfs of participants by treatment groups, age groups and gender at baseline, 6 months and 12 months

	Baseline		6 months		12 months	
	No. of participants (%)	Mean dmfs (SD)	No. of participants (%)	Mean dmfs (SD)	No. of participants (%)	Mean dmfs (SD)
Treatment group						
SDF	52 (100)	10.7 (9.1)	45 (51.1)	12.1 (9.6)	44 (48.9)	11.7 (8.4)
NaF	52 (100)	11.8 (10.0)	40 (47.1)	12.4 (9.8)	46 (51.1)	14.5 (12.4)
Age in years						
2	17 (16.3)	8.2 (7.8)	9 (10.6)	6.6 (5.8)	5 (5.6)	6.6 (5.5)
3	29 (27.9)	10.5 (9.9)	14 (16.5)	12.7 (11.2)	12 (13.3)	9.8 (8.0)
4	27 (26.0)	14.9 (10.5)	28 (32.9)	12.4 (9.8)	33 (36.7)	15.4 (13.0)
5	31 (29.8)	10.5 (8.6)	20 (32.9)	15.1 (10.5)	23 (25.6)	14.9 (10.6)
6	0 (0)	0 (0)	14 (16.5)	11.1 (7.2)	17 (18.9)	10.6 (6.72)
Gender						
Male	49 (47.1)	10.8 (9.0)	42 (49.4)	11.7 (8.96)	44 (48.9)	12.9 (10.4)
Female	55 (52.9)	11.7 (10.0)	43 (50.6)	12.7 (10.3)	46 (51.1)	13.3 (11.0)

Arrested caries vs not arrested by treatment groups

Table 4. Surface level analysis of active and arrested carious surfaces following intervention at 6 months and 12 months.

	6 months			12 months		
	Active (%)	Arrested (%)	Total (%)	Active (%)	Arrested (%)	Total (%)
SDF	41 (8.1)	463 (91.9)	504 (100)	13 (2.8)	445 (97.2)	458 (100)
NaF	94 (21.5)	344 (78.5)	438 (100)	150 (28.5)	376 (71.5)	526 (100)
Total	135 (14.3)	807 (85.7)	942 (100)	163 (16.8)	821 (83.3)	984 (100)

Logistic regression analysis was conducted to observe changes in the number of arrested caries and caries not arrested after application of the medicaments. Medicaments were applied at baseline with the six- month follow up. At six months, 78.5% of caries in NaF group had completely arrested and remaining 21.5% were not arrested. At 12 months, the number of arrested caries dropped to 71.5% and 28.5% active. Approximately 6% of the arrested caries had returned to active carious state. For the SDF group, 91.9% of total caries were arrested at six months follow up and this increased to 97.2% at 12 months (Table 4). The caries arrest rate in SDF group, was significantly higher than that of NaF group ($p < 0.001$). The analysis demonstrated that the 38% SDF was more effective than the 5% NaF varnish (OR: 7.7, 95% CI=3.14 -19.09) in arresting caries (Table 5).

Table 5. Multivariate model of arrest of caries-affected tooth surfaces by intervention, controlling by sex, age, decayed surfaces, tooth location, and lesion site at baseline*.

	6 months		12 months	
	OR (95% CI)	*p*- values	OR (95% CI)	*p*- values
Treatment group				
38.5% SDF	4.90 (2.01, 11.98)	<0.001	7.75 (3.14, 19.09)	<0.001
5% NaF (ref.)	1		1	
Sex				
Male	0.80 (0.35, 1.85)	0.609	0.52 (0.23, 1.16)	0.109
Female (ref.)	1		1	
Age at baseline (years)	1.58 (1.0, 2.48)	0.048	1.02 (0.64, 1.64)	0.927
Decayed surfaces	1.02 (0.97, 1.06)	0.485	0.93 (0.89 - 0.96)	<0.001
Posterior	0.77 (0.41, 1.45)	0.485	0.85 (0.37, 1.90)	0.689
Anterior	1		1	
Occlusal	1.02 (0.69, 3.35)	0.301	1.61 (0.97, 2.67)	0.066
Buccal / lingual	1.33 (0.62, 2.83)	0.464	1.42 (0.85, 2.38)	0.178
Distal	0.90 (0.53, 1.98)	0.759	0.81 (0.58, 1.14)	0.227
Mesial	1.52 (0.69, 3.35)	0.301	1.22 (0.87, 1.7)	0.242

*Unit of analysis = tooth surface $p > 0.05$

Adjusted odds ratios (OR) and associated 95% confidence intervals for the relationship between the presence of arrested caries and the intervention provided, gender and age variables estimated binomial generalized estimating equation (GEE) models are presented in Table 5. The multivariate model revealed a significant relationship between

number of arrested carious tooth surfaces and the intervention provided ($p < 0.001$) at 6 months and remained significant ($p < 0.001$) at 12 months in the SDF group.

As age increased the chances of teeth becoming arrested also increased (OR=1.58, 95% CI 1.0, 2.48). As per decayed surfaces, the odds of the surfaces becoming arrested at six months was 1.02 ($p > 0.05$) however at 12 months there was a significance ($p < 0.001$)

Surface analysis was also carried out to compare effectiveness by tooth location and lesion site. At 12 months, it was found there was no significant difference in arrested caries in posterior teeth compared to the anterior teeth. Moreover, there was no statistical significance in the arrest of the occlusal surface lesions compared to the buccal/lingual, distal and mesial surfaces.

There was no statistical significance in carious surfaces arrested between gender and age at 6 months and 12 months.

Caries increment by treatment groups at six and 12 months

Table 6. Surface level analysis of caries increment at 6 month and 12 months

	6 months			12 months		
	No new caries (%)	New caries (%)	Total (%)	No new caries (%)	New caries (%)	Total (%)
SDF	3338 (98.3)	59 (1.7)	3397 (100)	3244 (97.9)	70 (2.1)	3314 (100)
NaF	2982 (97.4)	79 (2.6)	3061 (100)	3274 (95.6)	151 (4.4)	3425 (100)
Total	6320 (97.9)	138 (2.1)	6458 (100)	6518 (96.7)	221 (3.3)	6739 (100)

Caries increment was also analysed for the 85 children at six months and 90 children at 12 months. At six months there were 79 (2.6%) new carious surfaces in NaF group and this increased to 151 (4.4%) at 12 months. In the SDF group, the rate of new carious surfaces was 1.7% at six months and increased to 2.1% at 12 months. Pearson's chi-squared test was used to evaluate the differences between the groups. At the six-month phase there was no statistical significance (OR: 0.6, 95% CI 0.3 -1.3, $p = 0.012$) in the rate of new carious surface development. However, the new carious surface formation at 12 months for SDF group was 2.1% which is statistically significantly ($p < 0.001$) lower compared to NaF group 4.4%.

Table 7. Multivariate model of increment of caries-affected tooth surfaces by intervention, controlling by sex, age, decayed surfaces, tooth location and lesion site at baseline*

	6 months follow up		12 months follow up	
	OR (95% CI)	*p*- values	OR (95% CI)	*p*- values
Treatment group				
38.5% SDF	0.66 (0.32, 1.33)	<0.001	0.41 (0.22, 0.76)	0.006
5% NaF (ref.)	1		1	
Sex				
Male	1.61 (0.78, 3.36)	0.193	1.25 (0.67, 2.35)	0.479
Female (ref.)	1		1	
Age at baseline (years)	0.83 (0.62, 1.11)	0.212	0.92 (0.70, 1.21)	0.568
Decayed surfaces	1.07 (1.04, 1.10)	< 0.001	1.07 (1.05, 1.10)	< 0.001
Posterior	0.87 (0.47, 1.61)	0.661	1.14 (0.62, 2.11)	0.668
Anterior	1		1	
Occlusal	3.97 (2.3, 6.83)	< 0.001	2.97 (1.62, 5.43)	< 0.001
Buccal / lingual	0.81 (0.48, 1.37)	0.428	0.76 (0.50, 1.13)	0.176
Distal	0.58 (0.33, 1.01)	0.058	0.78 (0.53, 1.14)	0.197
Mesial	1.09 (0.69, 1.72)	0.700	1.20 (0.83, 1.73)	0.331

*Unit of analysis = tooth surface $p > 0.05$

Adjusted odds ratios (OR) and associated 95% confidence intervals for the relationship

between the increase in carious surfaces and treatment provided, gender and age variables

estimated negative binomial regression generalised estimating equation (GEE) models are presented in Table 7. The analysis revealed no significant relationship between number of new carious lesion development and the intervention provided ($p = 0.246$) in the participants at 6 months follow up and was statistically significant ($p = 0.006$) at 12 months.

Surface analysis was also carried out to compare effectiveness by tooth location and lesion site. At 12 months, it was found that the chance of posterior teeth developing newer lesions was higher (OR: 1.14 95% CI 0.62, 2.11) than in the anterior region. Moreover, the occlusal surface lesions had a greater chance of developing new lesions (OR: 2.97, 95% CI 1.62, 5.43) as compared to the buccal/lingual, distal, and mesial surfaces. There was a statistical significant difference ($p < 0.001$) in caries increment at occlusal site lesion as compared to the other tooth surfaces.

When age and gender were added to the regression model, there was no statistical significance ($p > 0.05$) in development of new carious lesions at 6 months and 12 months.

Periodontal Health of Participants

Table 8. The percentage of healthy and bleeding gingiva at baseline, 6 month and 12 month.

	Baseline (%)	6 month (%)	12 month (%)
Healthy	90 (86.5)	71 (83.5)	74 (82.2)
Bleeding	14 (13.5)	14 (16.5)	16 (17.7)

There was some small variation of the total score for healthy and bleeding gingiva between the first, second and third phase of this trial. At baseline, 86.5% of the children had healthy gingiva.

The percentage variation of children with gingival bleeding had slight variation from 13.5% to 16.5% and 17.7% at baseline, six months, and 12 months, respectively.

Pearson chi square test was used to compare difference between the means showed there was no significant difference in gingival health of participants at 6 months ($p = 0.174$) and 12 months ($p = 0.650$).

pufa Index Scores

Table 9. Frequency of children with pufa index score.

	No. children	6 months pufa index score	12 months pufa index score
38% SDF	2	2	2
5% NaF	7	3	16
Total	9	5	18

Following the initial application of 38% SDF and 5% NaF varnish, the pufa index was used at phases two and three, to assess the presence of either visible pulp (p), ulceration of mucosa due to root fragments (u), fistula (f) or abscess (a).

Analysis by treatment groups observed that only two participants in the SDF group had developed a pufa score of one each during the period of clinical trial. At 12 months, in the NaF group, one child had a pufa index score of six (four pulp exposures and two abscesses), two children had a pufa index score of three and four children had a pufa index score of one.

In a negative binomial regression model, the chances of getting a pufa index score at 12 months in NaF was higher than individuals who received 38% SDF (OR=2.0, 95% CI 0.3-3.83), and there was statistical significance ($p = 0.021$) between the two treatment groups. However, there was no statistical significance when age ($p = 0.625$) and gender ($p = 0.397$) were placed in a regression model.

Acceptability of Treatments by Parents and Child

Parent acceptability of treatment

Table 9. Analysis of parent acceptance of treatment at 6 month and 12 month follow up

		6 months (n = 85)		12 months (n = 90)	
		SDF (%)	NaF (%)	SDF (%)	NaF (%)
I am satisfied with the treatment given to my child	*Satisfied*	45 (100)	40 (100)	44 (100)	38 (82.6)
	Dissatisfied	0 (0)	0 (0)	0 (0)	8 (17.4)
My child benefited from this treatment.	*Satisfied*	44 (97.8)	37 (92.5)	44 (100)	37 (84.6)
	Dissatisfied	1 (2.2)	3 (7.5)	0 (0)	9 (19.6)
Black staining of teeth bothered me.	*Disagree*	45 (100)	40 (100)	44 (100)	46 (100)

Parents completed the questionnaire or were assisted to complete the questionnaire, regarding the acceptability of treatment, at the six month and twelve-month phases. The answers have been categorised for ease of analysis to "satisfied and dissatisfied", and "agreed and disagreed". At the six-month follow up, 100% of the parents were satisfied with the treatment provided, although one parent from the SDF group stated that that there was no benefit from treatment. In the NaF group more parents were satisfied that the treatment provided benefited their children

At 12 months follow up, all the parents of children in SDF group were satisfied with the treatment provided to their child, satisfied that the treatment benefited their child and the black staining of their child's teeth did not concern them. For parents of children in NaF group, 82.6% were satisfied with the treatment and 17.4 % (8 parents) not satisfied.

The percentage of parents who were satisfied that their child benefited from treatment with NaF was 84.6%, while 19.6% were dissatisfied.

Interestingly all parents were not concerned about staining of teeth in their children in both the second and third phase.

There were no significant differences in acceptability of treatments in parents of the participants (Fisher's exact, $p = 0.006$).

Child Acceptability

Table 10. Analysis of child acceptance of treatment at 6 month and 12 months.

	6 months			12 months		
	SDF (%) n = 45	NaF (%) n = 40	Total (%) n = 85	SDF (%) n = 44	NaF (%) n = 46	Total (%) n = 90
Happy	41 (91.1)	39 (97.5)	80 (94.1)	44 (100)	39 (84.7)	83 (92.2)
Not happy	3 (6.7)	1 (2.5)	4 (5.9)	0 (0)	7(15.3)	7 (7.8)

Children were assessed for their acceptability of treatment by a visual analogue scale, in which they were requested to colour the face of how they felt about the treatment that they received in the previous visit. The majority of the children were happy with the

treatment provided at six months (94.1%) and 12 months (95%). According to treatment groups, at six months, a higher percentage of children (91.1%) in SDF group were happy with treatment received, with three (6.7%) not happy. These three children did not like the taste of the SDF solution and said it was bitter. One child did not complete the scale. For participants in NaF group, 97.5% were also happy with treatment received and one child (2.5%) was not happy. At 12 months, all children who presented in the SDF group were happy with the treatment and in NaF group, 84.7% were happy, and seven (15.3%) were unhappy. These seven children had experienced discomfort due to development of abscesses and pulpal exposures which resulted from unarrested dental caries. There was a significant difference (Fishers exact, $p = 0.012$) between the acceptability of treatment by the child between the treatment groups.
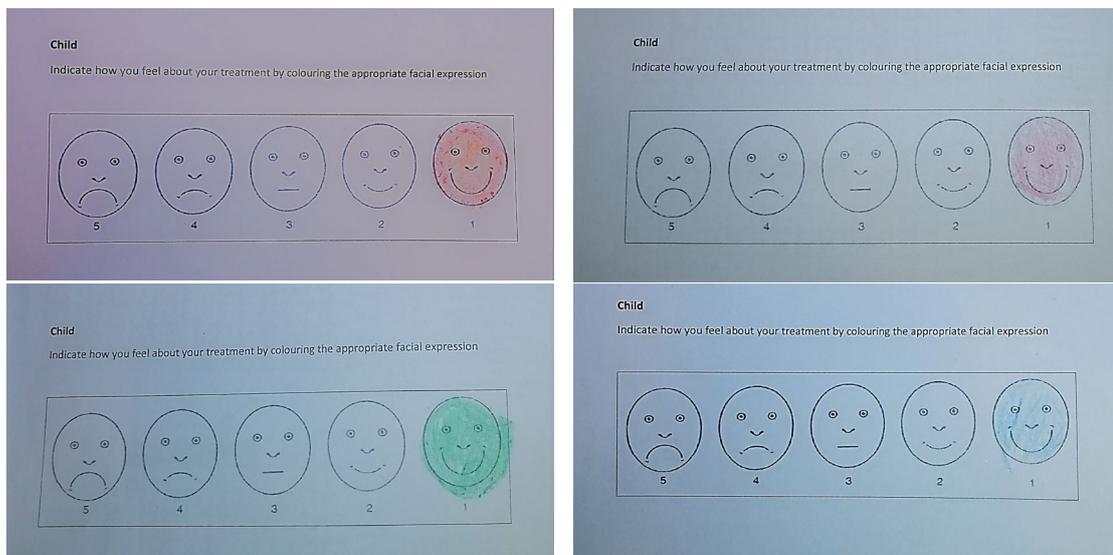
Figure 23. Completed child visual analogue scales.

Chapter 4 Discussion

Overview of the study

This study is the first RCT in cariology carried out in PNG. The clinical trial investigated the potential caries arresting effect of 38% SDF and 5% NaF in children aged two to five years living in a rural area near Port Moresby, the capital city of PNG. Concurrently, the study assessed the acceptability of the use of topical fluorides by the parent and child.

Studies have shown that the prevalence of dental caries in children is higher in areas of lower socioeconomic status and in disadvantaged societies (Kato et al., 2017; Sun et al., 2017). The mother's or guardian's educational status and parental income level is significantly related to ECC (Xavier et al., 2012).

The majority of the residents of Pari village are from a low socioeconomic background. They live in houses without running water or connection to sewerage. In PNG education is not obligatory, and it is free only for the first two years of primary school. In 2016, primary school attendance levels were 76 % for boys and 71 % for girls. Lack of money or complex family situations deprive many children of access to schooling. Some commence school at an older age, which often leads to scholastic failure. As a consequence, more than 30% of those aged 15-24 years are illiterate (UNESCO, 2020). Limited access to dental care facilities and financial constraints meant, for the children in this clinical trial, the baseline dental examination was their first dental experience.

SDF is a valuable tool for dental public health programmes directed at individuals who lack access to dental care facilities. It enables treatment which does not require caries removal and a technique which does not demand expensive or sophisticated dental equipment. The prevention and arrest of carious lesions will benefit children by reducing

the likelihood of developing infection and pain. SDF was found to be effective in arresting dentine caries in primary anterior teeth in Chinese pre-school children (Chu et al., 2002). A disadvantage of SDF use however, is black staining on teeth which can cause aesthetic concerns. Chu et al. (2002) found by explaining to parents that the black staining represented arrested dental decay treatment was more readily accepted (Chu et al., 2002).

NaF varnish (5%) has been shown to be effective in preventing ECC incidence in young, initially caries-free children (Weintraub et al., 2006). Mabangkhru and colleagues concluded from their randomized clinical trial in young children with active caries that although 5% NaF varnish was effective in arresting carious lesions it was less effective than SDF (Mabangkhru et al., 2020). Blackening and hardening of dentine caries lesions can occur with NaF varnish but to a lesser extent than SDF.

Several studies have indicated that there is high acceptability for use of 38% silver diamine fluoride among parents in Hong Kong and in the USA (Chu et al., 2002; Clemens et al., 2018; Crystal et al., 2017). NaF and SDF had no impact on parental satisfaction with children's dental appearance (Mabangkhru et al., 2020).

Demographic details

A study sample of 104 children should detect a mean difference between the two treatment regimens and also allow for a 20% dropout rate (Lo et al., 2001). At 12 months the dropout rate was 13.4% reflecting the willingness of parents to get treatment for their children and their hitherto limited access to dental services (Figure 24).

Figure 24. Parents and children waiting to be seen by researchers

ECC is a rapidly progressing form of dental caries affecting the primary dentition. The study children were exposed to manufactured processed sugary foods on a daily basis (Figure 25). Their high caries incidence was consistent with other study results associating high caries experience in children with disadvantaged parents from low socioeconomic backgrounds and with low educational status.

Figure 25. Accessibility of sugary-foods and betel- nut through vending stalls in Pari village.

Most participants presented with their mothers - many of whom did not have jobs or had dropped out at high school level and returned to the village. Parents and guardians understood that a hole in a tooth meant that the child was suffering from tooth decay and were eager to get treatment for their children. Most were either not aware of facilities which could provide dental care or did not have the financial means to travel to town for treatment. In PNG, dental treatment for children under 6 years of age is free. Many parents thought that a child's dental treatment cost as much as adult care and did not want to spend money unless the child had severe pain and swelling. This reflects a need for oral health promotion and community visits to rural areas near Port Moresby.

The total mean dmfs at baseline of the PNG study was 11.28 with a dmfs range from 1-43. The mean dmfs at baseline for the SDF group was 10.7 and for the NaF group 11.8, with no statistically significant difference between the two groups. The dmfs scores in this study included both active and arrested carious surfaces. Any carious tooth surface in phase one that might have been arrested following intervention was considered a carious tooth surface during calculation of dmfs. To differentiate between carious teeth and arrested teeth recorded at phase 2 and 3, the coding was modified, arrested carious teeth were coded AR and active carious surfaces as B. This simplified the statistical analysis of active caries and arrested carious tooth surfaces.

Effectiveness of bi-annual application of silver diamine fluoride

Various concentrations of SDF, 10% (Braga et al., 2009), 12% (Yee et al., 2009), 30% (Duangthip et al., 2016) and 38% (Chu et al., 2002; Llodra et al., 2005; Zhi et al., 2012) have been investigated for their effectiveness in arresting dental caries. All concentrations of SDF have been reported to be effective in arresting dental caries however 38% SDF has been reported to be optimal (Jabin et al., 2020). In a clinical trial, Fung et al. (2018) showed that the application of 38% SDF increased caries arrest rate by 18% to 20% compared to 12% SDF (Fung et al., 2018).

This trial used 38% SDF as the intervention group and 5% NaF as the control group. These concentrations of SDF and NaF were the same as reported in study by Chu et al. (2002). The Chu study however investigated the effectiveness of these two medicaments applied annually with and without the removal of carious on upper primary anterior teeth only. Their control group did not receive any treatment but participated in school oral health

programs that involved toothbrushing and 0.2% NaF mouthwash rinses every morning during school term (Chu et al., 2002).

A recent review by Do et al. (2020) on guidelines to the use of fluorides in Australia suggested the professional application of 38% SDF twice yearly to arrest active carious lesions in primary teeth in non-fluoridated areas (Do & Health, 2020). Although preceding this review the decision to use 38% SDF bi-annually in this study is thus consistent with these guidelines. Pari village is a rural with a disadvantaged community which has no access to proper water supplies for drinking or oral hygiene practices. Fluoridated toothpastes are considered non-essential due to the cost of a single tube being more than a packet of rice weighing one kilogram. Given these factors increasing the frequency of application of 38% SDF solution to bi-annual in participants with poorer oral hygiene may increase the caries arrest rate. The findings of the current study in which a significant proportion of carious lesions were arrested at phase 2 and 3 following bi-annual application agree with the findings of Zhi and colleagues (2012). In their randomized clinical trial with 212 Chinese children, aged 3–4 years, they found an annual application of 38% SDF solution arrested active dentine caries and increasing the frequency of application to every six months increase the caries arrested rate (Zhi et al., 2012).

Caries arrest with 38% SDF and 5% NaF varnish

This study found that at 12 months the caries arrest rate of 38% SDF and 5% NaF was 97.1% and 78.2% respectively. Logistic regression analysis of caries arrest at tooth surface level by the two treatment groups showed that there was a 7.7 times chance of a carious surface lesion being arrested following application of 38% SDF twice a year compared to 5% NaF. The recommendations for fluoride application for children

attending dental clinics, 5% NaF is applied at six monthly intervals to reduce the risk of development of dental caries lesions and arrest progress of non-cavitated lesions (AAPD, 2018). However, to control dentine caries, application of SDF is more effective than NaF (Mabangkhru et al., 2020). A study by Mabangkhru et al. (2020), with a similar protocol and treatment groups reported a 35% and 20.8% caries arrest rate in the 38% SDF group and 5% NaF group respectively at 12 months. These caries arrest rates are lower than in our study. This could be due to the application of medicaments in very young children as is more challenging due to their inability to cooperate also with their night feeding and no tooth cleaning. One of the main causes of ECC is the frequency feeding or nursing with a bottle. In addition, due to the age group involved in Mabangkhru study and high concentration of fluoride and silver in 38% SDF, to reduce level of toxicity, the medicament application was limited to one drop of SDF solution containing 1.12mg fluoride and 6.35mg of silver (Mabangkhru et al., 2020). The toxic dose range is reported by Horst et al. (2016) to be 380-520 mg/kg therefore dose was very low (Horst et al., 2016). SDF is more effective in arresting dentine caries than enamel. After application of SDF to a decayed surface, the squamous layer of silver-protein conjugates forms, increasing resistance to acid dissolution and enzymatic digestion (Horst et al., 2016). The PNG study participants had multiple carious teeth. The manufacturer's instructions (Riva Star, SDI Ltd) were to treat up to five teeth per capsule. Even if a child had more than five carious teeth, the same capsule was used to apply SDF on all teeth. SDF was applied with micro-brushes to the affected teeth. On account of the potential toxicity the micro-brush was dipped only once for up to three carious lesions.

Other studies (Chu et al., 2002; Lo et al., 2001; Zhi et al., 2012) have also reported higher caries arrest rate in bi-annual application of 38% SDF. Zhi and colleagues detected a caries arrest rate of 91% for 38% SDF applied bi -annually over a 24-month period (Zhi

et al., 2012). Llodra et al. (2009) reported a caries arrest rate of 85% following bi-annually application of 38% SDF. This was significantly higher than the caries arrest rate of 62% in a control group where no treatment was provided over 36 months (Llodra et al., 2005). Chu et al. (2002) investigated with similar medicament over 30 months. However, 38% SDF was applied annually while 5% NaF was applied every 3 months on anterior teeth only. They found that 38% SDF and 5% NaF had a caries arrest rate of 65% and 41% respectively. There was no difference in arrest rate when carious tissue was removed from the cavity before application of the medicaments. A limitation the Chu trial is its inclusion of anterior teeth only (Chu et al., 2002). This may not give a true representation of caries arrest rate of the two medicaments. A further study (Fung et al., 2018) reporting a higher caries arrest rate of 75% in the 38% SDF group who received treatment twice a year compared to 38% SDF and 12% application annually and 12% SDF application twice a year. Moreover, there was statistical significance between the groups involved in this study at 24 months and 30 months. The current study involved application of 38% SDF at six monthly intervals over a follow up period of 12 months while other studies reported a follow up period of 18 months, 24 months and 30 months. This may have contributed to the high caries arrest rate in this study compared to other studies of similar populations of low socioeconomic background and disadvantaged communities. Yee and co-researchers observed that as the follow up period increased following application of 38% SDF, the number of caries arrested lesions decreased over time however remaining statistically significantly higher than other treatment groups (Yee et al., 2009). Systematic reviews (Contreras et al., 2017; Gao et al., 2016) have suggested that even though annual application of 38% SDF is effective in arresting dental caries, the effectiveness of SDF can be improved by increasing the frequency of application to two times a year.

Caries prevention with 38% SDF and 5% NaF varnish

Topical fluorides have been reported to be effective in preventing the development and extent of dental caries in the primary dentition. Topical fluoride treatment accompanied by effective toothbrushing with fluoride toothpaste has been suggested as an effective caries prevention measure (Marinho et al., 2004).

This study showed a reduction in the incidence of dental caries following application of 38% SDF followed by a second application of 38% SDF at six months. Other clinical trials (Liu et al., 2012; Llodra et al., 2005; Monse et al., 2012)also reported the prevention of new caries development following application of 38% SDF in both primary and permanent dentition. This study showed that at 12 months, the incremental incidence rate of caries was 0.4% in the SDF group and 1.8% in the NaF group. This suggests that 38% SDF is considerably more effective than 5% NaF in preventing new carious lesions. The difference between the two treatment groups was statistically significant.

The PNG study concluded that both 38% SDF and 5% NaF applied bi-annually have the ability to prevent new caries lesions in primary teeth however 38% SDF is more effective than 5% NaF in preventing new lesion development.

pufa Index

The pufa Index is a new index developed to evaluate the prevalence and severity of oral conditions resulting from untreated dental caries. In this study we utilized this index to assess prevalence of non-vital teeth presenting as visual pulp exposed (p), ulceration caused by root fragments(u), fistula (f) or abscesses (a) following application of 38% SDF and 5% NaF at 6 months and 12 months (Monse et al., 2010).

The percentage of participants who presented with non-vital teeth at 12 months was 4.5% (n= 2) in the SDF group and 17.4% (n=8) in the NaF group. The mean number of non-vital teeth for the SDF group was 0.2 and in the 5% NaF group the mean was 2.0. These results are consistent with those of Chu et al. (2002) who reported a higher mean of non-vital teeth where 5% NaF was applied every 3 months compared with 38% SDF applied annually over 24 months (Chu et al., 2002). This study reported a significant difference in the pufa index scores between the two treatment groups ($p= 0.021$). Therefore, the results provided further evidence that 38% SDF is more effective than 5% NaF in arresting caries progression.

Acceptability of treatment by parent

Previous studies have reported a high acceptance of 38% SDF treatment by parents (Chu et al., 2002; Clemens et al., 2018; Zhi et al., 2012). Parents accepted the black staining that appeared on the teeth of their children who have received 38% SDF. As well as assessing perception of parents with regards to their children's appearance following application of SDF and NaF, our study also evaluated whether parents were satisfied with the treatment and whether they thought that the treatment had benefited their child. The parents were surveyed to investigate whether SDF and NaF treatments would be acceptable in the Pari community. Parents of children who received either SDF or NaF indicated high acceptability of treatment given to their children.

Our results concur with other clinical trials (Chu et al., 2002; Mabangkhru et al., 2020; Zhi et al., 2012) which report high parental acceptance of child appearance following application of SDF. Chu et al. (2002) suggest that explaining the effect of SDF and black discoloration as an effect led to parents being more understanding and resulted in high

acceptance of SDF (Chu et al., 2002). Our study included careful explanation to parents and discussion on the reason for the treatments and the meaning of the discoloured teeth. Parents of children who received SDF on their anterior teeth understood that the intense blackening of the carious area meant that the decay process has stopped (Figures 26-27). One parent of a child who received SDF on the upper anterior teeth commented that she was satisfied with the treatment because she noticed how smooth and shiny the affected teeth were after toothbrushing. However, most parents were not really concerned about the appearance of their children's teeth whether they were anterior or posterior. Another reason for high acceptability of treatment may also be due to both parents and children betel nut chewing. The staining of teeth, as a consequence of this chewing, is that parents were not concerned about the appearance of their children when the lesions became black stained. In an *in vitro* study evaluating the staining potential of SDF, Patel and colleagues demonstrated the potential of KI to reducing the black staining. Potassium iodide reacts with the free silver ions to produce a creamy white appearance (Patel et al., 2018). In our study, due to isolation difficulties and increased salvia following application of SDF to the posterior teeth KI was not able to be successfully placed on these teeth.

Figure 26. (a) Caries on anterior teeth at baseline. (b) Arrested caries at 12 months.

Figure 27. (a) Caries on anterior teeth at baseline. (b) Arrested caries and betel nut-stained teeth at 12 months.

Studies by Alshammari and colleagues (2019) and Crystal and co-researchers (2017) reported that black staining on posterior teeth was more acceptable than on anterior teeth. A Saudi Arabian study reported a higher rate of parent dissatisfaction due to appearance of black discoloration on their children's teeth (Alshammari et al., 2019). This may be due to the variation in socioeconomic background status of the participants compared to Pari village. Parents who participated in the study in Saudi Arabia were of higher income status and educational level. Therefore, the perception of their children's dental treatment may reflect parental income level, level of education and availability of dental facilities.

Many parents understood that their children's teeth were a primary dentition and would be replaced by an adult dentition as they grow older. Appearance therefore did not bother them. Notwithstanding, one parent expressed dissatisfaction that the treatment had not been of benefit -her child developed an abscess before the second phase. This parent however, was still happy to bring her child back to the second follow-up assessment, reasoning that the affected tooth was at the back of the lower jaw but there were other teeth that needed to be assessed. She understood that she had signed a consent form that clearly stated that she could leave the study anytime however was happy for her child to complete the trial.

Parents of children who received NaF also reported high acceptance of their children's appearance and treatment benefit. Parents also understood that pain and abscess formation causing discomfort in their child did not mean that treatment had not been of benefit. Notwithstanding, a small number of parents disagreed that treatment had benefited their child because the child had developed an abscess or had experienced discomfort. The majority of these parents and children did not return for follow up treatment in the second phase. One of the children had developed four pulpal exposures and two abscesses following only one application of NaF at baseline. Due to the extent of his carious lesions, he may have benefited from SDF, however was randomly allocated to the NaF group. All children who had developed pain and abscesses were referred to Port Moresby general hospital dental clinic for dental treatment.

This study concluded that regardless of the type of intervention received, parents accepted that the medicaments were effective, and they were not bothered by the black staining that resulted on their children's teeth.

Child acceptability of treatment

This is the first study to assess children's acceptability of treatment with 38% SDF and 5% NaF in a Melanesian country. Children's acceptability was assessed with a visual analogue scale of smiley faces ranging from very unhappy to very happy. The children were provided colouring pencils and requested to colour in the face that depicted how they felt about treatment after their previous appointment. At six months 94.1% of children accepted their treatment. Children who received NaF indicated higher acceptance than children who received SDF. Three participants who received SDF rated unhappy with the treatment at the second phase. On questioning these children reported they did not like the taste of the medicament that was put on their teeth as it was bitter. These children were noted as apprehensive in the first phase during application of medicament and led to modification of behaviour management at the second and third phase. Contrary to expectation all three returned for their 12-month visits – probably reflecting their parents' understanding of longer-term benefits accruing from staying in the study. At 12 month visit, the three children who were unhappy with the treatment were now happy. This may reflect both a familiarity with procedures (including medicament taste) and modified behaviour management on the part of investigators.

Most children who received 5% NaF were happy with the treatment. The medicament was clear Duraphat® from Colgate Palmolive Ltd which had a slight minty taste and smell well accepted by the children. Three children were unhappy with the treatment and another two were neutral. The children who were not happy about the treatment had experienced discomfort due to development of abscesses and pulp exposures. This study's findings are similar to results of study conducted by Kittiprawong et al. (2018). The study was conducted in Thailand where children received 38% SDF, 5% NaF and

both medicaments together. They assessed parental acceptance two weeks following treatment and child acceptance immediately after application. Child satisfaction was assessed in terms of time spent for treatment, whether the treatment was uncomfortable or not, their satisfaction for taste and smell, the colour of their teeth and the overall satisfaction. While this study did not focus on other variables, overall satisfaction of children who received SDF was 99%, and children who received NaF was 95% which is similar to the results of this study at 12 months (Kittiprawong et al., 2018).

It was concluded that 38% SDF and 5% NaF are acceptable to most children. While 5% NaF in different flavours is well received the metallic bitter taste of 38% SDF may initially be unacceptable. Children may become familiarised to the taste in subsequent appointments. Older children were observed to tolerate the taste of SDF better than children under the age of three. As both parents and children were seated together during the assessment a child's perception of the effectiveness of treatment may have been influenced by parental comment or attitude. At interview parental assessment of treatment was conducted first with implications that subsequent comments by their children may have had an influence on the child's responses.

Limitations

Ideally, the clinical trial would be conducted with blinded investigators at the second and third phases. It was also not feasible in this study to calibrate another investigator for phase two and three examinations. As there were no appropriate clinicians or researchers in PNG to conduct examiner calibration the principle investigator was calibrated by the primary supervisor pre-clinical or pre-field in Dunedin, New Zealand, prior to travel back to PNG for the clinical trial. The lead researcher carried out the examination and provided

treatment at second phase and again carried out the examinations at the third phase of the study. However, blinding of investigators is not possible as the 38% SDF stains black and much darker than 5% NaF. One of the main problems of SDF studies is being unable to blind examiners. This would be a cause for potential bias in this study.

The proposal was to re-examine 10% of the sample population to assess inter-examiner and intra-examiner reliability at baseline, phase two and phase three. This however was not feasible as it demanded unacceptable waiting times for both parents and the children.

This study used the WHO criteria to assess surface caries in the children's dentition and to assess the gingival status. This influenced data on assessment of carious lesion progression as well as assessment of oral health status. Radiography was also not possible in this case, therefore the decision to use the WHO criteria was made to reduce level of uncertainty when diagnosing the lesion. This may also have had an effect in the results of this study where occlusal lesions were 3 to 4 times more likely to develop as compared to interproximal lesions. The assessment of lesion progression would have been complicated by using the specific ICDAS caries assessment or the ECC coding system. Instead of a gingival health assessment, this study would have assessed plaque level on teeth by use of the visual plaque index system. This more standardised approach would have better aligned the investigation with other published studies.

The follow-up period for this study was only 12 months. Other studies assessing effectiveness of SDF and NaF have been followed for up to 30 months. Extending the follow up period would further standardize this study and improve the utility of our

results in comparing the effectiveness of the two medicaments. However, because the study was conducted as a part requirement for the three-year Doctorate in Clinical Dentistry program at the University of Otago, a longer period of follow up was not possible.

Chapter 5 Conclusion

While professional application of 38% SDF is an emerging practice in the dental profession, it is important to identify the underlying causes of high caries prevalence in children in any given population. Only then can effective strategies be implemented to reduce ECC prevalence. In PNG, more epidemiological studies are required to give a clear view of oral health disease in children. This should include community level studies of influences and attitudes of both children and their families. Data collection should be incorporated into daily practice to generate data-set accumulation over time.

Pre-treatment parental briefing is a critical component of SDF treatment. In addition to the black staining that occurred from application of SDF, two parents described mucosal irritation that resolved in two days. They were not concerned as they understood from information provided at baseline that this could be a temporary effect.

The taste of the 5% NaF used in this study was tolerated better by the children than the metallic bitter taste of 38% SDF. Children in the NaF group, however, expressed dissatisfaction due to pain and discomfort associated with pulp exposure or abscess development. All these sequelae of treatment must be conveyed to parents.

In socially deprived communities, the use of 38% SDF and distribution of fluoride in vehicles such as water and salt may be an effective way to increase fluoride exposure. With appropriate training of dental therapists and other non-dental health care providers, 38% SDF could be delivered through school dental programs and community prevention programmes. The outcomes of such methods in PNG may provide relevant information for similar disadvantaged societies.

This is the first clinical trial in cariology investigating SDF effectiveness in the Pari village area of PNG. Pari is a disadvantaged community in a society where betel nut chewing is a traditional activity amongst adults and is now becoming a common practice in younger children. PNG is diverse in culture and language and is dispersed over areas of rugged terrain with many areas having limited access to electricity or clean water. The demonstrated effectiveness of SDF in this study, and its non-reliance on sophisticated technology or equipment suggests investigation into the technique's broader application within PNG is warranted.

This study demonstrated that 38% SDF is more effective than 5% NaF in arresting dentine caries and preventing development of new lesion in primary teeth of children in PNG with low or no fluoride exposure. The study also showed that parents and their children were satisfied with treatment regardless of the medicament. All parents of participants who received 38% SDF were not concerned with the subsequent black staining that appeared on their children's carious teeth regardless of whether staining was on anterior or posterior teeth. This study described a simple effective preventive health measure, which may be more widely implemented in PNG.

Future PNG Research

Wider implementation of the dental preventive regime described will demand further research into both the SDF technique and relevant PNG-specific parameters. It would include:

a. Assessing the prevalence of dental caries in children in PNG and understanding specific factors contributing to the disease;

b. Assessing pain and infection episodes in children treated with 38% SDF;

c. Increasing follow up periods and assessment of potential long-term outcomes of 38% SDF in the growing child;

d. Increasing oral health promotion and education in conjunction with bi-annual application of 38% SDF and measure effectiveness with improving oral hygiene;

e. Assessing existing SDF use in PNG;

f. Evaluating parental attitudes in other suburban and rural communities that do not chew betel nut as a social norm; and

g. Evaluating the cost effectiveness of 38% SDF in public dental health programs.

Recommendations

1. Professional application of 5% NaF at regular 3 monthly or 6 monthly intervals, depending on the caries risk of patient is strongly recommended. NaF (5%) is not as effective as bi-annual application of 38% SDF.

2. Professional bi-annual application of 38% SDF:

   a. Should be used to effectively arrest dentine caries in primary teeth and does not require removal carious tissue.

   b. Should be incorporated into public dental health programs as well as other non-dental community preventive programs in rural communities of PNG.

   c. Should be incorporated into professional dental care in PNG for children who are moderate to high risk caries who are unable to cope with definitive dental treatment.

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Appendix I. University of Otago Human Research Ethics Approval

H18/120

Academic Services
Manager, Academic Committees, Mr Gary Witte

20 November 2018

Mrs A Meldrum
Department of Oral Sciences
Faculty of Dentistry

Dear Mrs Meldrum,

I am again writing to you concerning your proposal entitled "**Effectiveness of bi-annual application of 38% silver diamine fluoride and 5% fluoride on primary teeth of children in a rural setting near Port Moresby, Papua New Guinea**", Ethics Committee reference number **H18/120**.

Thank you for your email of 15th November 2018 with response attached addressing the issues raised by the Committee.

On the basis of this response, I am pleased to confirm that the proposal now has full ethical approval to proceed.

The standard conditions of approval for all human research projects reviewed and approved by the Committee are the following:

Conduct the research project strictly in accordance with the research proposal submitted and granted ethics approval, including any amendments required to be made to the proposal by the Human Research Ethics Committee.

Inform the Human Research Ethics Committee immediately of anything which may warrant review of ethics approval of the research project, including: serious or unexpected adverse effects on participants; unforeseen events that might affect continued ethical acceptability of the project; and a written report about these matters must be submitted to the Academic Committees Office by no later than the next working day after recognition of an adverse occurrence/event. Please note that in cases of adverse events an incident report should also be made to the Health and Safety Office:

http://www.otago.ac.nz/healthandsafety/index.html

Advise the Committee in writing as soon as practicable if the research project is discontinued.

Make no change to the project as approved in its entirety by the Committee, including any wording in any document approved as part of the project, without prior written approval of the Committee for any change. If you are applying for an amendment to your approved research, please email your request to the Academic Committees Office:

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gary.witte@otago.ac.nz

jo.farrondediaz@otago.ac.nz

Approval is for up to three years from the date of this letter. If this project has not been completed within three years from the date of this letter, re-approval or an extension of approval must be requested. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing.

The Human Ethics Committee (Health) asks for a Final Report to be provided upon completion of the study. The Final Report template can be found on the Human Ethics Web Page http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html

Yours sincerely,

Mr Gary Witte
Manager, Academic Committees
Tel: 479 8256
Email: gary.witte@otago.ac.nz

c.c. Professor W M Thomson   Department of Oral Sciences

Appendix II. PNG Ethics Approval

UNIVERSITY OF PAPUA NEW GUINEA
SCHOOL OF MEDICINE AND HEALTH SCIENCES
OFFICE OF THE EXECUTIVE DEAN

SCHOOL VISION
TO BE THE PREMIER MEDICAL AND HEALTH
SERVICES TRAINING INSTITUTION IN THE
SOUTH PACIFIC REGION, EQUIPPING FUTURE
LEADERS IN HEALTH SERVICES WITH THE
KNOWLEDGE, SKILLS AND ATTITUDES TO
MEET THE NEEDS OF THE NATION'S RURAL
AND URBAN COMMUNITIES

P.O. BOX 5623   FAX NO :(675)3250809
BOROKO   TEL. NO :(675) 3255802
PAPUA NEW GUINEA

11th October 2018

Dr. Yvonne Golpak
C/-UPNG SMHS Dentistry Division
PO Box 5623
Boroko, NCD

Dear Dr. Golpak

Subject: Approval for your Research proposal

On behalf of The School Research & Ethics Committee I have executively considered and approved your research proposal and granted ethical clearance for your project entitled:
"Effectiveness of bi-annual application of 38% silver diamine fluoride and 5% sodium fluoride on primary teeth of children in a rural setting near Port Moresby, Papua New Guinea"

Please have a copy of this letter available with you all times in the event that you may be requested to verify the nature of your interview etc with all mutually concerned parties. You may need to consult your supervisor on these and other matters.

Yours sincerely,

....
Professor Nakapi Tefuarani
Chairman , School Research and Ethics Committee and Executive Dean

Cc: Executive Officer
        Research File

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Appendix III. Medical history form

THE UNIVERSITY OF PAPUA NEW GUINEA

Division of Dentistry

Faculty of Dentistry
Te Kaupeka Pūniho
New Zealand's National Centre for Dentistry

Identification Number: ☐ ☐ ☐ ☐

	NO	YES	Details
Is your child being treated by a doctor at present?			
Is your child taking any tablets or medicines (prescribed or herbal) at present ?			
Has your child ever being hospitalised?			
Is your child allergic to any medicines, foods or other things?			

Has your child have or ever had any of the following medical conditions?

	NO	YES	Details
Rheumatic Fever			
Epilepsy			
Asthma			
Diabetes			
Heart conditions			
Tuberculosiis or other lung diseases			
Anaemia, leukaemia or other blood diseases			
Stomach or digestive conditions			
Hepatitis or other liver diseases			
Nerve or muscle conditions			
Contact with HIV/AIDS			

Name of Person giving information:_____

Signature: _____ Date: _____

Name of Person collecting information:_____

Signature:_____ Date:_____

Appendix IVa. WHO Oral health assessment form for children

World Health Organization
Oral Health Assessment Form for Children, 2013

Annex 4

Leave blank	Year	Month	Day	Identification No.	Orig/Dupl	Examiner
(1) ____ (4)	(5) _____ (10)			(11) _____ (14)	(15) (16)	__ (17)

General information: Sex 1=M, 2=F ___ (18)   (19) Date of birth _____ (24)   (25) Age in years __ (26)

_____ (Name)

Ethnic group (27) __ (28)   **Other group** (29) __ (30)   **Years in school** (31) __ (32)   **Occupation** __ (33)

Community (geographical location) (34) __ (35)   **Location** Urban (1) Periurban (2) Rural (3) __ (36)

Other data _____ (37) __ (38)   **Other data** _____ (39) __ (40)

Other data _____ (41) __ (42)   **Extra-oral examination** _____ (43) __ (44)

Dentition status by tooth surface

	17	16	55 / 15	54 / 14	53 / 13	52 / 12	51 / 11	61 / 21	62 / 22	63 / 23	64 / 24	65 / 25	26	27	
Occ					X	X	X	X	X	X					(45–52)
Mes															(53–66)
Buc															(67–80)
Dis															(81–94)
Oral															(95–108)

	47	46	85 / 45	84 / 44	83 / 43	82 / 42	81 / 41	71 / 31	72 / 32	73 / 33	74 / 34	75 / 35	36	37	
Occ					X	X	X	X	X	X					(109–116)
Mes															(117–130)
Buc															(131–144)
Dis															(145–158)
Oral															(159–172)

Primary teeth	Permanent teeth
	Status
A	0 = Sound
B	1 = Caries
C	2 = Filled w/caries
D	3 = Filled, no caries
E	4 = Missing due to caries
—	5 = Missing for another reason
F	6 = Fissure sealant
G	7 = Fix dental prosthesis/crown, abutment, veneer
—	8 = Unerupted
—	9 = Not recorded

Appendix IVb. WHO Oral health assessment form for children

World Health Organization
Oral Health Assessment Form for Children, 2013

Periodontal status

	55	54	53	52	51	61	62	63	64	65		
17	16	15	14	13	12	11	21	22	23	24	25	26	27

(173) ☐☐☐☐☐☐☐☐☐☐☐☐☐☐ (186)

(187) ☐☐☐☐☐☐☐☐☐☐☐☐☐☐ (200)

	85	84	83	82	81	71	72	73	74	75		
47	46	45	44	43	42	41	31	32	33	34	35	36	37

Gingival bleeding
Score
(0) = Absence of condition   (1) = Presence of condition
(9) = Tooth excluded   (X) = Tooth not present

Enamel fluorosis ☐ (201)

Severity

0 = Normal   3 = Mild
1 = Questionable   4 = Moderate
2 = Very mild   5 = Severe

8 = Excluded (crown, restoration, "bracket")

9 = Not recorded (unerupted tooth)

Dental erosion

Severity

(202) ☐

0 = No sign of erosion
1 = Enamel lesion
2 = Dentinal lesion
3 = Pulp involvement

No. of teeth

(203) ☐☐ (204)

Dental trauma

Status

(205) ☐

0 = No sign of injury
1 = Treated injury
2 = Enamel fracture only
3 = Enamel and dentine fracture
4 = Pulp involvement
5 = Missing tooth due to trauma
6 = Other damage
9 = Excluded tooth

No. of teeth

(206) ☐☐ (207)

Oral mucosal lesions

Condition

(208) ☐
(209) ☐
(210) ☐

Location

(211) ☐
(212) ☐
(213) ☐

0= No abnormal condition
1= Ulceration (aphthous herpetic, traumatic)
2= Acute necrotizing ulcerative gingivitis (ANUG)
3= Candidiasis
4= Abscess
8= Other condition
9= Not recorded

0 = Vermillion border
1 = Commissures
2 = Lips
3 = Sulci
4 = Buccal mucosa
5 = Floor of mouth
6 = Tongue
7 = Hard/soft palate
8 = Alveolar ridges/gingiva
9= Not recorded

Intervention URGENCY ☐ (214)

0 = No curative treatment needed

1 = Preventive or routine treatment needed

2 = Prompt treatment (including scaling) needed

3 = Immediate (urgent) treatment due to pain or infection of dental and/or oral origin

4 = Referred for comprehensive evaluation or medical treatment (systemic condition)

Appendix IVc. pufa Index scores

P/p = pulp

U/u = ulceration

F/f= fistula

A/a = abscess

Tooth	55	54	53	52	51	61	62	63	64	65
Status										
Tooth	75	74	73	72	71	81	82	83	84	85
Status										

p=   u=   f=   a=

Total pufa score =

Appendix V. Patient Information Sheet

THE UNIVERSITY OF PAPUA NEW GUINEA

Parent and Child Information Sheet

Research Title: Managing tooth decay with 38% Silver diamine fluoride and 5% Sodium fluoride varnish on baby teeth of children in a rural setting, near Port Moresby, Papua New Guinea

Introduction

Thank you for your interest in this project. Please read this information sheet carefully before deciding to participate in this study. If you decide not to allow your child to participate, you and your child will be taught how to keep a mouth clean and why this is important for general health. Your child will receive a toothbrushing kit.

What is the aim of this research project?

We want to find out if the solution known as "silver diamine fluoride" can be used to stop and avoid rotting baby tooth in a village setting like yours. This project is part of my requirement for Doctorate in Clinical Dentistry-Paediatric Dentistry at University of Otago (Dunedin, New Zealand).

Who is funding this project?

1. University of Papua New Guinea, School of Medicine and Health Sciences Health Education and Clinical Sciences research grant 2018

2. Sir John Walsh Research Institute research grant 2018

Who are we seeking to participate in the project?

All children aged 2 to 5 years old will have their mouth checked. Your child will be asked to join this study if he or she has one bad or rotten tooth.

Your child will not be asked to join the study if he or she has a medical condition that needs special medications.

You as the parent will sign a special permission (consent) form to show that you agree for your child to join this study.

Once we have you and your child's permission, we will do a complete mouth check for your child.

Your child will receive either two decay stopping agents.

This treatment will be provided in the community therefore there will be no costs for the treatment.

Your child's details will not be shown to anyone else except the people who carry out this study. All records will be available only to the dental workers who are seeing you and your child and the supervisors at the University of Otago in Dunedin, New Zealand. All paper records will be kept in a safe place at University of Papua New Guinea, Division of Dentistry and destroyed after 10 years according to university laws.

If you participate, what will you be asked to do?

If you agree for your child to take part in this project, you will be asked to sign a special permission (consent) form and to provide your child's details. Your child will have a mouth examination. The findings will be recorded. Your child will be assigned to a treatment group. An envelope will be given to your child with details of the treatment. Treatment will be over 3 visits. In the first and second visit, tooth preventative agents will be put on your child's teeth. During each visit, you and your child will learn how to keep your mouth clean. A tooth-brushing kit will be given to your child at each visit.

It is understood that your child may feel uncomfortable and scared but the dentists are trained to provide care in a child- friendly manner.

Is there any risk of discomfort or harm from participation?

To date, there has been no report of harmful effects from this treatment. Although, permanent black discoloration will appear on the rotten baby teeth that receive treatment of silver diamine fluoride, this is balanced by its benefits. Harmful effects will be avoided by not including children who have known allergies. The possibility of gum irritation will be avoided by careful protection of skin inside the mouth by use of cotton rolls.

Five percent sodium fluoride varnish can easily come off the tooth when eating or toothbrushing so your child will be asked not to chew food or brush 30 minutes after application.

What specimens, data or information will be collected, and how will they be used?

We will be using a special form to record personal details and tooth examination findings. Personal information about your child will include name, date of birth, age, gender and the location/residential area. Throughout the study your child will not be personally identified. A number will be used. Photographs of your child's teeth will be taken at each of the three visits using a mobile phone camera specifically assigned to this research.

Data will be analysed to compare the different treatment agents.

What about anonymity and confidentiality?

The investigators, assistants and supervisors will treat all information as private. The findings will only be used by the researchers for scientific purposes.
The data collected will be securely stored in a hard-drive and only the researchers will be able access this. Hard copies of the data obtained as a result of the research will be retained for at least 10 years in secure storage at the University of Papua New Guinea.
The results of the project will be included in Dr Yvonne Golpak's thesis and will be available in the University of Otago Library (Dunedin, New Zealand). Details of your child will remain anonymous.

If you agree to participate, can you withdraw later?

You may withdraw from participation in the project at any time during the study without any harm to yourself.

Any questions?

If you have any questions now or in the future, please feel free to contact either:

Dr. Yvonne Golpak or Dr. Alison Meldrum

Department of Oral Sciences

Telephone number:+675727 84 234 (PNG), +64 3 479 7113 (NZ)

E-mail: golyv820@student.otago.ac.nz

   alison.meldrum@otago.ac.nz

Appendix VI. Consent and Assent Forms

THE UNIVERSITY OF PAPUA NEW GUINEA

UNIVERSITY of OTAGO — *Te Whare Wānanga o Otāgo* — NEW ZEALAND

Faculty of Dentistry — *Te Kaupeka Pūniho* — New Zealand's National Centre for Dentistry

CONSENT FORM FOR PARTICIPANTS Parent and Child

Research Title: Managing tooth decay with 38% Silver diamine fluoride and 5% Sodium fluoride varnish on baby teeth of children in a rural setting, near Port Moresby, Papua New Guinea

I have read the Information Sheet concerning this study and understand the aims of this research project.

1. I have had sufficient time to talk with other people of my choice about participating in the study.

2. I confirm that I meet the criteria for participation which are explained in the Information Sheet.

3. All my questions about the project have been answered to my satisfaction, and I understand that I am free to request further information at any stage.

4. I know that our participation in the project is entirely voluntary, and that we are free to withdraw from the project before its completion.

5. I know that as a parent, I am required to bring my child to each of the three visits.

6. At the first and second visit, preventative agents will be applied to my child's teeth. At each visit, photographs of my child's teeth will be taken.

7. At the final visit, my child and I will be given simple task. I will be given a simple questionnaire to answer and my child will be given a set of

different faces to colour the one that reflects the way he/she feels about the treatment. No blood or tissue samples will be taken from my child.

8. I know that the baseline assessment and questionnaire will explore my personal information and if the line of questioning develops in such a way that I feel hesitant or uncomfortable I may decline to answer any particular question(s), and /or may withdraw from the project without disadvantage of any kind.

9. I understand the nature and size of the risks of discomfort or harm which are explained in the Information Sheet.

10. I know that when the project is completed all personal identifying information will be removed from the paper records and electronic files which represent the data from the project, and that these will be placed in secure storage and kept for at least ten years.

11. I understand that the results of the project may be published and be available in the University of Otago Library, but that either (i) I agree that any personal identifying information will remain confidential between myself and the researchers during the study, and will not appear in any spoken or written report of the study.

12. I know that there is no remuneration offered for this study, and that no commercial use will be made of the data.

Signature of parent: Date:

Name of person taking consent: Date:

Appendix VII. Assessment of Acceptability of Treatment for Parent and Child

Parent

Please circle the best answer that characterizes how you feel about each statement;

1= Strongly agree, 2= Agree, 3=Neutral, 4= Disagree 5=Strongly disagree

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
I am satisfied with the treatment given to my child	1	2	3	4	5
My child benefited from this treatment	1	2	3	4	5
Black staining of teeth bothered me	1	2	3	4	5

Child

Indicate how you feel about your treatment by colouring the appropriate facial expression.
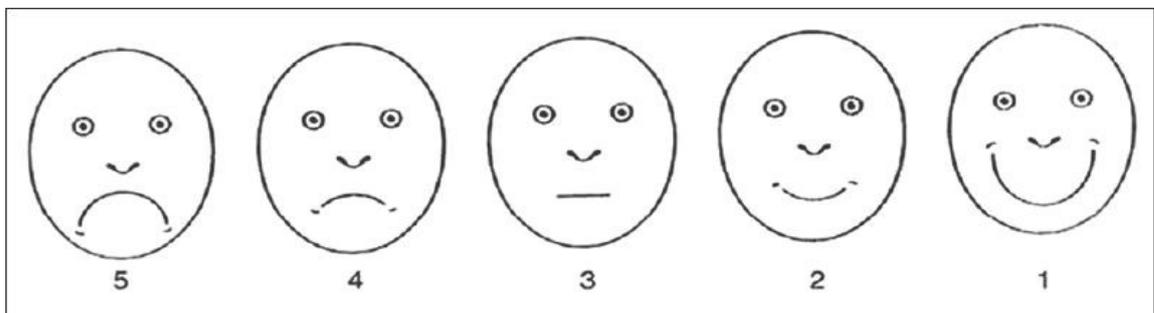
Appendix VIII. Oral Hygiene Instructions

Oral hygiene instructions for Parent and Child

1. We are providing you an oral hygiene kit. There is a child and an adult toothbrush inside the kit with a toothpaste sachet. We encourage you to buy a new toothpaste tube when the sachet is used up.

2. Child's name …………. Brush your teeth two times a day for two minutes. Brush your teeth in the morning after breakfast and before you go to bed. Use a smear layer or pea- sized toothpaste to brush your teeth. Do not eat after you brush your teeth at night.

3. Parent name………Your child is very young and will need assistance and an encouragement brushing their teeth twice daily. We encourage parents to supervise toothbrushing for their young children or to do toothbrushing together with your child. This will encourage your child to get into habit of toothbrushing as they grow older.

4. Please remember that the medicament may be more effective with daily toothbrushing.

Appendix IX. Map of study site - Pari Village, Central Province, Papua New Guinea

Extracted from "The Demographic Behaviour of an Indigenous Population in Urban Papua New Guinea: the Motu Koitabu of Hanuabada" by Esther Lavu, 2012 Source: Environment Systems Research Institute, DeLerme, USGS

Appendix X. Confirmation of ANZCTR

Dear Alison Meldrum,

Re: A study to compare the decay arrest of two different fluoride products when applied to the teeth of children aged between 2 and 5 years in a rural setting near Port Moresby, Papua New Guinea.

Thank you for submitting the above trial for inclusion in the Australian New Zealand Clinical Trials Registry (ANZCTR).

Your trial has now been successfully registered and allocated the ACTRN: ACTRN12620000452998

Web address of your trial: https://www.anzctr.org.au/ACTRN12620000452998.aspx
Date submitted: 7/12/2019 5:28:38 PM
Date registered: 8/04/2020 9:43:06 AM
Registered by: Alison Meldrum
Principal Investigator: Alison Meldrum

Please note that as your trial was registered after the first participant was enrolled, it does not fulfil the criteria for prospective registration and will therefore be marked as being Retrospectively Registered on our website.

If you have already obtained Ethics approval for your trial, please send a copy of at least one Ethics Committee approval letter to info@actr.org.au or by fax to (+61 2) 9565 1863, attention to ANZCTR.

Note that updates should be made to the registration record as soon as any trial information changes or new information becomes available. Updates can be made at any time and the quality and accuracy of the information provided is the responsibility of the trial's primary sponsor or their representative (the registrant). For instructions on how to update please see https://www.anzctr.org.au/Support/HowToUpdate.aspx.

Please also note that the original data lodged at the time of trial registration and the tracked history of any changes made as updates will remain publicly available on the ANZCTR website.

The ANZCTR is recognised as an ICMJE acceptable registry (http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/) and a Primary Registry in the WHO registry network (https://www.who.int/ictrp/network/primary/en/index.html).

If you have any enquiries please send a message to info@actr.org.au or telephone +61 2 9562 5333.

Kind regards,
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