THE EFFECT AND FEASIBILITY OF THE SIMS **PROGRAMME TO IMPROVE PRESHOOL CHILDREN'S** ORAL HYGIENE LEVEL AND RELATED BEHAVIOURS: A CLUSTER RANDOMISED CONTROL TRIAL

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FACULTY OF DENTISTRY
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THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF DOCTOR OF DENTAL PUBLIC HEALTH

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The Effect and Feasibility of The SIMS Programme to Improve Preschool Children's Oral Hygiene Level and Related Behaviours: A Cluster Randomised Control Trial

Field of Study: **Dental Public Health**

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ABSTRACT

Background: The preschool oral healthcare programme (POHP) was introduced by the Ministry of Health in 1984 to provide oral healthcare to 5-6-year-old children in Malaysia. Due to some limitations, a new programme called the '*Senyuman Indah Milik Semua'* Programme (SIMSP) was introduced with the aim to improvise the POHP. In the SIMSP, a triad of dental therapists (DTs), teachers, and parents was set up to promote children's oral hygiene level, oral health behaviours (OHBs), and parents' oral health literacy (OHL). The POHP only involved DTs.

Objectives: The primary objective of the study was to assess the effect of SIMSP versus POHP on oral hygiene level of 5-6-year-old children in the Kampar District, Perak over 6 months. The secondary objectives were: (i) to assess the impact of SIMSP versus POHP over 6 months in terms of children's OHBs and parents' OHL; (ii) to assess the implementation fidelity of SIMSP's protocol; and (iii) to explore the process implementation of SIMSP from the perspectives of the dental team.

Methods: This study was a pragmatic, cluster-randomised, parallel-group, matched pair, examiner-blind, controlled trial with a 1:1 allocation ratio where preschools in Kampar district were the clusters. Using computer generated numbers, 14 government preschools were allocated to intervention (SIMSP) and another 14 to control (POHP) groups with allocation concealed at cluster level (317 sample per group). Children and parents who fulfilled the inclusion criteria were enrolled by DTs. The study tools included a questionnaire to assess demographics and children's OHBs, the International Caries Detection and Assessment System (ICDAS), the Oral Cleanliness index, and the Malay version of Dental Health Literacy Assessment Instrument (Malay-DHLAI). Data were collected before intervention, and again after 6 months. Implementation fidelity data was self-reported by DTs and teachers. Focus group discussions (FGD) were conducted among DTs and health assistants (HA) in the SIMSP. Quantitative data were analysed

using SPSS software. Qualitative data were transcribed verbatim and thematically analysed using Nvivo software.

Results: At 6-month, 83.4% of children in the SIMSP and 76.4% in POHP completed oral examinations, while response rates for questionnaire was 91.5% and 81.1%, respectively. Mean plaque score decrement was higher in SIMSP than POHP (ES = +0.64). Significantly more SIMSP children took carbonated drinks <1-3x/week ($p = 0.033$). Parents in the SIMSP had a significantly higher mean knowledge score (mean = 0.54, SD = 2.75, $p = 0.024$) and higher OHL scores (ES = +0.97) than parents in POHP. The implementation fidelity data showed majority of parents (83.1%) attended the parent-DT meetings, majority of teachers delivered the in-class oral health lessons including worksheets (96.8%) and supervised daily toothbrushing (93.7%), and all DTs delivered the oral health infographics to parents (100%). FGD participants perceived that SIMSP was an appropriate programme, effective to improve parents' OHL, and received good support from the administrators. The main barrier was to get full parental involvement in the SIMSP. Recommendations for improvement included a dental officer in the SIMSP, gain feedback from other stakeholders, and collaborate with private sectors on the SIMSP.

Conclusion: The SIMSP was shown to be effective in reducing children's dental plaque scores, carbonated soft drinks intake, and improving parental OHL than the POHP over 6 months. The SIMSP's implementation fidelity was high, and the programme was perceived as acceptable by the dental team with rooms for improvement.

Keywords: dental plaque, oral hygiene, preschool, child, Malaysia, behaviour, health literacy

ABSTRAK

Latar Belakang: Program penjagaan kesihatan pergigian prasekolah (POHP) diperkenalkan oleh Kementerian Kesihatan pada tahun 1984 untuk menyediakan rawatan kesihatan pergigian kepada murid prasekolah berumur 5-6 tahun di Malaysia. Menyedari beberapa kekurangan dalam program POHP, satu program baru yang dinamakan Program Senyuman Indah Milik Semua (SIMSP) diperkenalkan dengan tujuan untuk menambahbaik POHP. Melalui SIMSP, Juruterapi Pergigian (DT), guru prasekolah, dan ibu bapa bekerjasama untuk mempromosikan kesihatan pergigian murid prasekolah, meningkatkan tabiat kesihatan mulut (OHB) yang positif kanak-kanak prasekolah dan literasi kesihatan pergigian (OHL) ibu bapa berbanding POHP yang hanya melibatkan DT.

Objektif: Objektif utama kajian ini adalah untuk menilai kesan SIMSP berbanding POHP terhadap tahap kebersihan pergigian murid prasekolah berumur 5-6 tahun di Daerah Kampar, Perak selama 6 bulan. Objektif sekunder adalah: (i) untuk menilai kesan SIMSP berbanding POHP selama 6 bulan dari segi OHB murid prasekolah dan OHL ibu bapa; (ii) untuk menilai kepatuhan pelaksanaan protokol SIMSP; dan (iii) untuk menilai proses pelaksanaan SIMSP dari segi kesesuaian, keberkesanan, fasilitator, halangan, dan cadangan penambahbaikan dari perspektif pasukan pergigian..

Kaedah: Kajian ini berbentuk eksperimental pragmatik, dengan pemilihan kluster secara rawak kepada kumpulan intervensi atau kumpulan kawalan dengan nisbah peruntukan 1: 1 di mana prasekolah di daerah Kampar, Perak diambil sebagai unit kluster. Dengan menggunakan nombor yang dihasilkan oleh komputer, 14 prasekolah kerajaan diperuntukkan sebagai kumpulan intervensi (SIMSP) dan 14 lagi sebagai kumpulan kawalan (POHP). Terdapat 317 sampel di dalam setiap kumpulan kumpulan dan peruntukan kumpulan diselindungi di peringkat kluster. Murid prasekolah dan ibu bapa

yang memenuhi kriteria pemilihan akan didaftarkan oleh DT. Kajian ini menggunakan borang kaji selidik yang telah divalidasi, *Oral Cleanliness Index*, *International Caries Detection and Assessment System* (ICDAS), dan *Dental Health Literacy Assessment Instrument* (DHLAI). Pengumpulan data kajian telah dijalankan pada permulaan kajian dan selepas 6 bulan. Data kepatuhan pelaksanaan protokol SIMSP dilaporkan sendiri oleh DT dan guru. *Focus group discussion* (FGD) dijalankan di kalangan anggota pasukan pergigian SIMSP. Data kuantitatif dianalisis menggunakan perisian SPSS. Data kualitatif ditranskripsikan secara verbatim dan dianalisis secara tematik menggunakan perisian Nvivo.

Hasil: Selepas 6 bulan, 83.4% murid prasekolah di SIMSP dan 76.4% di POHP memenuhi pemeriksaan lisan, sementara kadar respons untuk soal selidik masing-masing adalah 91.5% dan 81.1%. Purata penurunan skor plak lebih tinggi pada SIMSP daripada POHP (ES = +0.64). Lebih ramai murid prasekolah SIMSP mengambil minuman berkarbonat <1-3x / minggu ($p = 0.033$). Ibu bapa di SIMSP mempunyai skor pengetahuan min yang jauh lebih tinggi (min = 0.54, SD = 2.75, $p = 0.024$) dan skor OHL yang lebih tinggi (ES = +0.97) daripada ibu bapa di POHP. Data kepatuhan pelaksanaan protokol SIMSP menunjukkan majoriti ibu bapa (83.1%) telah menghadiri mesyuarat ibu bapa dengan DT, tahap kepatuhan guru untuk menyampaikan pelajaran kesihatan mulut dalam kelas termasuk lembaran kerja pergigian, dan mengawasi memberus gigi harian di sekolah masing-masing 96.8% dan 93.7%. Tahap pematuhan DT untuk menyampaikan infografik kesihatan mulut kepada ibu bapa adalah 100%. Pasukan pergigian berpendapat bahawa SIMSP adalah program yang sesuai dan berkesan untuk meningkatkan OHL ibu bapa. Mereka berpendapat pelaksanaan SIMSP disokong baik oleh pihak pentadbiran perkhidmatan kesihatan pergigian dan prasekolah sementara halangan utama SIMSP adalah mendapatkan penglibatan ibu bapa sepenuhnya. Saranan untuk penambahbaikan adalah melibatkan pegawai pergigian dalam pasukan SIMSP, untuk mendapatkan

maklum balas mengenai SIMSP dari pihak berkepentingan lain, dan berkolaborasi dengan sektor swasta.

Kesimpulan: SIMSP terbukti berkesan dalam mengurangkan skor plak gigi pelajar prasekolah, dan pengambilan minuman ringan berkarbonat,serta meningkatkan OHL ibu bapa berbanding POHP dalam tempoh 6 bulan. Kepatuhan pelaksanaan SIMSP adalah tinggi dan program ini dianggap sesuai untuk peringkat prasekolah dengan beberapa ruang untuk diperbaiki.

Kata kunci: plak gigi, kesihatan pergigian prasekolah, Malaysia, tabiat pergigian, literasi, kesihatan pergigian

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LIST OF SYMBOLS AND ABBREVIATIONS

ART	:	Atraumatic restorative technique
DHLAI	:	Dental health literacy assessment instrument
DMFS	:	Decayed, missing, filled surfaces
DMFT	:	Decayed, missing, filled teeth
DPHS	:	Dental Public Health Specialist
DT	:	Dental therapist
ECC	:	Early childhood caries
FVA	:	Fluoride varnish application
HA	:	Health assistant
ICDAS	:	International caries detection and assessment system
ITT	:	Intention to treat
MOH	:	Ministry of Health
NOHP	:	National Oral Health Plan
NOHPS	:	National Oral Health Survey of Preschool Children
OHA	:	Oral health attitude
OHB	:	Oral health behaviour
OHE	:	Oral health education
OHK	:	Oral health knowledge
OHP	:	Oral health promotion
OHP	:	Oral health programme
PFM	:	Permanent first molar
POHP	:	Preschool oral health programme
SES	:	Socioeconomic status

LIST OF SYMBOLS AND ABBREVIATIONS

SIMSP	:	*Senyuman Indah Milik Semua (SIMS)*
SIMSP	:	*Senyuman Indah Milik Semua Programme (SIMSP)*
TBD	:	Toothbrushing drill

LIST OF APPENDICES

CHAPTER 1: INTRODUCTION

1.1 Background of study

Children's education in Malaysia begins as early as 4 years old at the preschool level. However, this is not compulsory. Nevertheless, majority of children below 7 years of age enrol into the preschool education for a period of two years aged 5-6 years as preparation for entering into the primary school education at the age of seven years. Primary school education is compulsory for all children in the country.

Preschool education in Malaysia can be divided into government and private preschools. Government preschools are managed either by the federal government or state government agencies. Examples of preschools managed by federal government agencies are the National preschools or known as *Prasekolah* by Department of Education, *KEMAS* preschools by the Community Development Department, and *Perpaduan* preschools by the Department of National Unity. Examples of preschools under the supervision of state governments are Federal Territory Islamic Religious Council (MAIWP) Islamic preschools and Perak Islamic Religious Department (JAIP) preschools. Children from low income families are given priority for admission into government preschools. However, children from higher income groups may also enrol if there are vacancies.

As for private preschools, they are private educational institutions registered with the Ministry of Education Malaysia and provide preschool education to children aged 4 to 6 years. The private preschools often operate in residential areas, at shop lots, dedicated buildings, government premises, business buildings and complexes, corporate buildings, community halls, public halls, and places of worship with the approval from the local authorities.

Preschool children are one of the focus groups in the delivery of primary healthcare delivered by the Ministry of Health (MOH), Malaysia (Oral Health Division,

2003). The preschool oral healthcare programme (POHP) was launched in 1984 to provide oral healthcare to 5-6-year-old preschool children in the country. In the POHP, a group of DTs will visit preschools twice a year to provide an oral examination, oral health education (OHE), toothbrushing drill (TBD), apply fluoride varnish, and perform simple dental treatment using Atraumatic Restorative Technique (ART). The objective of the POHP is to inculcate oral health awareness and maintain good oral health amongst children of preschool age.

In spite of the POHP implementation for the past 3 decades, findings from the National Oral Health Survey of Preschool Children (NOHPS) conducted in 2005 and 2015 showed that the prevalence of caries in the primary teeth of 6-year-olds was 76.2% (mean dft = 5.5) in the 2005 survey and 71.3% (mean dft = 4.83) in the 2015 survey. (Oral Health Division, 2005, 2017). As for oral cleanliness, the findings from NOHPS (2015) showed that 40.1% had no visible plaque, 52.6% had little plaque and 7.2% had substantial plaque. Around 7% of preschool children needed extraction of carious permanent teeth and 9.8% had dental abscess (Oral Health Division, 2017).

Studies have revealed that early childhood caries (ECC) in children is a significant marker for future decay in the permanent teeth (Mejàre et al., 2014; Peretz, Ram, Azo & Efrat, 2003). If no proactive action is taken to reduce caries risk in children with ECC, a high number of children in this age group in Malaysia will develop dental decay in their permanent teeth. ECC is largely influenced by behavioural factors and therefore prevention of ECC cannot be based on a single method or to choose one method over another (Philip, Suneja, & Walsh., 2018). As such, a comprehensive approach is required.

Permanent First Molars (PFM) normally erupt between the ages of 6–7 years and they have the highest risk of developing dental caries. Apart from past ECC experience, high sugars diet, poor oral cleanliness, and parents' poor knowledge on the eruption time

of PFM were among the predisposing factors for dental caries in the permanent teeth (Songur, Derelioglu, Yilmaz, & Kosan, 2019). To avoid preschool children with ECC from developing dental decay in the permanent dentition, favourable oral health habits need to be established routinely at the preschool age. As children do not live in isolation, the influence of parents, family members, and school teachers in promoting healthy oral health behaviours (OHB) are extremely crucial (Tinanoff et al., 2019).

Realising the importance of the school environment and family's influence in determining the children's OHB, active involvement of parents/caregivers and teachers in children's oral health is essential (Petersen & Kwan, 2004). Oral health promotion programmes should be designed to incorporate interventions that can improve parents' knowledge and get their active participation to care for their children's oral health, and provide a platform for parents to have an open communication with oral healthcare providers. Teachers can also play a big role to nurture and inculcate good oral health and related behaviours among preschool children when they attend preschool centres.

1.2 Problem statement

Until now, caries prevalence and poor oral hygiene among preschool children in Malaysia remain high. As a testament to the nation's commitment towards better oral health for its nation, the Malaysia's National Oral Health Plan 2011 - 2020 (NOHP 2020) has targeted that 50% of 6-year-olds should have caries-free teeth by the year 2020 with a target mean dft < 2 (Oral Health Division, 2011). However, this target has not been achieved after almost 10 years.

At a local level in the Kampar district, Perak where the study was conducted, the prevalence of caries-free teeth among 6-year-olds in 2014 – 2017 were relatively low; the prevalence of caries-free teeth was 41.4 % in 2014 and decreasing to 37.9% in 2017 (Oral Health Division, 2019). These percentages were consistently lower than the 50% caries-

free target in the NOHP 2020 (Oral Health Division, 2011). This has caused a serious concern among dental policymakers especially when ECC has been shown to be a strong indicator for future caries in the permanent teeth (Peretz et al., 2003).

The existing POHP is believed to had been ineffective to enhance the oral health of preschool children in the country. Since its implementation in 1984, the POHP faces many limitations including limited financial resources, lack of staff to cover all preschools, lack of time, limited dental equipment, and most importantly poor involvement of parents and teachers in the POHP. On top of this, the curative treatment in the POHP has always been a priority for the attending DTs due to the high treatment need of the children. As a result, there is a lack of time for DTs to focus on OHE and promotion programmes with the preschool children effectively. Therefore, efforts to promote positive OHB, good oral hygiene level, and healthy eating habits among the preschool children have been lacking in the current POHP. **Table 1.1** shows the strategies of the current POHP and its weaknesses.

Table 1.1: Strategies of the existing POHP in the Kampar district, Perak and its limitations.

Domain	Strategy in the guidelines	Issues / weaknesses
Human resource	Team of 3 or 4 DTs	Non-exclusive team. The same DT will visit primary and secondary schools in the same year. Due to the high disease burden and extensive job scopes, the focus on primary and secondary schools outweighs their attention for the POHP. Even though the number of dental officers has increased in recent years, the POHP is still highly dependent on DTs due to the limited availability of mobile dental equipment.

Number of visits	2 times a year 1st visit: Dental check up, OHE, TBD 2nd visit: a. Reinforce OHE or other health promotion activities b. Reinforce TBD c. Conduct role-play or control of oral diseases (if within resource constraints) d. Dental treatment	Visits are not well planned and made in unplanned and impromptu manner. Due to the high disease burden, reinforcement of OHE and TBD is often not implemented during the 2nd visit. The DTs are more focused on curative treatment based on the findings during dental check up in the 1st visit.
Parents' involvement	Parents to be informed of dental visit	Parents' involvement is very minimal or non-existing. Many parents were not informed of the dental visits beforehand by teachers. Meetings with parents are unstructured, spontaneous and opportunistic. Sometimes, dental health talks are given during the parent-teacher meeting or student registration day which are not effective.
Teachers' involvement	Organise seminar for preschool teachers. Teachers to supervise regular TBD for preschool children and reinforce OHE messages.	No materials provided for teachers to convey OHE messages and conduct class activities. Therefore, most teachers do not carry out what the DT recommended.

Based on the limitations above, it was acknowledged that there is a need to review the existing POHP particularly in the Kampar district, Perak. Caries development is multifactorial and influenced largely by the social determinants of oral health (Fisher-Owens et al., 2007). However, the influence of the POHP, teachers, and parents in promoting healthy OHB, good oral hygiene level, and caries prevention among preschool

children cannot be ignored. Following discussions with the Perak State Deputy Director of Oral Health and senior oral health officers, it was agreed that if future oral health status of preschool children in the Kampar district to be improved through the preschool programme's efforts, improvement of the existing POHP must include the community at large via community-based interventions to reach the whole population of preschool children and their families in the Kampar district.

Most of the current POHP activities only focus on preschool children. As children live with parents and spend a lot of time in school, positive oral health habits among children will require the joint efforts of DTs, parents and teachers working together on children's oral health. Suggestions have been made to involve active participation of teachers and parents/guardians of preschool children in the improved POHP.

The proposed intervention programme to improve the current POHP was named the '*Senyuman Indah Milik Semua'* programme (SIMSP) or 'Beautiful Smile for All' programme. The SIMSP was developed through evidence-based practice, recommendations from the NOHPS 2015 report, and team discussions among the stakeholders. The SIMSP is essentially the POHP but with active participation of teachers in delivering in-class OHE and supervising daily toothbrushing at school, and parents who monitor child's OHB at home. The SIMSP will be conducted by an exclusive team of DTs who will implement the intervention in the community with the help of parents and teachers in the Kampar district, Perak. The primary aim of the SIMSP is to cultivate favourable OHB and good oral hygiene level among preschool children during their 2-year attendance at preschools before the permanent teeth erupt in order to maximize the chance for a caries-free permanent dentition throughout their lifetime. Improvement of parents' oral health literacy (OHL) would also be emphasised. In the SIMSP, a triad of DTs, parents and teachers will work together on children's oral health while the existing

POHP only involves DTs visiting preschools twice a year. **Table 1.2** shows the summary of comparison between the SIMSP and POHP.

Table 1.2: Comparison between the SIMSP and the POHP

No	Subject	SIMSP	POHP
1	Human resource	Team of 3-4 DTs (exclusive preschool team)	Team of 3-4 DTs (non-exclusive preschool team)
2	Number of preschoo1 visits	3 visits per year	2 visits per year
3	OHE to preschool children	OHE messages given every two weeks by class teacher for 6 months, Daily supervised toothbrushing by teacher	OHE given during 1st visit by DT
4	OHE materials to preschool	OHE booklet to teachers Dental worksheets	None
5	Social media engagement with parents	Oral health infographics send to parents every 2 weeks for 5 months via electronic messaging.	None
6	Caries Risk Assessment (CRA)	Caries management is based on CRA of the child	None
7	Parental involvement	Attend a meeting at school with the DTs. Receive tailored OHE from DTs based on child's oral health status and CRA. Parents to monitor child home toothbrushing.	Unplanned Opportunistic meeting

The details of the SIMSP will be described in the method section. In this study, the effect of the SIMSP on preschool children's oral health will be compared with the existing POHP.

1.3 Rationale of study

This current study was important because there was a need to improve the current POHP particularly in the Kampar district where the prevalence of preschool children with caries-free teeth in this district has been decreasing from 2014 to 2017 and the prevalence has not improved since (Perak Oral Health Division, 2019).

Currently, the Oral Health Programme of the Ministry of Health Malaysia is formulating a programme called the Dedicated Preschool Team. Since the SIMSP was formulated through evidence-based practice, recommendations from the NOHPS 2015 report, and team discussions among the stakeholders, the SIMSP has the potential to be absorbed into the national oral healthcare programme to replace the existing POHP if the SIMSP was found to be effective to change OHB and improve oral hygiene level of the preschool children. Furthermore, the SIMSP would utilise the readily available human resource such as the DTs, preschool teachers, and parents. Therefore, the possibility of the SIMSP to be implemented at the national level was high. The involvement of parents and teachers in children oral health would be the most important part of the SIMSP as the programme promotes healthy home and school environments for oral health. However, the DTs would require training to use the CRA tool and conduct OHE with parents. Similarly, preschool teachers should be provided with training to deliver the in-class OHE and the daily toothbrushing with preschool children.

Positive effect of the SIMSP on preschool children would provide evidence to justify future financial funding, the provision of material resources, and manpower to run the programme effectively which are lacking in the existing POHP. Similarly, the SIMSP

would promote effective use of resources and provide job satisfaction to DTs and the dental team knowing that the programme is effective over and above the POHP.

Last but not least, the SIMSP would provide a framework for evidence-based programme targeting preschool children's oral health that can be disseminated and adopted by other countries in Southeast Asia region and an example of what is working well in comparison to other similar programmes in the developed countries.

1.4 Conceptual framework of study

This study sought to assess the potential effectiveness of the SIMSP on preschool children's oral health as well as the feasibility to conduct the intervention in the local setting.

The potential effectiveness was focused on children's oral hygiene level, oral health and related behaviours, and parents' OHL. The feasibility aspects were assessed based on the participants' adherence to the study by assessing the implementation fidelity of the SIMSP protocol. In addition, a process evaluation of the SIMSP intervention was carried out using the perspectives of DTs and HAs by assessing the perceived appropriateness, effectiveness, feasibility, and suggestions for improvement of the SIMSP. The conceptual framework of the study is shown in **Figure 1.1** below.

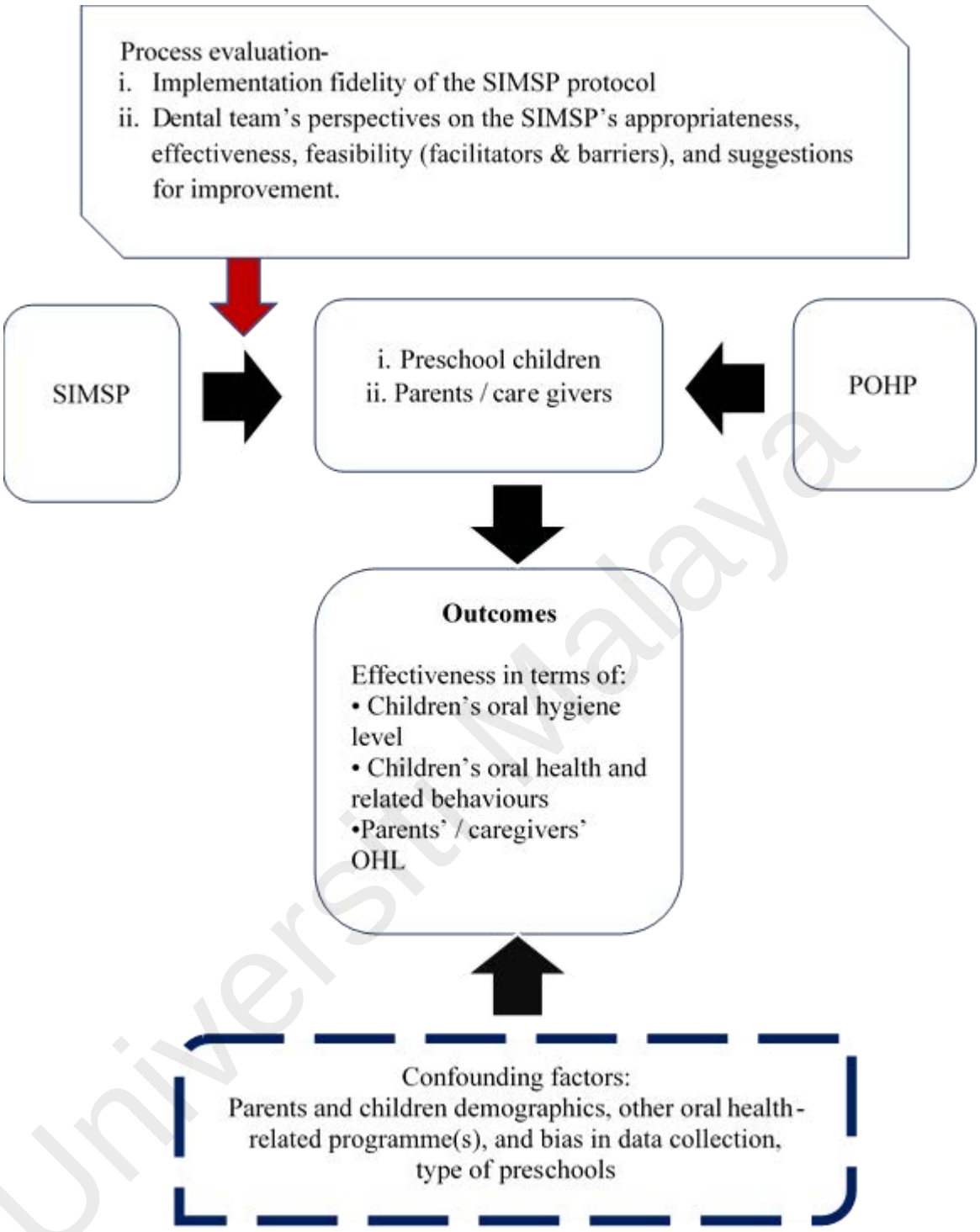

Figure 1.1: Conceptual framework of the study

1.5 The research questions

The research questions of the study are described below.

a) Will the SIMSP be more effective to improve preschool children's oral hygiene level and oral health and related behaviours in the Kampar District over and above the existing POHP?

b) Will the SIMSP be more effective to improve parents' OHL in the Kampar District over and above the existing POHP?

c) Can the SIMSP be implemented according to the SIMSP protocol?

d) Whether SIMSP is appropriate from the perspectives of the dental team?

e) What are the effects of the SIMSP on the target groups as perceived by the dental team?

f) What are the facilitators and barriers in the implementation of the SIMSP from the perspectives of the dental team?

g) What are the suggestions to improve the SIMSP from the perspective of the dental team?

1.6 Aim and objectives

The aim of this study was to assess the effect and feasibility of the SIMSP in improving the oral hygiene level and oral health and related behaviours among 5-6-year-old children, and parents' OHL in the Kampar District over and above the existing POHP over 6 months.

1.6.1 The primary objective

The primary objective was to assess the effect of the SIMSP over and above the existing POHP in improving the oral hygiene level of 5-6-year-old children in the Kampar District over 6 months.

1.6.2 The secondary objectives

The secondary objectives were:

1. To assess the impact of the SIMSP over and above the existing POHP in 6 months in terms of:

   a) Children's oral health and related behaviours

   b) Parents' OHL

2. To assess the implementation fidelity of the SIMSP protocol in terms of:

   a) Parents' compliance in attending the parent-DT meeting at school.

   b) Teachers' compliance in delivering in-class OHE, dental worksheets, and supervising daily toothbrushing with the preschool children.

   c) DT's compliance in sending oral health infographics to parents via Whatsapp application (or paper infographics).

3. To undertake a process evaluation of the SIMSP by exploring the perspectives of the dental team on the following factors:

   a) Appropriateness of the SIMSP

   b) Effectiveness of the SIMSP

   c) Facilitators to implement the SIMSP

   d) Barriers to implement the SIMSP

   e) Suggestions for improving the SIMSP

1.7 Hypotheses

The following hypotheses have been formulated to test the effect of the SIMSP over and above the POHP.

1.7.1 Null hypothesis (H0)

a) There is no significant difference between the SIMSP and the existing POHP in improving oral hygiene level among 5-6-year-old children in the Kampar district over 6 months.

b) There is no significant difference between the SIMSP and the existing POHP in improving oral health and related behaviours among 5-6-year-old children in the Kampar district over 6 months.

c) There is no significant difference between the SIMSP and the existing POHP in improving OHL among parents of 5-6-year-old children in the Kampar district over 6 months.

1.7.2 Alternative Hypothesis (H1)

a) The SIMSP is significantly more effective to improve oral hygiene level among 5-6-year-old children in the Kampar district over and above the existing POHP in 6 months.

b) The SIMSP is significantly more effective to improve oral health and related behaviours among 5-6-year-old children in the Kampar district over and above the existing POHP in 6 months.

c) The SIMSP is significantly more effective to improve OHL among parents of 5-6-year-old children in the Kampar district over and above the existing POHP in 6 months.

CHAPTER 2: LITERATURE REVIEW

2.1 Literature review methodology

A systematic review of the literature to identify relevant studies on the effect of oral health promotion or education programmes on preschool children's oral health, oral health behaviours, and parental OHL was carried out. To promote evidence-based approach to literature searching and develop well-built questions, the search terms were identified based on the PICO model (University of Oxford, 2009). As such, the specific search terms and the PICO model are outlined below:

P (population) = preschool children;

I (Intervention) = Oral health promoting school, oral health education or promotion;

C (Comparison) = Control;

O (Outcome) = Preschool children's dental plaque, caries, oral health behaviours; Parental knowledge, oral health literacy

Based on the PICO model, the identified search terms were: children OR young children OR preschooler [Mesh] AND (oral OR dental) AND health AND (education OR promotion) OR 'oral health promoting school' OR toothbrushing [Mesh] AND (plaque OR caries OR behavio* OR practice OR knowledge OR oral health literacy) [Mesh]. The search was run from 01/01/2010 to 2020 in Dentistry & Oral Sciences Source @EBSCOhost and MEDLINE Complete @EBSCOhost databases via UM library (http://www.diglib.um.edu.my). In addition to the stated databases, related studies were also searched through google scholar website (scholar.google.com) and PubMed. Only articles in English language were considered. In this study, young children were defined as those aged below 7 years. The search yielded 546 articles, of which only 16 involved young children and were relevant to the study. The relevant articles were retrieved and summarised in a table (Guyatt et al., 1993). The references of the selected articles were

also checked for relevant studies. The main findings of the chosen studies were interpreted and discussed without meta-analysis.

2.2 Oral health of young children

Oral health is a vital element for all human being. It is one of the fundamental elements of the overall health. In ensuring one has an excellent oral health throughout lifetime, good oral health habit should start early in life to avoid oral disease in later years. Oral disease is a lifestyle related diseases and can be very costly to treat (Sheiham, 2001). Numerous oral health problems can be prevented and reversed during early commencement. However, in some nations there are large number of children, parents and teachers who have inadequate knowledge on the causes and prevention of oral disease (Rajab, Petersen, Bakaeen, & Hamdan, 2002). Dental caries is caused by localised chemical dissolution of the tooth surface by metabolic events in the biofilms or dental plaque that cover the affected area (Kidd & Fejerskov, 2016). Irregular removal of dental plaque will allow dental caries to develop over a period of time, added with diet consists of mainly sugars or monosaccharides (Boustedt, Dahlgren, Twetman, & Roswall, 2020; Kidd & Fejerskov, 2016; Meyer & Enax, 2018). Caries in early years of life is called ECC. It is defined as the presence of 1 or more decayed, missing or filled tooth surfaces in any primary tooth in a child 71 months or younger (Drury et al., 1999). ECC is the most frequent chronic disease in young children and may perhaps develop as soon as teeth erupt (Douglass, Douglass, & Silk, 2004).

Primary teeth with untreated decay was the 10th most prevalent condition, affecting 9% of the global population, or 621 million people worldwide (Kassebaum et al., 2015). In Malaysia, caries prevalence among preschool children remains high. Referring to the data from the NOHPS 2005 revealed that 76.2% (mean dft = 5.5) of 5-year-olds had caries in primary teeth and the prevalence only reduced to 71.3% (mean dft

= 4.8) in 2015 survey (Oral Health Division, 2005, 2017). The caries prevalence in both surveys were well above the national target of 50% caries in this age group by 2020. In addition, majority of 5-6-year-old children had dental plaque (Oral Health Division, 2017). ECC is a public health problem and it requires the involvement of all health professionals that provide care to children together with efforts from family members (Congiu, Campus, & Lugliè, 2014; Jaime, Carvalho, Bonini, Imparato, & Mendes, 2015).

2.2.1 Importance of good oral health in young children

The deciduous teeth are essential in giving facial fullness and aesthetically pleasant facial shapes. Absence of deciduous teeth will affect the masticatory activity, alter the facial features to some extent and influence the child physiologically, emotionally and socially (Bönecker, Abanto, Tello, & Oliveira, 2012). Strong teeth that function fully will allow a normal psycho-physical development of the children, which is very important for their age (Begzati et al., 2015). Presence of ECC causes dental destruction and pain in children, and more likely to cause children to skip school and perform poorly in class due to toothache, and may affect their general health and quality of life (Jackson, Vann Jr, Kotch, Pahel, & Lee, 2011; Nora et al., 2018). ECC also has major impacts on the quality of life of the family/caregivers including having to take time off work due to children's toothache, and financial implications due to salary cut and frequent dental visits (Righolt, Jevdjevic, Marcenes, & Listl, 2018). Also, children with extensive ECC and children with posterior caries have a higher risk to develop caries in their permanent dentition than caries-free children (Peretz et al., 2003). To establish good oral health and to avoid preschool children with ECC from developing dental decay in future permanent dentition, favourable oral health habits need to be instilled in them. Brushing with fluoridated toothpaste and sugary diet avoidance are two of the most successful measures to prevent dental caries in this age group (Boustedt et al., 2020).

2.2.2 Determinants of young children's oral health

ECC is a public health problem determined by biological, social and behavioural factors (Begzati et al., 2015). There are multiple factors that interact in the aetiology of ECC including parental factors and other health determinants such as socioeconomic status, culture, stress and health behaviours (Hooley, Skouteris, Boganin, Satur, & Kilpatrick, 2012). In an ECC management manual published by WHO (2019) stated that almost all risk factors for ECC are modifiable. But emphasis was given for the importance of establishing good eating habits in childhood to minimize the risk of ECC. Since eating patterns track from childhood to adulthood, establishing appropriate habits in the early years is a major target (WHO, 2019).

Parents are the primary social influence that can affect a child's development in the early childhood years. Their beliefs and practices are known to be associated with their children's ECC (Hooley et al., 2012). ECC does not only affect the low social economic status (SES) families but high SES families as well (Çolak, Dülgergil, Dalli, & Hamidi, 2013). However, other studies claimed that the main risk factor for ECC is the low SES status of parents (Congiu et al., 2014). Bacterial transmission from parent to child can occur through the habit of biting hard food into smaller pieces before giving it to the child and this is an example of a cultural habit (Mani, John, Ping, & Ismail, 2012). Favourable oral health behaviours are key determinants to good oral health. However, OHB in young children is very much influenced by many factors including OHL of parents, culture, environment and social customs (Firmino et al., 2018).

The conceptual model of child's oral health provides a framework to guide understanding on the broader influences of child's oral health and the contributing factors to the development of ECC (Fisher-Owens et al., 2007). The model recognises the presence of a complex interplay of causal factors and incorporates the aspect of time,

recognising the evolution of oral health diseases and influences on the child-host over time. The triad was adapted from the traditional Keyes model which illustrated the interaction between microflora (bacteria plaque), tooth (as the host), substrate (diet) and time that resulted in development of dental caries (Jordan & Keyes, 1966).

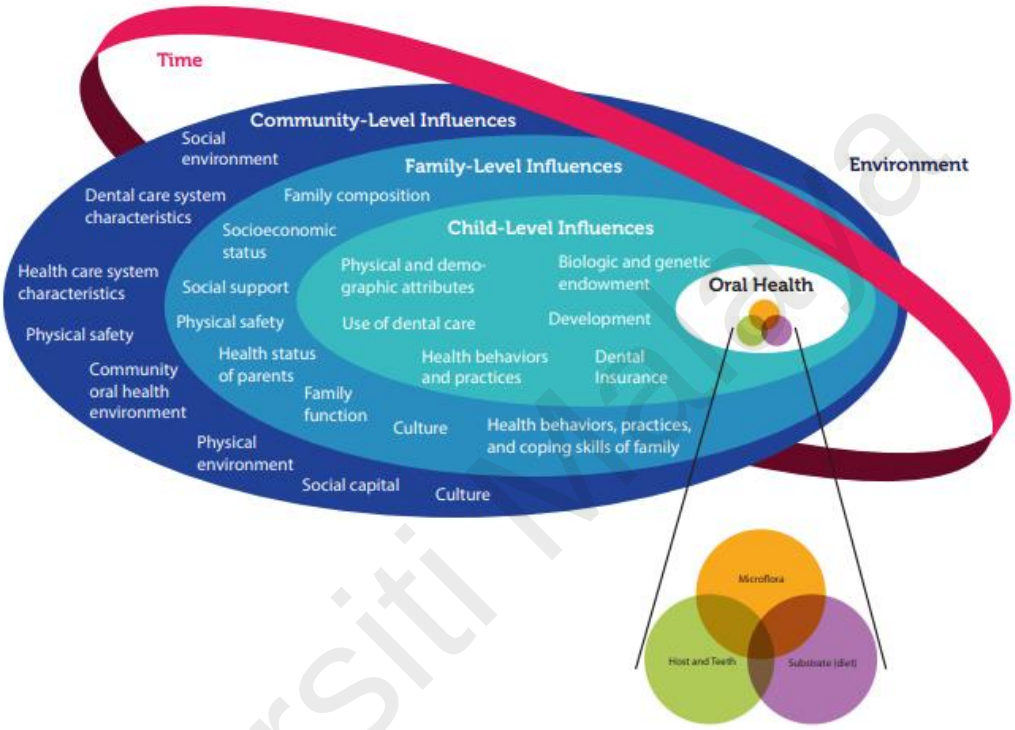

Figure 2.1: The conceptual model of child's oral health (Fisher-Owens et al., 2007)

2.2.2.1 Child-level influences on children's oral health

Based on the model, individual factors that influence children's oral health include physical and demographic attributes, biological and genetic endowment, development, health behaviour and practices, dental insurance and use of dental care (Fisher-Owens et al., 2007).

A child's oral health can be affected by his general physical health. Lower birth weight babies or children with poor nutrition in early life have an increased chance of

developing teeth with hypoplasia which weaken the structure of enamel and increase susceptibility to caries (Abreu et al., 2015; Salanitri & Seow, 2013).

Biological and genetic endowment such as high cariogenic bacteria levels in saliva, development flaws, susceptible tooth morphology, i.e. deep pits and fissures and special needs individuals are associated with high caries experience (Atar & Körperich, 2010; Sánchez-Pérez, Irigoyen-Camacho, Molina-Frechero, & Zepeda, 2019). Other biological factors that negatively affect oral health are malnutrition in children and reduced secretion of saliva because saliva acts as a buffering agent and is a protective factor against initiation of caries (Dawes et al., 2015; Sheetal, Hiremath, Patil, Sajjansetty, & Kumar, 2013).

Higher rates of cariogenic bacteria Streptococcus Mutans were found in children with poor oral hygiene (Boyce et al., 2010). Reviews have concluded that tooth brushing twice a day using fluoridated toothpaste at an earlier age reduces the risk of developing teeth decay (dos Santos, Nadanovsky, & de Oliveira, 2013; Wright et al., 2014).

Dental treatment can be very costly and dental insurance coverage is crucial to lessen financial barriers to obtain dental care for children. Absence of dental insurance coverage has been linked to a higher probability of caries since these children are more likely to be unable to get professional care (Vujicic, Buchmueller, & Klein, 2016). However, this factor is not relevant in the Malaysian context because the oral health services for children are government funded and preschool children are entitled for free dental treatment at government dental clinics.

2.2.2.2 Family–level influences

Based on the model, factors that influenced a child's oral health include family composition, family function, SES, health status of parents, health behaviours, practices

and coping skills of family, social support, physical safety and culture (Fisher-Owens et al., 2007).

Children's oral health outcomes are influenced by their family attributes such as family structure and household size. Children raised by a single parent or reconstituted families have an increased likelihood of caries lesions. This may be linked to lower household income, family stress, and reduced attention to oral health (Kumar, Kroon, & Lalloo, 2014; Piovesan, Antunes, Guedes, & Ardenghi, 2010).

SES have shown by many studies as important indicator of oral health because the SES of parents can have a direct and indirect influence on their children's oral health (Piovesan et al., 2010; Schwendicke et al., 2015). Knowledge and skills for making healthy behaviour choices were reflected from parents' education level which is an important socioeconomic indicator. Higher educated parents are reported to show better attitude and control towards sugar intake of their family compared to low educated parents (Van den Branden, Van den Broucke, Leroy, Declerck, & Hoppenbrouwers, 2013). SES has also been shown to affect health literacy of parents, which in turn affects their health and the health of their children (Baskaradoss, 2018).

Parents' health behaviours can directly affect their children's oral health. Parents are responsible for establishing good oral health behaviours in their children from very young age such as helping and supervising tooth brushing, Lower rates of ECC among children are associated with parental supervision while brushing (Hamilton, Cornish, Kirkpatrick, Kroon, & Schwarzer, 2018; Hooley et al., 2012). Parents should be able to acquire professional dental care for their children as early as possible. Children with higher rates of ECC were more likely to have parents who were afraid of dentist and did not think that deciduous teeth were important (Fontana, 2015).

Mothers play a significant part as the primary role model for their children's behaviour. As the primary caregiver, mothers have a huge influence on daily dietary practices. Compared to fathers, there is a stronger association between dental caries in mother and children (Hooley et al., 2012; Proença, Franco, Rodrigues, Costa, & Costa, 2015). Mothers who possess more positive oral health attitude and good oral health behaviours are likely to care more for their children's oral health such as enforcing regular toothbrushing at home (Hooley et al., 2012). Children are not born with cariogenic bacteria in their mouth. Transfer of bacteria such as *Streptococcus Mutans* in saliva usually passed from mother to child through the sharing of eating utensils, sucking of the pacifier or kissing can occur as mothers can be the principal source of the bacteria (Francisco Ramos-Gomez, Crystal, Ng, Tinanoff, & Featherstone, 2010). Development of ECC was associated with the vertical spread of cariogenic bacteria from mother to child in the first year of life (Leong, Gussy, Barrow, de Silva-Sanigorski, & Waters, 2013).

At certain extent, culture can have an influence on oral health outcome. Culture influence can be through diet, health related belief, behaviour, and attitude (Mani et al., 2012; Reddy & Anitha, 2015). Increased indulgence to between-meal snacks, sweetened liquid in nursing bottle, sweets, and pre-chewed rice were poor infant feeding practices found in South East-Asian families (Mani et al., 2012).

2.2.2.3 Community-level influences

Social environment, social capital, physical environment, physical safety, culture, community oral health environment, dental care and healthcare system characteristics are among the factors that contribute to community-level influences on child's oral health (Fisher-Owens et al., 2007). Children who live in a deprived and disadvantaged

environment are more likely to suffer from poor oral health (Arora, Schwarz, & Blinkhorn, 2011).

As one of the important components of the social environment in children's life, preschools can serve as a platform to promote health programmes. As school teachers are trained to teach based on their students' cognitive level, preschool teachers can serve as agent of change at the community level to improve their students oral health (Mota, Oswal, Sajnani, & Sajnani, 2016).

Community oral health programmes such as oral health promotion campaigns and healthy public policies are associated with improved children's oral health. Children's oral health is likely to be better when they live in a community that values good oral health (Fisher-Owens et al., 2007). Public policy includes public water fluoridation programme which increases children's intake of fluoride and provides a positive effect on children's dentition. Areas of living with low level of fluoridated water was linked with higher caries risk (Iheozor-Ejiofor et al., 2015; Slade, Grider, Maas, & Sanders, 2018).

Accessibility to an effective healthcare system that provides curative, preventive and promotive care is crucial to achieve good oral health. Socioeconomic and clinical indicators such as pain are associated with the use of dental services. Strategies to promote public dental health is needed including the reorientation of services that can facilitate dental access for preschool children (Ardenghi, Vargas-Ferreira, Piovesan, & Mendes, 2012).

2.3 Improving the oral health of young children

It is undeniable that children's oral health is influenced by multiple factors and these factors are likely to be complex and overlapping (Kim Seow, 2012). With limited

resources and huge disease burden, it is almost impossible for local oral health services to provide curative, preventive and promotive care to all preschool children in their locality. Since caries development is highly related to good oral health practice, the best way to achieve good oral health relies on the formation of the vital behaviours such as toothbrushing with fluoride toothpaste and controlling sugars intake (Cooper et al., 2013).

To reduce the prevalence and burden of ECC worldwide, the International Association of Paediatric Dentistry Bangkok Declaration recommends the following four key areas requiring action with multiple stakeholders:

1. Raise awareness of ECC with parents/caregivers, dentists, dental hygienists, physicians, nurses, health professionals, and other stakeholders.
2. Limit sugar intake in foods and drinks and avoid free sugars for children under 2 years of age.
3. Perform twice daily toothbrushing with fluoridated toothpaste (at least 1000 ppm) in all children, using an age-appropriate amount of paste.
4. Provide preventive guidance within the first year of life by a health professional or community health worker (building on existing programmes e.g. vaccinations where possible) and ideally, referral to a dentist for comprehensive continuing care (Pits et al, 2019).

2.3.1 Planning for intervention programmes

Behavioural interventions in school can support children to acquire independent and persistent healthy behaviours as schools offer a potential and conducive setting for such interventions (Kwan, Petersen, Pine, & Borutta, 2005). The conventional health-promotion methods that exclusively highlight on changing oral health behaviours through dental health education, are mostly unsuccessful to achieve sustained oral health gains (Kay & Locker, 1996). Since children's cooperative ability is low, it is important to

determine the causes of dental caries in children, to provide oral health information to their parents or caregivers, and to control teeth demineralisation. Interventions that aimed to improve the intraoral environment can reduce the risk of dental caries and therefore stop dental caries development (Kidd & Fejerskov, 2016).

2.3.1.1 Evidence based approach

To accomplish local, state and national objectives to improve health of the population, it is recommended to adopt for evidence-based strategies. Evidence-based public health practice can yield multiple benefits, including access to more and better quality information on what has been shown to improve the public's health, a higher prospect of successful programmes and policies being applied, better workforce productivity, and more efficient use of public and private resources (Brownson, Baker, Deshpande, & Gillespie, 2017). The strategies formulated must aim to optimize the reach, with clear implementation process, adoptable and sustainable (Araújo-Soares, Hankonen, Presseau, Rodrigues, & Sniehotta, 2019).

Incorporation of scientific evidence in interventions or policy development, implementation and evaluation of progress and outcomes through rigorous and critical methods should always be practiced by researchers or public health practitioners. There are a few concepts that are essential to achieve a more evidence-based approach to public health practice. First, researchers need to obtain scientific information on the health promoting programmes and policies that are most likely to be effective. Second, in order to transform scientific evidence into practice, researchers need to combine evidence-based interventions information with the realities of a specific and real environment. Relevant on ground issues need to be considered when formulating an intervention. Afterwards, clear definition of the processes involved is needed to provide a pragmatic user-friendly framework and smooth implementation of the intervention. Finally, the

intervention, if proven effective, can be disseminated more consistently at local and state levels (Khanlou & Peter, 2005).

2.3.2 Behavioural change interventions

Improved health outcomes and good quality of life for people living with chronic and non-communicable illnesses can be achieved through behaviour change for better and effective self-management (Araújo-Soares et al., 2019). Early childhood period offers a unique opportunity for effective behavioural interventions because early childhood is a critical stage for forming healthy habits and lifestyles (Skouteris, McCabe, Swinburn, & Hill, 2010). Since children spend a significant time in school on daily basis, schools can provide a good setting for promoting general health as well as oral health (Bundy et al., 2017).

2.4 The preschool oral healthcare programme in Malaysia

A structured preschool oral healthcare programme (POHP) in Malaysia was introduced in 1984 that aims to provide oral healthcare to 4-6-year-old children who attend government preschool centres or kindergartens throughout the country (Oral Health Division, 2003). During the early years of its implementation, this programme focused more on the preventive and promotive activities for children who attend the preschools. Children who required curative care are referred to the nearest government dental clinic by the attending DTs. Priority of service is given to government-aided preschools and would extend the service to private preschools upon request, and if resources permitted to do so. Visits to preschools are carried out by DTs and assisted by health assistants (HAs). For this programme, the dental team will visit preschools twice a year. During the first visit, the activities that will be conducted are an oral examination, OHE, TBD, OHE and fluoride varnish application (FVA) containing 22,600 parts-per-million fluoride (ppmF). After 6 months, the dental team will revisit the preschools for second FVA

(22,600 ppmF) and simple restorative treatment (if required). Reinforcement of OHE through promotional activities such as role play, storytelling or puppet show is carried out if time permits.

The general objective of this programme is to inculcate oral health awareness among the children and to maintain good oral health amongst them. The programme's specific objectives are to enable preschool children to maintain good oral hygiene, to ensure preschool children are accessible to oral health personnel and oral healthcare, to control the incidence of oral diseases in preschool children, and to empower teachers and carers to provide healthy food choices (Oral Health Division, 2003).

Over the years, curative care had been included in the programme by means of the ART technique (Sajjanshetty, Hugar, Jain, Soujanya, & Khan, 2013). Young children who require simple treatment are treated at the kindergarten by DTS. Only those who require extensive treatment are referred to the dental clinic. The POHP was further facilitated with the establishment of the preschool teams under the 7th Malaysia Plan (1996 - 2000) (Oral Health Division, 2003). The implication from this establishment is that more DT posts were created to run the programme. In 2003, the Guidelines for Preschool Oral Health Programme was published as the reference to implementing the POHP (Oral Health Division, 2003). From the guidelines, the responsibilities of DTs are: (1) To notify preschools teacher of the programme schedule before visiting the preschool; (2) To encourage parents to be present during both visits through a letter; (3) Conduct the activities in the first visit which are an oral examination, OHE, TBD, FVA and update parents of their children's oral health status; (4) conduct the second visit whose activities include to reinforce OHE or other health promotion activities, reinforce TBD, FVA, conduct role-play, and provide dental treatment using ART technique; (5) Data collection and update of work record (Oral Health Division, 2003).

The POHP limitations in controlling caries and dental plaque in young children have been highlighted in the 2015 NOHPS (Oral Health Division, 2017). Various recommendations have been highlighted in the report in order to improve the POHP. Among the recommendations were to strengthen the healthcare provider's role in providing oral health advice to parents/guardians, promote OHL and the involvement of parents, reinforce teachers and consolidate the use of social media to promote oral health to young children.

2.5 School-based oral health promotion programmes in young children

Oral health promotion in schools has traditionally focused on educational approaches that transfer knowledge about disease or healthy behaviours. However, evidence suggests that these approaches alone have limited long-term effects. Instead, a focus on activities that develop children's skills, oral hygiene practices, and healthy oral health habits is more successful in improving individual oral health behaviours (Benzian et al., 2017). To increase the chance of a caries-free permanent dentition throughout a lifetime, it is paramount to cultivate dentally healthy habits among preschool children whose permanent teeth are erupting (American Academy of Pediatric Dentistry, 2009).

A vital feature for school-based oral health promotion programmes is children's engagement in the programme. Leaflets, posters or any other written communications can reinforce information but may have limited impact when used alone. It is more likely to achieve behaviour change through personalised interactions, skills training and reinforcement. The Communication-Behaviour Change model provides a framework for considering some of these design issues (Pine, 2007). A hierarchy of engagement the child will have from a programme provides a method to classify health education programmes in terms of their probable impact and is presented in **Table 2.1**. From this classification, most conventional oral health education programmes would be between

Level 1 and 3. This would explain the findings that may result in knowledge gain, some initial change in attitudes but no long-term behaviour change. By comparison, school-based intervention programmes which include parents' and guardians' involvements is classified at Level 6. This programme can offer long term benefits as children gain knowledge and maintain good oral health behaviours through reinforcement from their parents.

Table 2.1: Communication-behaviour change framework to indicate levels of school programme and outcomes (Pine, 2007)

Hierarchy of Engagement				
Level of school programme	Child	Communication method	Examples of methods & materials used in schools	Communication – behaviour change model
Level 1	Passive	Written	Leaflets, posters	Expose to health message of brushing 2x daily; approve & show interest; understand (knowledge)
Level 2	Passive	Verbal	Lessons about teeth, plaque, brushing	
Level 3	Active	General interaction	Colouring books; brushing on teeth model; taking parts in stories	Agree to the message (Attitude / belief); acquire the skills (Behaviour); incorporate the new attitude and knowledge into memory; retrieve information when necessary & make decisions from memory recall (Intention, contemplation)
Level 4	Active	General interaction with reinforcement	Lessons continued in a series; Parent involvement e.g. take home toothbrush & toothpaste; brushing aids; brushing charts	
Level 5	Active	Personalised interaction	Counting own teeth; brushing own teeth	
Level 6	Active	Personalised interaction with reinforcement	Brushing own teeth on repeated occasions; Parent involvement e.g. take home toothbrush & toothpaste; brushing aids; brushing charts	Act on decision (Action). Reinforce behaviour and maintain the new health behaviour over time (Maintenance)

2.5.1 Rationales for parents and teacher's participation

Parents and caregivers really need to understand the risk factors of ECC. Therefore, OH promotion for young children must include parents and caregivers (Ismail, Tanzer, & Dingle, 1997). Development of new technologies and services offers opportunities to improve the scope of interventions delivery in order to help behaviour change and self-management. Use of caries risk assessment procedure on the community level can help for design of community interventions, and to manage time and allocation of limited resources (F. J. Ramos-Gomez, Crystal, Ng, Crall, & Featherstone, 2010). For the individual child, risk assessment is an essential key element for identifying the potential sources of his oral health problems and help with the decision-making and management of ECC. The different risk categories should ideally be linked to personalized preventive measures and follow-up intervals (Tinanoff et al., 2019).

Education is one of the fundamentals to promote oral health. Children look for training and encouragement to have responsibility for their own health. Education in school can stimulate development of skills, and establishment of good values, which will lead the children to act positively in relation to their own health including oral health (Garbin, Garbin, Dos Santos, & Lima, 2009). Teachers can play a big role to provide continuous health education and encouragement to their students. With their training and expertise to deliver information suitable to their students' cognitive level, teachers are essential personnel as agent of change. (Fernando, Kanthi, & Johnson, 2013).

2.5.2 Parents and teachers involvement to promote good oral health in young children

Oral health providers may face challenges to motivate and empower parents to promote healthy oral health habits in of young children. However, such challenges can yield positive results if appropriate interventions are applied (Gao, Lo, McGrath, & Ho, 2013).

Besides parent's involvement, teachers' involvement can contribute enormously to the prevention of oral disease and promotion of oral health among preschool children (P. E. Petersen et al., 2015). Suitably tailored school-based interventions that are formulated according to child's educational needs, may well provide a healthy environment that allows health promotion, improvement of health-related knowledge, and maintain behaviour change to affect health outcomes such as health status and quality of life (Freeman et al., 2016).

Teachers can play a big role as a mediator between the oral health service, the children, and parents. A study by Antunes et al., (2008) concluded that teachers were interested to embark on OHE in their schools, and to help promote healthy habits amongst preschool children. However, the teachers should be better qualified in the subject so that they could feel encouraged and confident to do so (Antunes, Antunes, & Corvino, 2008). Findings from a research in Iran showed that teaching preschool students about body hygiene had an effective influence on their hygienic awareness during primary school compared to children who were not taught about the subject during preschool. However, the formation of hygienic behaviours is a multi-dimensional issue and can be affected by some different factors besides the presence or lack of presence of preschool training. Investigating these factors from all aspects can provide more clear standards to plan for more effective training curriculum for children (Sharifnia, Hojati, & Sharifnia, 2011).

School-based caries prevention interventions usually encourage children to establish and maintain effective oral health routines that are critical for caries control. These interventions often provide supervised toothbrushing practice and hygiene skills training at school (Albino & Tiwari, 2016). These interventions can be strengthen with parents and primary caregivers' involvement by continuing the supervision at home (Cooper et al., 2013).

2.6 Effectiveness of school-based oral health education/promotion programmes to improve preschool children's oral health, oral health behaviours, and parents' OHL

There are many studies on OHE or oral health promotion (OHP) programmes that aimed to improve the oral health of young children. The interventions varied in terms of locations and were based at health/dental clinics, nurseries, or preschools. To date, systematic evidence that shows the effectiveness of school-based oral health education/promotion programmes on preschool children's oral health, oral health behaviours, and parental OHL in a single study is limited. Many studies targeting young children that involved parents often evaluated parental oral health knowledge (OHK) alone, which is one of the domains for OHL.

School-based oral health intervention programmes for preschool aged children also varied in terms of participants involved (inclusion of parents and/or teachers), and types of intervention conducted. Various oral health activities had involved children, parents and teachers. In these studies, levels of success varied and depended on the variability of the OHE, the educational methods and materials used, levels of participation from children, teachers, parents and health officials, levels of empowerment and reinforcement, use of fluorides, access to clinical prevention and curative services, duration of follow-ups, and levels of oral disease. Most of the outcome measures were related to changes in plaque and gingival bleeding scores, and caries prevalence, incidence and increment. The OHB outcomes were mainly related to improvement in toothbrushing frequency, proper use of fluorides, intake of sweet food and drinks, and between-meal snacking. No study has reported on parent's OHL as the outcome, but a few studies reported on the improvement of OHK.

A systematic review on school-based oral health interventions in children aged 4 to 12 years published in 2013 concluded that there were limited evidence on the clinical effects of school-based oral health interventions aimed at changing behaviours related to toothbrushing habits and the frequency of cariogenic food and drinks consumption in children for caries prevention (Cooper et al., 2013). It was suggested that more high-quality research utilising behaviour change theories in the design and evaluation of interventions should be conducted for interventions aiming at changing oral health and related behaviours in children and their parents.

Another systematic review of the literature on the topic showed that most health behaviour change interventions had used a limited number of behaviour change techniques, and were mostly confined to information-giving and toothbrushing instructions. With the advancement of many new techniques to promote oral health, the author concluded that it was timely to review the approaches in the design and delivery of OHP interventions. This in turn can enhance the power of interventions and reduce childhood dental caries by supporting interventions that promote lasting behaviour change (Adair, Burnside, & Pine, 2013).

Another systematic review and meta-analysis was conducted in 2017 with the objective to identify relevant studies on the effectiveness of OHE in the school context for improving dental caries and oral hygiene among preschool children (Stein, Santos, Hilgert, & Hugo, 2018). The systematic review found limited studies assessing the effectiveness of interventions to reduce dental caries in this age group. Five studies showed a reduction in plaque levels, and two studies with gingivitis as the outcome measure showed no significant effect. From these studies, the authors concluded that traditional OHE actions were effective in reducing plaque levels, but not gingivitis. There

was no long-term evaluation on plaque, gingivitis, and dental caries in the school environment for this age group.

Apart from the systematic reviews above, many primary studies on the oral health of young children had used supervised toothbrushing as a common intervention activity for preschool children and it was shown to be effective against caries (Agouropoulos, Twetman, Pandis, Kavvadia, & Papagiannoulis, 2014; Dimitropoulos et al., 2020; Jaime et al., 2015; Jiang, McGrath, Lo, Ho, & Gao, 2020; Macpherson, Anopa, Conway, & McMahon, 2013; Petersen et al., 2015; Pisarnturakit & Detsomboonrat, 2020; Samuel, Acharya, & Rao, 2020). Macpherson reported that the National Supervised Toothbrushing Programme and Dental Decay in Scotland had led to improvements in dmft scores among participants. The improvement in the dental health of five-year-olds in the study was associated with the uptake of frequent toothbrushing exercise with fluoride toothpaste among the nursery children (Macpherson et al., 2013).

Another study involving preschool children aged 4 to 6 years in southern Thailand showed lower DMFT and DMFS increments in the intervention than in the control group in a community-based randomised controlled clinical trial. The intervention in this 2-year study were as follows: (i) Supervised daily toothbrushing at school after lunch for at least two minutes using a soft bristled toothbrush with a pea-sized (0.25gm) toothpaste containing 1450 ppm fluoride, rinse with minimal amount of water, and spit once after toothbrushing; (ii) Teacher provides OHE to children at least twice in each semester or four times a year; (iii) Regular communication between teachers and parents or caretakers about their child's oral health; and (iv) Teacher is provided with new materials, e.g. dental models, posters, music compact discs, a flipchart, and oral health related games for pupils. For control, children followed the policy of toothbrushing with fluoridated toothpaste after lunch. This policy was unstructured with weak or often no supervision by teachers.

The fluoride concentration in toothpaste was either 1,000 ppm or less with uncontrolled amounts of toothpaste applied. Through monitoring of the intervention schools, the authors identified 5 schools as cooperative and 2 schools as non-cooperative. For the more cooperative schools, the benefits were greater where up to 40.9% reductions in caries were observed. Besides that, significant improvements in dental plaque scores were also observed in the intervention group, and the results were greater in the more cooperative schools. This study also resulted in significant improvements in dental plaque scores in the intervention group after 24 months (Petersen et al., 2015).

A 2-year randomised control trial evaluated the effect of twice yearly application of fluoride varnish in preschool children as an adjunct to school-based OHP and supervised daily toothbrushing with toothpaste containing 1000 ppmF (Agouropoulos, Twetman, Pandis, Kavvadia, & Papagiannoulis, 2014). In the study, all children received OHE with oral hygiene instructions twice yearly and attended daily supervised toothbrushing. However, the intervention group was treated with fluoride varnish (0.9% diflurosilane) twice yearly while the control group had placebo applications. The results showed no significant difference in caries prevalence or increment between the groups after 2 years. The study concluded that twice yearly fluoride varnish applications in preschool children had no significant caries-preventive benefits when provided as an adjunct to school-based daily supervised toothbrushing with 1000 ppm fluoride toothpaste.

A 2-year randomised trial for 3-5-year-old children from very low SES was conducted in India. The interventions included sugary snack consumption prohibition in school, teacher supervised daily toothbrushing using fluoridated toothpaste, and OHE were carried out with regular follow-up at 6 months, 1, and 2 years. The active control received toothbrushing and OHE whereas the negative control group received only OHE.

At 24 month follow-up, mean caries increment in the intervention group was 0.4, the active control group was 0.9, and the negative control was 0.8. The authors concluded that prohibition of sugary snacking in school and daily supervised toothbrushing, with or without OHE is effective to prevent ECC among preschool children with health neglect in very poor resource settings (Samuel et al., 2020).

A randomised control trial (RCT) conducted in Thailand compared two caries prevention programmes involving intensified preventive regimen based on a 'high-risk' approach among Thai kindergarten children. Children with at least 2 carious lesions were considered as high risk for dental caries development were identified and were randomised into two groups. Half of the children were assigned to high risk basic (HRB) group and the other half were assigned to high risk intensive (HRI) group. Both HRB and HRI were provided with the basic prevention regimen (OHE, hands-on toothbrushing practice for teachers and caregivers, daytime toothbrushing supervised by teachers at least once a week, and sealant on newly erupted first permanent molars). However, HRI group were given additional intensified preventive regimen (FVA, primary molar sealant, and silver diamine fluoride (SDF) application on carious lesions). All HRB, HRI and LRB were provided with toothbrush, fluoridated dentifrice, and a guidebook. Results after 24 months showed that new caries development in the HRB group (75%) was higher than that in the HRI group (65.7%) and the LRB group (21.1%). There was no significant differences in caries increment between the HRB and HRI groups at the start of the study ($p = 0.709$). The authors concluded minimal additional benefit achieved from the intensified prevention. Basic prevention could give almost the same preventive effect with substantially less effort and lower cost (Pisarnturakit & Detsomboonrat, 2020).

A study by Jiang et.al. (2020) investigated the effectiveness of integrating motivational interviewing (MI) and interactive caries risk assessment (RA) using

Cariogram into prevailing health education (PE) in preventing ECC in a RCT conducted in Hong Kong for 2 years. In the study, 692 recruited parent-child dyads were randomly assigned into three groups (PE, PE+MI, and PE+MI+RA). Each parent in PE group received three oral health pamphlets entitled "Cleaning Teeth - I can do it", "Eat Appropriately", and "Early Childhood Caries". The pamphlets were chosen from those designed by professional bodies and contained texts with pictorial illustrations for readers to understand the home-care behaviours required for preventing ECC. Parents in group PE+MI each received the pamphlets as mentioned above, and an individual face-to-face MI session with one of four trained MI counsellors. The MI session was typically structured into four processes (engaging, focusing, evoking, and planning), in which the counsellor followed the MI spirits (collaboration, acceptance, evocation, and compassion) and used the MI core skills (reflection, open questions, affirmation, and summary) to steer the conversation toward a specific change. Each parents in the PE+MI+RA received the pamphlets as mentioned above, an MI session as above, and RA introduced at different stages of the MI session depending on the parent's response, to stimulate parent's thinking and help him/her to identify the discrepancy between the status quo and personal goals, to explore possible behavioural changes and their respective health gains (reduction in caries risk), to make better informed decisions and set his/her own goal and agenda (what to change and to what extent). After 12 months, caries increment was significantly lower in the PE+MI group (β = -0.717, 95% CI: -1.035, -0.398) and the PE+MI+RA group [β = -0.600, 95% CI: -0.793, -0.407] than in PE group. There was a significantly greater reduction in plaque score in PE+MI group (β = -0.077, 95% CI: -0.106, -0.048) and PE+MI+RA group (β = -0.075, 95% CI: -0.113, -0.036), as compared with PE group. Significantly better improvements were found in parental efficacy and children's OHB in PE+MI and PE+MI+RA groups as well. The conclusion from the study was that the integration of MI improved the effectiveness of PE in preventing ECC, enhancing

parental efficacy, and improving children's OHB. However, incorporation of the RA does not further improve the effectiveness of MI. The clinical significance from this study was that public health workers need to select effective interventions to empower parents for improving children's OHB and prevent ECC (Jiang et al., 2020).

Improvement in oral cleanliness or plaque score was evaluated in two studies (Dimitropoulos et al., 2020; Sharma, Hebbal, Ankola, & Murugabupathy, 2011). A 4-week community intervention study involving mothers of preschool children in Belgaum City, India evaluated the provision of OHE through mobile-phone short messaging system (SMS). The authors compared the effectiveness of two OHE media (SMS and pamphlets) by evaluating the visible plaque index (VPI) of the preschool children pre and post interventions. At follow-up, preschool children from the SMS group showed a greater decrease in VPI score (VPI) (Sharma et al., 2011). Dimitropoulos et al (2020) evaluated the outcomes of a co-designed, community-led OHP programme for Aboriginal children in rural and remote communities in New South Wales, Australia. The comprehensive OHP programme was co-designed with local Aboriginal communities including daily toothbrushing, water bottle programme, regular application of fluoride varnish, regular distribution of toothbrushes and fluoride toothpaste and OHE, and tested on 88 children aged 5 to 12 years. There was a significant reduction in plaque scores and gingivitis as well as improvement in positive OHBs. The co-design element of the programme was critical to its success. This was done by engaging local Aboriginal communities to co-design and deliver the OHP with the aim to reduce caries prevalence among Aboriginal children (Dimitropoulos et al., 2020).

A study conducted in India compared the effect of OHE given by dental professionals and schoolteachers on students' oral health (Chachra, Dhawan, Kaur, & Sharma, 2011; Karuveettil, Kumar, Janakiram, & Joseph, 2020). The study was a non-

RCT which compared the effectiveness of OHE delivery by dentists and teachers over 1 year. The results showed significant improvements in knowledge, attitude, and practice (KAP) regarding oral health among schoolchildren who received OHE either from dentists or teachers. Therefore, the authors concluded that OHE can be delivered effectively by multidisciplinary teams (Karuveettil et al., 2020).

Naidu et. al., (2015) conducted a RCT to evaluate the effect of MI on oral healthcare KAP of parents and caregivers of preschool children. Test-group received a talk on OH using an MI approach and two telephone call follow-ups as part of the MI protocol while the control group received a talk using conventional OHE and both groups were given written oral health information as well. At the end of the 4-month study, both groups showed an increase in knowledge on fluoride use and toothbrushing, and improvement in dietary practice and dental attendance. In the experiment group, there were significant increases in mean child toothbrushing frequency and reductions in oral health fatalism ($p < 0.05$). The researchers concluded that the use of MI approach to deliver oral health information had positive effect on parent/caregivers' oral health KAP compared to conventional OHE (R. Naidu, Nunn, & Irwin, 2015).

A retrospective cohort study conducted in France assessed the effect of schools with an OHP that had various educational activities conducted with carers (parents, teachers, and school nurses) of the children. The results showed an inconclusive effect of the OHP programme to improve oral health among the children. The study concluded that an OHP had little effect to reduce disparities in the oral health of children, even if dental status improved in a few schools (Tubert-Jeannin, Leger, & Manevy, 2012).

A 3-year retrospective controlled clinical trial to assess the effect of a school-based OHE programme on caries incidence in children was conducted in Brazil (Jaime et. al, 2015). The intervention group received an OHE programme carried out in three

steps: (1) firstly, the school dentist gave a lecture to the children's parents; (2) afterwards, the dentist gave a short course to the school staff; and (3) the teachers gave a six-module course to the students, based on different themes: "the importance of the mouth", "dental caries", "oral hygiene", "dietary habits", "deleterious oral habits" and "importance of visiting the dentist". Each module lasted for one month, and the programme was carried out over 6 months in a simple, low-cost, continuous basis. The control schools did not take part in the OHE Programme. Additionally, both the intervention and control schools also had daily dental treatment available for the children and the dentists provided two talks per year on oral health as part of basic health system programme. The results showed that more children from the experimental group reported that they knew about dental caries and reported to use dental floss daily, but no significant difference in caries incidence was observed between the experimental and control groups.

In terms of follow-up evaluations, the duration of studies varied from short-term (4 weeks) to long-term (6 years) follow-ups. A study that had follow-ups up to 2 years demonstrated significant improvements in caries levels of deciduous teeth and plaque levels (Petersen et al., 2015). Shorter-term studies involved evaluations of children's and parents' OHK improvement (Chachra et al., 2011; R. Naidu et al., 2015; Sharma et al., 2011) and improvements in plaque levels (Sharma et al., 2011). In terms of OHB change in preschool children, no long-term follow-ups were reported, so it is impossible to determine whether the programmes achieved sustainable changes in OHB.

In summary, most of the school-based oral health interventions included in-school supervised toothbrushing exercise and the delivery of OHE by schoolteachers which resulted in lower caries incidence, improved oral cleanliness, and better OHBs among preschool children. Additional preventive treatment such as fluoride varnish application was shown to have limited impact on caries as long as daily fluoride exposure in the form

of fluoridated toothpaste containing 1000 – 1450 ppm fluoride was included in the package. Many of the studies that included parental involvement showed significant improvements in parents' OHK. Longer term and high-quality research that is designed based on behaviour change theories is extremely needed. These interventions must include a robust evaluation plan to certify the effectiveness of the interventions for changing oral health and related behaviours in young children and their parents.

Table 2.2: Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children.

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
Primary school-based behavioural interventions for preventing caries (Review) Cooper AM, O'Malley LA, Elison SN, Armstrong R, Burnside G, Adair P, Dugdill L, Pine C (2013)	To assess the clinical effects of school-based interventions aimed at changing behaviour related to toothbrushing habits and the frequency of consumption of cariogenic food and drinks in children (4 to 12 year olds) for caries prevention. **Systematic review**	Inclusion criteria: English papers published from 1966-1997 Search: Cochrane Oral Health Group's Trials Register Medline Embase CINAHL PsycINFO ClinicalTrials.gov ZETOC Web of Science (1990 to 18 October 2012). Proquest Dissertations and Theses database	Included four studies involving 2302 children.	Three studies which reported plaque outcomes all found a statistically significant reduction in plaque in the intervention groups Two trials involved parents. They were given tasks relating to the school OH programme with their children. Secondary outcome measures from one study reported that the intervention had a positive impact upon children's OHK	Limited evidence for the effectiveness of these interventions on plaque outcomes and on children's OHK acquisition. None of the interventions were reported as being based on behavioural theory. Further high-quality research to utilise theories in the design and evaluation of interventions for changing OHBs in children and their parents is needed.

Table 2.2 Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children (continued)

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
Analysis of health behaviour change interventions for preventing dental caries delivered in primary schools (Adair et al., 2013)	To describe and analyse the behaviour change techniques that have been used in primary school-based interventions to prevent dental caries. To identify opportunities for improving future interventions by incorporating a comprehensive range of behaviour change techniques. **Systematic review**	This article analyses five interventions across six studies previously identified in a Cochrane systematic review of primary school-based interventions for preventing caries	Six full papers covering 5 interventions of randomised controlled trials in school-based interventions for preventing childhood caries. All of the studies included at least one behaviour change technique as well as interventions that targeted both oral hygiene and cariogenic food behaviours.	In primary school setting, a limited number of behaviour change techniques were used. These were further limited to information giving and toothbrushing instruction or demonstration	Many school programmes designed to improve oral health are making limited use of a consistent theory-based approach and the wide range of behaviour change techniques available. Need to review OH promotion approaches design and delivery to increase the power of interventions to reduce dental caries by supporting lasting behaviour change.

Table 2.2 Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children (continued)

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
Effectiveness of oral health education on oral hygiene and dental caries in schoolchildren: Systematic review and meta-analysis (Stein et al., 2018)	To evaluate the effectiveness of OHE actions in the school context in improving oral hygiene and dental caries in schoolchildren through systematic review and meta-analysis. **Systematic review and meta analysis**	Clinical trials of schoolchildren between 5 and 18 years were included. Eligible studies were those which the following outcomes: caries, plaque accumulation, gingivitis, toothache, or tooth loss and which had been published from 1995 to2015, in any language.	A total of 4417 references were found, from which 93 full texts were evaluated and 12 included in the meta-analysis	Five studies showed a reduction in plaque levels, and two studies with gingivitis as the outcome found no significant effect. There was not enough evidence on the effectiveness of the interventions in reducing dental caries.	Traditional OHE actions were effective in reducing plaque, but not gingivitis. There is no long-term evidence in respect of the effectiveness of these interventions in preventing plaque accumulation, gingivitis and dental caries in the school environment.

Table 2.2 Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children (continued)

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
Mobile-phone text messaging (SMS) for providing oral health education to mothers of preschool children in Belgaum City (Ratika Sharma et al., 2011)	Compared the effectiveness of two media (text messages and pamphlets) in imparting health education to mothers of preschool children. Visible plaque scores of their children were also recorded pre- and post-intervention **Community Intervention Study** 4 weeks	143 preschool children-mother dyads Control group - 72 children (mean age 3.3) Intervention group - 71 children (mean age 3.6)	A total of 21 messages either in the form of text messages or pamphlets were sent in seven days (3 messages per day). Messages were repeated every week for four weeks. Pamphlets sent daily to the mothers through the children. Text messages were sent to the mobile phones of mothers.	There was a significant increase in scores of knowledge, attitudes and practices in the text message group compared to the pamphlets group after the intervention. SMS group showed a greater decrease in Visible plaque index score (VPI)	Text messaging appears to be an effective means of imparting oral health education.

Table 2.2 Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children (continued)

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
National Supervised Toothbrushing Programme and Dental Decay in Scotland (Macpherson et al., 2013)	To test the hypothesis that the national nursery toothbrushing programme roll-out would be associated with a reduction in caries in five-year-old children across Scotland and to assess any changes over time in the inequality in the distribution of dental caries **Cross-sectional dental epidemiology (Multiple surveys)**	99,071 five-year-old children who participated in multiple cross-sectional dental epidemiology surveys in 1987 to 2009.	Supervised toothbrushing in nurseries and distribution of fluoride toothpaste and toothbrushes for home use.	The mean $d_3$mft in Years -2 to 0 (relative to that in start-up Year 0) was 3.06, reducing to 2.07 in Years 10 to 12 (difference = -0.99; 95% CI -1.08, -0.90; $p < 0.001$). The uptake of toothbrushing correlated with the decline in $d_3$mft (correlation = -0.64; -0.86, -0.16; $p = 0.011$).	An improvement in the dental health of five-year-olds was detected and is associated with the uptake of nursery toothbrushing.

Table 2.2 Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children (continued)

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
The effect of motivational interviewing (MI) on oral healthcare knowledge, attitudes and behaviour of parents and caregivers of preschool children: an exploratory cluster randomised controlled study (Naidu et al., 2015)	To compare the effect of MI, in contrast to traditional OHE, on OHK, OHA, beliefs and OHB among parents and caregivers of preschool children in Trinidad. **Cluster randomised controlled trial and semi-structured** **Focus groups** 4 months	79 parents and caregivers Test group, n=25 Control group, n=54	Test-group received a talk on dental health using an MI approach and two telephone call follow-ups as part of the MI protocol. Control-group received a talk using traditional DHE. Both groups received additional written dental health information.	Knowledge items and dental attendance increased in both groups. Increase in mean child toothbrushing frequency and reduction in oral health fatalism ($p < 0.05$ t-test) in test-group Findings from FGD suggested MI talk and telephone follow-up were well accepted and helpful to support parents' efforts to improve their preschool children's OH practices	There was some evidence that using an MI approach when delivering oral health information had a positive effect on parent/ caregiver oral health knowledge, attitudes and behaviours compared to traditional DHE.

Table 2.2 Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children (continued)

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
Addressing children's oral health inequalities: caries experience before and after the implementation of an OH promotion programme (Tubert-Jeannin et al., 2012)	i. To evaluate the dental status of 5-year-old children in Clermont-Ferrand in 2009; ii. To measure changes in children's dental status between 2003 and 2009 iii. To estimate the impact of an oral health promotion programme implemented in 9 schools since 2005 **Retrospective cohort** 6 years	i. 5-year-olds attending public schools in deprived areas (oral health promotion) ii. 6 schools randomly selected schools in Clermont-Ferrand (non-oral health promotion) 620 schoolchildren	i. Schools with oral health promotion programme -various educational activities conducted with the carers (parents, teachers, school nurses) of the children. ii. Schools without oral health promotion	i. The mean dmft was 1.18 (SD2.61); 27.6% had at least one tooth affected ii. The only difference observed was increased in the 'f' ($p<0.001$) iii. In deprived areas, mean dmft increased in schools without the oral health promotion programme ($p=0.04$).	The oral health promotion programme has done little to reduce disparities in oral health, even if dental status improved in four schools.

Table 2.2 Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children (continued)

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
Caries-preventive effectiveness of fluoride varnish as adjunct to oral health promotion and supervised toothbrushing in preschool children: a double-blind randomised controlled trial. (Agouropoulos et al., 2014)	To evaluate the effect of biannual fluoride varnish applications in preschool children as an adjunct to school-based oral health promotion and supervised toothbrushing with 1000 ppm fluoride toothpaste. **Randomised control trial** 2-year programme	10 different preschools in Athens 424, 2-5-year-old preschool children, 328 children completed the trial	All children received oral health education with hygiene instructions twice yearly and attended supervised toothbrushing once daily. The test group was treated with fluoride varnish (0.9% diflurosilane) biannually while the control group had placebo applications.	No significant differences in caries prevalence or increment were displayed between the groups after 1 and 2 years, respectively. There was a reduced number of new pre-cavitated enamel lesions during the second year of the study ($p = 0.05$) but the decrease was not statistically significant	Biannual fluoride varnish applications in preschool children did not show significant caries-preventive benefits when provided as an adjunct to school-based supervised toothbrushing with 1000 ppm fluoride toothpaste.

Table 2.2 Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children (continued)

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
The Most Effective and Essential Way of Improving the Oral Health Status Education (Chachra et al., 2011)	i. To develop the preventive package for improving the oral health status of children utilizing the different communication approaches. ii. To find out the most feasible and effective communication approach for delivering OHE and the preventive package (PP). To evaluate the changes produced in terms of various soft and hard tissue parameters **6 months**	972 children Age 5-16 years Randomly selected and randomly assigned one to each group: 1. Control group, No OHE and PP. 2. Direct delivery of OHE and PP by dentist. 3. Indirect delivery of OHE and PP by teachers trained by dentist 4. Delivery of OHE and PP by teachers trained by members of social organization.	Oral health education kit 1. Teaching material: A standardized OHE material in Hindi. Coloured photographs for 10-16 years old children. Short stories for children aged 5-9 years. 2.Materials for toothbrushing demonstration 3.Materials for fluoride mouth rinses Intervention package was delivered once in 15 days for a period of 6 months.	The results indicate that direct communication through the dentist proved to be the most effective communication approach as compared to the other two indirect communication approaches.	Direct communication through dentist proved to be the most effective communication approach compared to indirect communication by schoolteachers and through members of social organization. Although the latter two approaches were almost equally effective in implementing the oral health preventive package to the school children.

Table 2.2 Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children (continued)

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
Effectiveness of a curriculum-based educational intervention on oral health behaviour and dental caries experience among Indian schoolchildren (Karuveettil et al., 2020)	To assess the effectiveness of an oral health curriculum in improving the oral health behaviour and dental caries experience in schoolchildren. **A non-randomised trial** 1 year trial Two intervention arms were designed with one group receiving health education from a dental health professional and other from a school teacher.	600 schoolchildren. The oral health curriculum was customized for three different age groups (lower primary [LP], upper primary [UP], high school [HS]). OHB recorded using a Knowledge, Attitude and Practice (KAP) questionnaire evaluated at baseline, 6 months, and 1 year. Caries experience was measured Pre and Post – intervention using dmft indices.	Two intervention arms. Group A (Instructor A – oral health curriculum imparted by dentist) Group B (Instructor B – oral health curriculum imparted by schoolteacher). Intervention: each grade received one session every 4 months and reinforcements for each session were given in the next session. A supervised toothbrushing activity was conducted for LP children. A reinforcement session was given after final questionnaire administration.	There were significant improvements in KAP regarding oral health among Indian schoolchildren. Significant reductions in decayed primary teeth in LP and UP schoolchildren post-intervention. However, there was no significant difference in primary outcome between the two intervention arms.	A curriculum-based health education intervention customized for different age groups was found to be effective in improving oral health behaviour and dental caries experience among Indian schoolchildren.

Table 2.2 Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children (continued)

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
School-based intervention for improving the oral health of children in southern Thailand. (Petersen et al., 2015)	To assess the benefit of an enhanced oral health promotion programme combined with a closely supervised toothbrushing programme in schools, using toothpaste containing 1,450 ppm F- and 1.5% arginine, on oral health and dental caries. **Community school based randomised controlled clinical trial** 2 year study	15 southern Thailand schools Age 4 to 6 years Control group: 8 schools with 1,766 children Intervention group: 7 schools with 1,940 children Of the intervention schools five were classified as cooperative school and two as non-cooperative schools, based on the criteria of 80% participation in the prescribed toothbrushing activities.	Control group: children followed the policy of toothbrushing with fluoridated toothpaste after lunch. This policy was unstructured with weak or no supervision by teachers. Intervention group: Supervised tooth-brushing was in school after lunch. 2 sets of soft bristled toothbrush and fluoridated toothpaste were supplied to every child for school and home use by participants. Intervention received enhanced oral hygiene programme and classroom-based health education.	Lower DMFT and DMFS increments in intervention group. For the more cooperative schools, the benefits were greater: up to a 40.9% reduction in caries for DMFS. Significant improvements in dental plaque scores with greater improvements seen in the intervention group, greater still in the cooperative schools.	Positive effect from use of fluoridated toothpaste (1,450 ppm F- and 1.5% arginine) administered by schoolteachers via enhanced school OH program. This optimised OH interventions for may have a significant impact on caries incidence resulting in reductions of up to 34% reductions in caries for all intervention and up to 41% for the most cooperative.

Table 2.2 Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children (continued)

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
Oral Health Education Programme on Dental Caries Incidence for School Children (Jaime et al., 2015)	To assess the effect of a school-based oral health education programme on caries incidence in children. **Retrospective controlled clinical trial** 3 years	240 children aged 5 to 7 years from two public schools in Monte Sião, Brazil Intervention group: 120 students Control group: 120 students	Intervention group participated in a school-based oral health education programme: The programme was carried out in three main steps: 1) the school dentist initially gave a lecture to the children's parents; 2) the school dentist then gave a short course to the school staff 3) the teachers gave a six-module course to the students, based on different themes Control group: did not participate in the programme	More students from the experimental group stated knowing what was dental caries and declared that they use dental floss daily, but no significant differences in caries incidence was observed between the experimental and control groups.	The school-based oral health education program is not adequately efficient to decrease caries incidence after three years, but some issues about oral health knowledge could be slightly improved.

Table 2.2 Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children (continued)

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
Outcomes of a co-designed, community-led oral health promotion programme for Aboriginal children in rural and remote communities in New South Wales, Australia (Dimitropoulos et al., 2020)	To determine the impact of an OH promotion programme on the oral health status and oral hygiene behaviours of Aboriginal children living in Central Northern NSW as well as OHK and OHB of their parents /guardians **Consecutive surveys** 2 years	3 schools, 88 children aged 5 to 12 years	A comprehensive OH promotion programme was co-designed with local Aboriginal communities including daily toothbrushing, water bottle programme, regular application of fluoride varnish, regular distribution of toothbrushes and fluoride toothpaste and OHE.	There was a significant reduction in tooth decay, plaque scores and gingivitis. The mean number of teeth affected by tooth decay was 4.13, compared to 5.31 in 2014. An increase was also seen in positive oral hygiene behaviour.	The co-design elements of the programme were critical to its success. Engaging local Aboriginal communities to co-design and deliver OH promotion can reduce the burden of tooth decay experienced by Aboriginal children.

Table 2.2 Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children (continued)

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
School Interventions–based Prevention of Early-Childhood Caries among 3–5-year-old children from very low socioeconomic status: Two-year randomised trial (Samuel et al., 2020)	To assess the effectiveness of school-based interventions to prevent early childhood caries (ECC) among preschool children from very low socioeconomic background **Double blind, three parallel arm clinical trial** 2 years.	420 preschool children aged 3–5 years participated.	School only interventions such as prohibition of sugary snack consumption in school, teacher supervised daily toothbrushing using fluoridated toothpaste, and OHE were implemented with regular follow-up at 6 months, 1, and 2 years. Intervention group had all three interventions. Active control received tooth-brushing and OHE Negative control received only OHE. Decay at d1/d2 using criteria, visible plaque and gingival inflammation were assessed at all follow-ups.	Caries risk reduction in the study group was 20 percent and 12 percent when compared to active, negative controls after 2 years. Mean caries Increment in the intervention group was 0.4, the active control group was 0.9, and negative control was 0.8.	Prohibition of sugary snacking in school and daily supervised toothbrushing, with or without OHE is effective in preventing ECC among preschool children with health neglect in very low-resource settings.

Table 2.2 Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children (continued)

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
Motivational interviewing to prevent early childhood caries: A randomised controlled trial (Jiang et al., 2020)	To investigate the effectiveness of integrating motivational interviewing (MI) and interactive caries risk assessment (RA) into Prevailing health education (PE) in preventing early childhood caries. **Randomised controlled trial** 12 months	Preschool children aged 3-4 years 692 parent-child dyads were recruited	Recruited parent-child dyads were randomly assigned into three groups (PE, PE+MI, and PE+MI+RA), and received respective interventions. A questionnaire was completed at baseline and after 6 and 12 months to collect information on socio-demographic background, parental efficacy and children's OHB. Children's oral hygiene status and dental caries were recorded at baseline and after 12 months.	94.7% parent-child dyads remained in the study after 12 months. Significantly lower caries increment and plaque score in PE+MI and PE+MI+RA than in PE group. Significantly better improvements in parental efficacy and children's OHB in PE+MI and PE+MI+RA groups than in PE group (all $p < 0.05$). Difference between PE+MI group and PE+MI+RA group across all outcome measures (all $p > 0.05$).	Conclusions: Integration of (MI) improves the effectiveness of PE) to prevent ECC, enhance parental efficacy, and improve children's OHB. Incorporation of the CRA does not further improve the effectiveness of MI. Clinical significance: Public health workers need to select effective intervention to empower parents for improving children's OHB and preventing ECC.

Table 2.2 Summary table of the oral health effects of various school based OHE and OHP interventions among preschool children (continued)

Title & Author	Objective, study design & follow-up	Sample attribute, age & number	Intervention	Outcome	Conclusion
Comparison of two caries prevention programmes among Thai kindergarten: a randomised controlled trial (Pisarnturakit & Detsomboonrat, 2020)	The aim of this study was to compare two preventive programmes involving intensified preventive regimen based on a 'high-risk' approach. **Randomised control trial** 24 months	121 preschool children Aged 3-5 years old Children with at least 2 carious lesions were considered as high risk for dental caries development. High risk children were randomised into High high-risk basic (HRB) and high -risk intervention (HRI) group.	HRB received basic prevention regimen (OHE, hands-on tooth-brushing practice for teachers and caregivers, daytime toothbrushing supervised by teachers at least once a week, sealant on newly erupted PFM) HRI received intensified preventive regimen (F-varnish application, and silver diamine fluoride (SDF) application on carious lesions). Low risk basic (LRB) group, HRB and HRI were provided toothbrush, fluoridated dentifrice, and a guidebook.	The 89 children completed the study 19 in LRB, 35 in HRB and 35 in HRI. The new caries development at 24 months of the HRB group (75%) was higher than that of the HRI group (65.7%) and the LRB group (21.1%). One-way analysis of variance indicated no significant differences of caries increment between the HRB and HRI groups at the end of the study ($p = 0.709$).	The negligible difference in caries increment between the HRI and HRB groups implies that intensified prevention produced minimal additional benefit. Offering all children only basic prevention could have obtained virtually the same preventive effect with substantially less effort and lower cost.

2.7 Indices for measuring dental plaque score and dental caries in young children

The goal of proper oral hygiene care is to remove microbial biofilms and consequently prevent the formation and build-up of dental plaque. Microbial biofilms are mainly implicated in the aetiopathogenesis of caries and periodontal disease (Chandki, Banthia, & Banthia, 2011). Poor oral hygiene leads to poor dental plaque control, which in turn can cause gingivitis and eventually may lead to periodontal disease (Listgarten, 1988). Due to the harmful effect of poor oral hygiene, many clinical studies have focused on achieving good oral hygiene in the prevention and control of oral disease.

2.7.1 Measurement of dental plaque

Dental plaque is a soft and sticky film that builds up on the teeth and holds millions of bacteria. Periodical removal of dental plaque through toothbrushing and interdental flossing can avoid the bacteria in dental plaque from causing tooth decay and gum diseases (Van Der Weijden & Slot, 2011).

Over the years, several plaque indices have been developed to assess the levels of individual control of dental plaque and these indices have been widely used in epidemiological surveys. Some of the most well-known indices which have been used in various studies for children are listed below:

i. Plaque Index (Silness & Löe, 1964)

The measurement was based on documenting soft debris and mineralized deposits on the index teeth. All four surfaces of the teeth (buccal, lingual, mesial, and distal) are given a score from 0-3; 0 - No plaque; 1- A film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may be seen in situ only following application of disclosing solution or by using the probe on the tooth surface; 2 - Moderate

accumulation of soft deposits within the gingival pocket, or the tooth and gingival margin which can be seen with the naked eye; 3 - Abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin. The score for the patient is obtained by summing the scores for all index teeth and dividing by 6.

ii. Oral Hygiene Index (OHI) (J. C. Greene & Vermillion, 1960)

This index is comprised of combining Debris Index and Calculus index, each of this index is in turn based on 12 numerical determinations representing the amount of debris or calculus found on the buccal and lingual surfaces of each of three segments of each dental arch. The maxillary and mandibular arches are composed of three segments. Each segment is inspected for debris or calculus. From each segment, one tooth is used for calculating the individual index, for that segment in particular. The tooth used for the calculation must have the greatest area covered by either debris or calculus.

For Debris Index, the amount of the surface covered by dental plaque was scored as 0, 1, 2 or 3. 0 - No debris or stain present, 1- Soft debris covering not more than one third of the tooth surface, or presence of extrinsic stains without other debris regardless of surface area covered, 2- Soft debris covering more than one third, but not more than two thirds, of the exposed tooth surface and 3- Soft debris covering more than two thirds of the exposed tooth surface.

For Calculus Index, the amount of the surface covered by dental calculus was scored as 0, 1, 2 or 3; 0 - No calculus present, 1- Supragingival calculus covering not more than third of the exposed tooth surface., 2- Supragingival calculus covering more than one third but not more than two thirds of the exposed tooth surface or the presence of individual flecks of sub gingival calculus around the cervical portion of the tooth or both. and 3- Supragingival calculus covering more than two third of the exposed tooth

surface or a continuous heavy band of subgingival calculus around the cervical portion of the tooth or both.

After the scores for debris and calculus are recorded, the Index values are calculated. For each individual, the debris scores are totalled and divided by the number of segments scored. The same method is used to obtain the calculus index scores.

iii. Simplified Oral Hygiene Index (OHI-S) (J. G. Greene & Vermillion, 1964)

This index differs from the OHI in terms of the tooth surface scored (6 rather than 12). The criteria used for assigning scores to the tooth surfaces are the same as those use for the OHI. The selection of tooth surfaces were the six surfaces examined for the OHI-S are selected from four posterior and two anterior teeth.

iv. The Modified Plaque Index (Shick & Ash, 1961)

An index was developed to score small changes in the amount of plaque present on the gingival halves of the coronal surfaces of the teeth. The amount of the surface covered by dental plaque was scored as 0, 1, 2 or 3. The absence of dental plaque on the gingival half of the facial surface of a tooth was scored as 0; the presence of dental plaque covering less than one-third of the gingival half of the facial surface was scored as 1; the presence of dental plaque covering one third or less than two-thirds of the gingival half of the facial surface was scored as 2; and the presence of dental plaque covering two-thirds or more of the facial surface was scored as 3. The same scoring procedure was used for the lingual surfaces of the teeth. Thus, each tooth received a facial and a lingual score. In order to convert the scores of dental plaques into a percentage-score (PS), the individual scores (S) of each tooth were added to get the total score (TS) of the dental plaques for each subject. The total score was divided by the highest possible theoretical score and this quotient was multiplied by 100 to arrive at a percentage score for each individual.

v. The Plaque Control Record (O'Leary, Drake, & Naylor, 1972)

This is a simple method of recording the presence of plaque on individual tooth surfaces. The tooth surfaces are mesial, distal, buccal, and lingual surfaces. A disclosing solution is painted on all exposed tooth surfaces. After the patient has rinsed, the operator examines each stained surface for soft accumulations of plaque at the dentogingival junction. When found, they are recorded by making a dash/red colour in the appropriate spaces on the record form. Those surfaces, which do not have soft accumulations at the dentogingival junction, are not recorded. After all teeth are examined and scored, the index is calculated by dividing the number of plaque containing surfaces by the total number of available surfaces.

vi. Index of Oral Cleanliness (Bearn, Aird, Jenkins, & Kinane, 1996)

This index requires no specialist knowledge or equipment, only the ability to identify the presence of plaque. The index was developed based on the patterns of plaque distribution and reliably assesses whole mouth cleanliness. It has been validated against the Silness and Loe Plaque Index. The Index of Oral Cleanliness provides a reliable, rapid and quantitative method of scoring oral hygiene. For scoring, the teeth are dried with air and the examination of the dentition should start on the facial surfaces of the upper anterior teeth, progressing as necessary to buccal surfaces of posterior teeth, lingual surfaces of posterior teeth, and then all other tooth surfaces, without the use of disclosing solution or probes. The amount of the surface covered by dental plaque is scored as 0, 1, or 2. The absence of dental plaque on the gingival half of the facial surface of a tooth is scored as 0; the presence of dental plaque covering one-third of the gingival half of the facial surface is scored as 1; the presence of dental plaque covering one third or more than two-thirds of the gingival half of the facial surface is scored as 2. The presence of calculus is ignored, and the highest applicable score is recorded for the dentition.

Table 2.3: Summary of indices for dental plaque measurement

No	Indices	Description
i.	Plaque Index (Silness & Löe, 1964)	Surfaces of the teeth (buccal, lingual, mesial, and distal) are given a score from 0-3.The index for the patient is obtained by summing the indices for all six teeth and dividing by six.
ii.	Oral Hygiene Index (OHI) (Greene & Vermillion, 1960)	Composed of the combined Debris Index and Calculus index. 3 index teeth from 3 different segment for each maxilla and mandible, total of 12 surfaces scored (buccal and lingual). The tooth used for the calculation must have the greatest area covered by either debris or calculus. Teeth surfaces covered by dental plaque / calculus was scored as 0, 1, 2 or 3. Debris / calculus scores are totalled and divided by the number of segments scored.
iii.	Simplified Oral Hygiene Index (OHI-S)(Greene & Vermillion, 1964)	The criteria used for assigning scores to the tooth surfaces are the same as those use for the OHI but involves only 6 surfaces (4 posterior teeth, 2 anterior teeth)
iv.	The Modified Plaque Index (Shick & Ash, 1961)	The amount of the surface (buccal and lingual) covered by dental plaque was scored as 0, 1, 2 or 3. The total scores are converted to percentage-score (PS).
v.	The Plaque Control Record (O'Leary et al., 1972)	Record presence of plaque on individual tooth surfaces (mesial, distal, buccal, and lingual surfaces). Disclosing solution is painted on all exposed tooth surfaces. Index is calculated by dividing the number of plaque containing surfaces by the total number of available surfaces.
vi.	Index of Oral Cleanliness (Bearn et. al, 1996	Record presence of plaque on individual tooth surfaces (Buccal and lingual). Charting done without the use of disclosing solution or probes. The highest applicable score is recorded for the dentition.

2.7.2 measure for assessment of caries activity

Dental caries is a disease of the calcified tissues of the teeth with complex multifactorial causes. Caries develops through the interactions of various factors including the host (tooth), agent (bacteria), substrate (sugars), and time. ICDAS is a clinical scoring system for use in clinical practice, dental education, research, and epidemiology, and provides a framework to support and enable personalized total caries management for improved long-term health outcomes (Ismail et al., 2007).

Evidence and further understanding of the caries process has continued to support the fact that caries as a disease caused by dynamic process of remineralisation or demineralization of the dental tissue. It is influenced by multiple modifiers which tend to push the mineral equilibrium in one direction or another (Holt, 2001).

Previously, the epidemiological surveys have mainly focused on DMFT/DMFS to evaluate the prevalence of caries. However, such studies rely on recording of cavitated lesions only. While ICDAS allows the recording of both cavitated and non-cavitated lesions in a continuum. Various studies have evaluated the feasibility of using ICDAS II in epidemiological surveys by comparing it with the WHO criteria (Braga, Oliveira, Bonini, Bönecker, & Mendes, 2009; Mendes et al., 2010). The ICDAS was developed to bring forward the current understanding of the initial process and progression of dental caries to the field of epidemiological and clinical research (Shivakumar, Prasad, & Chandu, 2009). In 2002, The ICDAS I was developed and was further modified to ICDAS II in 2005 (Diniz, Rodrigues, Hug, De Cássia Loiola Cordeiro, & Lussi, 2009). The ICDAS I and II criteria incorporate concepts from the research conducted by Ekstrand et al in 1995 (Ekstrand, Kuzmina, Bjørndal, & Thylstrup, 1995).

2.7.2.1 ICDAS: The scoring system

Clean and dry teeth are the primary requirements for dental examination using the ICDAS system. Dry tooth surface is the key to detect non-cavitated lesion. The ICDAS coding for coronal caries ranges from 0 to 6 depending on severity of the lesion. **Table 2.4** shows the basic of the ICDAS codes.

Table 2.4: ICDAS coding

Code	Description
1	Sound surfaces: No evidence of caries after 5 seconds of air drying
2	First visual change in enamel: Opacity or discoloration (white or brown) is visible at the entrance to the pit or fissure seen after prolonged air drying
3	Distinct visual change in enamel visible when wet, lesion must be visible when dry
4	Underlying dark shadow from dentine
5	Distinct cavity with visible dentine
6	Extensive (more than half the surface) distinct cavity with visible Dentine

Currently, examiners are discouraged to use sharp explorer for detection of dental caries as it may damage the intact enamel covering the early demineralisation on tooth surface. Preventative treatments which encourage the remineralisation of non-cavitated lesions can be promoted globally following the changing trend to record the non-cavitated lesions in the daily practice. This will result in preservation of tooth structure, function and aesthetics and ultimately reduced DMF all together (Gugnani, Pandit, Srivastava, Gupta, & Sharma, 2011).

A few studies have also demonstrated good inter- and intra-examiner reproducibility and the accuracy of ICDAS II in detecting occlusal caries, especially in the outer half of the enamel. One study was performed in 2010 to evaluate intra- and inter-

examiner reproducibility of ICDAS II on occlusal caries diagnosis when different time intervals were allowed to elapse between examinations. The weighted kappa values for intra- and inter-examiner reproducibility were 0.76 to 0.93 and it was observed that the time span did not have a major impact on assessing intra- and inter-examiner reproducibility (Jablonski-Momeni et al., 2010).

2.8 Health literacy

Literacy is defined in the Oxford dictionary as the ability to read and write or competence or knowledge in a specified area (Oxford, 2011). Health literacy can be defined as one's ability to obtain, understand and utilize basic health related information. (Health, Human Services, & People, 2000). Health literacy is about patients' understanding of health information, and how health information is applied in their daily lives, applying the health information to make health-related decisions, and act on it. It is vital to patients' well-being to be able to comprehend health information and make decisions from that information. Patients with good health literacy are able to make good health decisions because they can find, understand, and evaluate the health information in global health care (Kasemsap, 2017). Research has shown that literacy skills forecast an individual's health status more greatly than age, income, employment status, education level and racial or ethnic group (American Medical Association, 1999).

Functional health literacy refers to one's ability to read, comprehend, and act on health information. This includes to adequately function as a patient and to be able to run tasks such as reading and comprehending prescription labels, understanding appointment slips, completing health forms, following instructions for diagnostic tests, and understanding other essential health-related materials (Parker, Baker, Williams, & Nurss, 1995). Health literacy has been acknowledged as an increasingly important life skill, especially when it is related to health care. One's general literacy may not equal with his

or her functional health literacy. An individual may be able to read and understand materials with familiar content at home or at work but struggles to understand medical material that contains unfamiliar vocabulary and concepts. Even well-educated patients can be functionally health illiterate at times when they do not understand the meaning of health information. Patients with insufficient health literacy may misunderstood diagnoses, drug administering directions, and self-care instructions. The effects of poor health literacy can be detrimental to one's health and well-being as the opportunities for disease prevention or treatment are missed (Andrus & Roth, 2002). Systematic reviews in medicine have shown that low literacy level was associated with unfavourable health outcomes such as poor health knowledge, high morbidity rates, poor general health status and poor utilisation of health resources (Berkman, Sheridan, Donahue, Halpern, & Crotty, 2011; DeWalt & Hink, 2009). Low parental health literacy is linked with harmful health behaviours that affect child's health based on comprehensive reviews of literatures (Morrison, Myrvik, Brousseau, Hoffmann, & Stanley, 2013).

There is an increasing acknowledgment that health literacy does not depend on the skills of individuals only but a result of individuals' capacities to understand the health literacy–related demands of the health care system. System adjustments are necessary to align health care demands better with the public's skills and abilities (French, 2014). A health literate health care organisation is represented by the following 10 attributes (Institute of Medicine, 2013):

1. Management that makes health literacy fundamental to its mission, structure and operations.
2. Incorporates health literacy into planning, evaluation measures, patient safety, and quality improvement.
3. The workforce are health literate and progress monitored.

4. The populations is included in the design, implementation, and evaluation of health information and services.
5. Addresses the needs of the local populations with a range of health literacy skills but at the same time avoids stigmatization.
6. Utilizes health literacy approaches in interactive communications and validates comprehension of the receiver.
7. Easy access to health information is provided with services and navigation assistance.
8. Distributes print, audio-visual, and social media content that is easy to understand and act on.
9. Addresses health literacy even in high-risk situations, which may include care modifications and communications about medicines.
10. Clear communication about treatment costs.

Patient-centred health care system provides opportunities to reform health services, integrating principles of health literacy into organisational objectives, infrastructure, policies and practices, workforce development, and communication strategies. By adopting most of the 10 attributes in even a modest way, health services will make a substantial contribution to improved population health.

2.8.1 Health Literacy as outcomes of health education

Health literacy has been conceptualised to explain how health information can facilitate to maintain health (Freeman, 2015). Health literacy is one of the goals to be achieved through health education interventions by fostering the capacity of individuals to obtain, interpret and understand health information and services (World Health Organization, 2013).

Providing meaningful and reliable information when giving health education is required to build health literacy. Use of plain language during communication helps the listener or reader to understand the first time they hear or read it. Health information materials should be sensitive to differences and diversity in cultures, sex, age and individuals in their content, format and delivery approach.

2.8.2 Oral Health Literacy

Oral health literacy (OHL) is defined as the degree to which individuals have the capacity to obtain, process and understand basic oral health information and services needed to make appropriate oral health decisions (Sabbahi, Lawrence, Limeback, & Rootman, 2009). OHL was identified as key to promoting oral health and preventing oral health disease. (Horowitz & Kleinman, 2008; Koh et al., 2010).

In children, caregivers' OHL is significantly associated with children's dental disease status. (Miller, Lee, DeWalt, & Vann, 2010). Parents with higher OHL levels are expected to have better knowledge and understanding of oral health information. They would be more familiar with the importance and care of their children's primary teeth and actions to be taken when needed (Horowitz et al., 2014). Lower OHL levels among caregivers were associated with worse OHB of their children, such as night time bottle use and no daily toothbrushing (Vann Jr, Lee, Baker, & Divaris, 2010). Parent's OHL has a modifying role in the association between preschool children's oral health status and their oral health-related quality of life (Divaris, Lee, Baker, & Vann Jr, 2012).

Low OHL among caregivers or patients can be contributed by unclear oral health information / messages given by oral healthcare providers (Schiavo, 2011). To avoid this, health personnel need to have good communication skills to improve health messages delivery to their patients (Horowitz et al., 2014). Patients should be provided with information in a way they can understand in order to help them to make informed oral

health choices and take informed actions. However, this does not mean that people will always act or adhere in ways that healthcare providers prescribe (Pleasant et al., 2016).

2.8.3 OHL Instruments

Earlier health literacy measurements mainly focused on reading ability and the links between adults' reading skills and health outcomes. Current measurements extend well beyond the capacity to read only. Nutbeam in 2008 conceptualised health literacy as having three distinct levels: basic/functional (reading and writing skills for everyday life); communicative/interactional (cognitive and literacy skills combined with social skills); and critical (empowerment to handle information and have control over situations) (Nutbeam, 2008).

As of now, there are fifteen OHL instruments for adults with two instruments are developed for paediatric use (Ludke, Kudel, & Weber, 2008; H. M. Wong et al., 2012). They have been developed and validated for use by researchers and healthcare workers. These instruments are used for measuring OHL on the basis of general health literacy instruments.

The earliest instruments developed in dentistry to assess levels of OHL were REALD-30 and REALD-99 (Arozullah et al., 2007; Richman et al., 2007). However, REALD-30 doesn't have comprehension test. REALD-99 is a longer version of REALD-30 and has been developed to increase the chance of assessing OHL accurately (Richman et al., 2007). This instrument was tested by comparing OHL word recognition and oral health outcome measure. REALD-30 has been used to examine the relationship of caregiver's literacy with children's oral health outcomes. In this study, there was an association between parent's OHL and children's oral health status (Miller et al., 2010).

The OHL Instrument (OHLI) contains reading comprehension and numeracy sections. The reading comprehension section is a 38-item test with words omitted from one passage on dental caries and another on periodontal disease. The numeracy section has 19 items to test comprehension of directions for taking common prescriptions associated with dental treatment, post extraction instructions and dental appointments. OHLI also contains 17-item oral health knowledge test (Veerasamy, 2010).

Test of Functional Literacy in Adult (TOFHLiD) uses text passages and prompts related to fluoride use and access to care to assess reading comprehension and numerical ability. The reading comprehension section of TOFHLiD consists of three passages about follow-up instructions for a caregiver following the application of fluoride varnish to their child's teeth, consent for dental treatment, and a description of insurance (Medicaid) rights and responsibilities. The numeracy section of the TOFHLiD has 12 questions related to four topics. The first topic is related to instructions for fluoridated toothpaste use which comprised of five questions. Second topic consists of three questions about paediatric dental clinic appointment, the third topic is about bottle prescription labels for fluoride drops with two questions and the fourth topic for fluoride tablets with two questions (Gong et al., 2007).

Theoretical pathway linking health literacy with oral health decision making and outcomes was introduced in Comprehensive Measure of Oral Health Knowledge (CMOHK) (Macek et al., 2011). It was created to measure word recognition, conceptual knowledge, reading comprehension and communication skills. This instrument has 20 basic oral health knowledge items; and eight items in each, regarding the prevention and management of dental caries, periodontal disease and oral cancer respectively.

Rapid Estimate of Adult Literacy in Medicine-Dentistry (REALM-D) was a combination of the Rapid Estimate of Adult Literacy in Medicine (REAIM) and the Rapid

Estimate of Adult Literacy in Dentistry (REALD) (Atchison, Gironda, Messadi, & Der-Martirosian, 2010). The instrument consists of three parts with words arranged in increasing difficulty. The author argued that the ability to read and pronounce the medical terms is needed in order to communicate with a health care provider and REALM-D could be a useful for screening tool for low health literacy. This argument implies that a word recognition instrument also measures a patient's ability to participate in shared decision-making (Atchison et al., 2010).

Gironda and colleagues developed a shortened version of REALD-99, naming it Rapid Estimate of Adult Literacy in Dentistry-20 (REALMD-20). It is used for detection of limited medical/ dental health literacy in patients attending for treatment in dental/medical clinics. Even though the tool is useful for measuring patients' reading ability, it is not an effective measure of comprehensive health literacy. However, it serves as useful OH literacy screening tool for clinicians (Gironda, Der-Martirosian, Messadi, Holtzman, & Atchison, 2013).

Several tools had been adapted for particular populations or cultural groupings such as the Hong Kong Rapid Estimate of Adult Literacy in Dentistry (HKREALD-30) (Wong et al., 2012), Hong Kong OHL Assessment Task for Paediatric Dentistry (HKOHLAT-P) (Wong et al., 2013) and the OHL Assessment-Spanish (OHLA-S) (Lee, Stucky, Rozier, Lee, & Zeldin, 2013).

The Baltimore Health Literacy and Oral Health Knowledge Project (BHLOHKP), utilized a comprehensive questionnaire to assess knowledge in 4 broad topic areas:1. Basic oral health; 2. Prevention and management of dental caries; 3. Prevention and management of periodontal disease and 4. Prevention and management of oral cancer. The BHLOHKP was designed to assess whether conceptual knowledge in these 4 broad

topic areas was associated with word recognition and reading comprehension (Macek et al., 2011).

Sistani and colleagues developed and pilot tested an OHL Adults Questionnaire (OHL-AQ) which comprises four sections: reading comprehension, numeracy, listening, and decision-making. This tool was developed to address limitations of existing oral health literacy instruments, including their length, lack of generalizability across populations, and their focus on measuring either the ability of a person to read specific dental health vocabularies or the ability to read and comprehend oral health information and calculate numbers (Sistani, Montazeri, Yazdani, & Murtomaa, 2014).

Jones et al developed the Health Literacy in Dentistry scale (HeLD) as they sought to develop a reliable, valid and culturally appropriate instrument to assess OHL among vulnerable groups. Using the Health Literacy Measurement Scale (HeLMS) as a foundation, a number of theoretical constructs were included which assume "a person's ability to seek, understand and use oral health information is important in being able to access and benefit from oral health care services" (Jones, Parker, Mills, Brennan, & Jamieson, 2014)

Dental Health Literacy Assessment Instrument (DHLAI) was designed to measure OHL among parents of pre-schoolers. It is suitable to be used in this study compared to other OHL instruments which measure adult's OHL in general. This instrument is further described in next section.

Table 2.5: Instruments to measure OHL

OHL Instrument	**Author**	**Assessment**
Test of Functional Literacy in Adult (TOFHLiD)	(Gong et al., 2007)	Comprehension, numerical ability

Rapid Estimate of Adult Literacy in Dentistry – 30 (REALD – 30)	(LeeR et. al., 2007)	Word recognition
Rapid Estimate of Adult Literacy in Dentistry – 99 (REALD – 99)	(Richman et al., 2007)	Word recognition
Dental Health Literacy Assessment Instrument (DHLAI)	(Ludke et al., 2008)	Parents OHL, Oral health knowledge, Comprehension, Motivation and skills
Oral Health Literacy Instrument (OHLI)	(Sabbahi et al., 2009)	Oral Health Knowledge (Reading Comprehension and numeracy)
Comprehensive Measure of Oral Health Knowledge (CMOHK)	(Macek et al., 2010)	Word recognition, Conceptual knowledge, reading comprehension, Communication skill
Rapid Estimate of Adult Literacy in Medicine-Dentistry (REALM-D)	(Atchison et al., 2010)	Word recognition, communication skills
Baltimore Health Literacy and Oral Health Knowledge Project survey (BHLOKP)	(Macek et al., 2011)	44 item questionnaire conceptual knowledge across 4 domains
Hong Kong Rapid Estimate of Adult Literacy in Dentistry (HKREALD-30)	(Wong et al., 2012)	30 item word recognition common dental words (adaptation and shortened from READLD-99)
OH Literacy Assessment-Spanish (OHLA-S)	(Lee et al., 2013)	Word recognition and comprehension
OH Literacy Assessment-English (OHLA-E)	Lee et al (2012)	Word recognition and comprehension
Rapid Estimate of Adult Literacy in Dentistry-20 (REALMD-20)	(Gironda et al., 2013)	20 item word recognition

Hong Kong OH Literacy Assessment Task for Paediatric Dentistry (HKOHLAT-P)	Wong et al (2013)	Mainly literacy and numeracy tasks
OH Literacy Adults Questionnaire (OHL-AQ)	(Sistani et al., 2014)	17 items in 4 sections, reading comprehension, numeracy, literacy and decision making
Health Literacy in Dentistry (HeLD)	(Jones et al., 2014)	Modelled on the Health Literacy Measurement Scale (HeLMS)

2.8.4 Dental Health Literacy Assessment Instruments

The Dental Health Literacy Assessment Instrument (DHLAI) was developed in the United States of America by Ludke et al in 2008 for measuring parents' OHL (Veerasamy, 2015). This instrument consists of three sections where the first section measures oral health knowledge, the second section measures parents' comprehension skill from their ability to understand healthcare instructions while the third section consists of parent's skills and motivation to improve their children's oral health.

The DHLAI was used in a study in New Zealand to find the level of OHL of parents of pre-school age children regarding their child's oral health. The study found that 38% of participants had poor OHL regarding their child's oral health. The results also revealed that associations existed between parents' OHL and socio-demographic variables such as ethnicity, education and family income (Veerasamy, 2010).

The Malay version of DHLAI was developed by Ismail et al in 2016. Content validation of the questionnaire was conducted by five Dental Public Health Specialists in the Ministry of Health in order to validate the intended objectives of the questionnaires. Face validation was conducted in a pilot study which involved 40 mothers of preschool children. From the pilot study, the questionnaire was found to be clear and relevant and the time needed to answer the questionnaire was approximately 10 minutes.

Psychometric validation of the OHL questionnaire was tested in a previous study involving 150 mothers of preschool children (Ismail, 2016). The psychometric properties were empirically verified by factor analysis, and followed by internal and test-retest reliability analysis. The overall Cronbach Alpha coefficient for the total scale was 0.89 and ranged from 0.882 to 0.956 for the subscales that indicated acceptable internal consistency.

2.9 Use of digital media for oral health education

In this current time, health messages can be delivered through the use of digital media. Digital media is defined as any media that are encoded in machine-readable formats. Digital media can be created, viewed, distributed, modified and preserved on digital electronics devices. Development of digital media presents new tools for engaging with youths to convey health promotion messages (Guse et al., 2012). By using this method of delivery, submission of information will be more effective if carried out in a structured manner and in a clear flow arrangement (Berniyanti et al., 2019). Previous studies have demonstrated that the utility of text messaging for promotion of health-related activities can give positive results (Hashemian, Kritz-Silverstein, & Baker, 2015; Sharma et. al., 2011).

Based on a survey in 2018 by the Malaysian Communications And Multimedia Commission, it was found that internet has become a pivotal medium in social engagement where text communication and visiting social networking platform were the most common activities for internet users (96.5% and 85.6% respectively) in Malaysia with over-the-top (OTT) social media platforms such as WhatsApp and Facebook were the most popular communication and social networking platform (Malaysian Communications and Multimedia Commision, 2018). The use of digital platform is getting widely accepted by internet users because of its key appeals, easy accessibility,

customisation, and control, as well as low cost to access. Currently, more users are abandoning short message service (SMS) to take advantage of the other messaging services. The usage of OTT platform for streaming and media consumption is gaining popularity, especially with faster and better coverage of internet services offered to consumers. Majority of internet users (61.8%) had shared content online, particularly among younger users with educational content and entertainment/humorous content being the most usually shared content. Most of the content were shared online via social media (73.8%) and group messaging (70.6%) (Malaysian Communications and Multimedia Commision, 2018).

WhatsApp has become an application of choice as a cross-platform instant messaging application for smartphones. Cross platform means the software is available for various softwares such as iOS, Blackberry OS, Android, Symbian, Series 40 and Windows Phone, and enables seamless communication between the various devices possible. In addition to text messaging, users can also send images, videos as well as audio media messages to each other. The entire process of sending the message/image will be free (Pandian, Srinivasan, & Mohan, 2014). A narrative review concluded that WhatsApp is now emerging as a tele-dentistry tool that can be utilised for various purposes in oral health care with increasing convenience to dentists, patients, dental students and educators, and in a wide range of settings thereby improving access to and quality of oral health care. Further research exploring its usage in oral healthcare should be encouraged (Yale, Kumar, & Sharma, 2018). A study in Indonesia used the WhatsApp platform as a dental and oral health online communication forum for dentist, nurses and elementary teachers. The result showed that dentists, nurses and elementary teachers were able to access online communication forum through WhatsApp without constraint (Berniyanti et al., 2019).

Use of digital media to promote health continues to grow in popularity. Many health sectors have widely adopted social media softwares for health promotion, public health communication, and organisational promotion activities. MOH of Malaysia acknowledged that there are growing trends of online health information-seeking behaviours and demand for the availability of validated health information (Rahim, Ibrahim, Salim, & Ariffin, 2019). Besides having an official website (moh.gov.my), MOH also utilises 4 social media applications such as Facebook (Kementerian Kesihatan Malaysia), YouTube *(Kementerian Kesihatan Malaysia),* Twitter (KKM Putrajaya) and Instagram *(Kementerian Kesihatan Malaysia)* as platforms to engage with the public (Ministry of Health Malaysia, 2020). These communication platforms are used as alternative communication channels to deliver health messages, conduct disease surveillance, spread health awareness, and address public health issues to the public. Even though digital media can contribute enormously to promote health, digital media should not be viewed as a solution to the complexities of behaviour change and improved health outcomes (Neiger, Thackeray, Burton, Giraud-Carrier, & Fagen, 2013). Public health organisations should continuously make improvements to produce effective strategies to disseminate health information and achieve better audience engagement on social media (Rahim et al., 2019).

2.10 Health promotion evaluation

Evaluation is defined as systematic collection of information about activities, characteristics and outcomes of programmes, services, policy or processes, in order to make judgements about the programme/process, improve effectiveness and/or inform decisions about the future development (Bryson, Patton, & Bowman, 2011). Evaluation is also defined as the process of measuring how successful the program has been in relation to the planned goals (McKenzie, Neiger, & Thackeray, 2012). Evaluation of health promotion is important for a variety of reasons including; (1) As a means of

developing effective interventions; (2) Sharing and disseminate examples of good practice; (3) Making best use of limited resources; (4) Providing feedback to staff and participants; and (5) Informing policy development and implementation (Petersen & Kwan, 2004).

To conduct health promotion evaluations, some principles should be followed: (1) Set aims and objectives for intervention. Aims and objectives should be identified and established during planning process. Since it is almost impossible to assess all elements involved in an intervention, researchers must identify which component in the intervention they want to evaluate; (2) Clarify purpose of evaluation. It should be clear at the beginning of the intervention on the purpose of evaluation, as this will determine what information is gathered and how it is obtained. The purpose could either be to evaluate the effectiveness, efficacy, acceptability, equity or quality of the intervention; (3) Consider both process and outcome measures. Process evaluation is about assessing the implementation process while outcome evaluation concerns about the effects of an intervention. Evaluation can be achieved either through direct or indirect evaluations; (4) Select appropriate methods to collect info. Various methods are available for data collection. Combination of quantitative and qualitative methods adds rigour to the evaluation process, as the data provides the researchers details on how the intervention works; (5) Disseminate information. Results from the evaluation should be shared with the relevant parties regardless whether the outcome was positive or otherwise because knowing what does not works is as valuable as knowing what does (Naidoo & Wills, 2016).

2.10.1 Process and outcome evaluations

Process evaluations are studies that run parallel to or follow intervention trials to understand the trial processes or underlying mechanisms in relation to context, setting,

professionals and patients. The aim of process evaluation is to assess the quality of the implementation to identify the intervention's efficiency, appropriateness, adequacy, accessibility and acceptability. (Naidoo & Wills, 2016). Process evaluation provides explanations for the trial results and enhances understanding on whether or how interventions could move from research to practice (Grant, Treweek, Dreischulte, Foy, & Guthrie, 2013). Process evaluation can be conducted using various methods for example through interviews, diary entries, observations, content analysis of documents and treatment fidelity monitoring (Moore et al., 2015).

Failure or poor outcomes of a health programme may due to its implementation rather than the design of the intervention (Naidoo & Wills, 2016). Implementation fidelity and innovation feedback are two elements for evaluating the implementation of interventions (Aarons, Hurlburt, & Horwitz, 2011). Fidelity is defined as the degree to which the major components of the programme have been faithfully delivered (Barry, Kuosmanen, & Dowling, 2018). Treatment fidelity is an ongoing assessment and monitoring of a study which can be conducted through different methods such as audiotaping, videotaping, self-report through checklists and questionnaire (Borrelli et al., 2005). Treatment fidelity consists of two general components: (1) treatment integrity, the degree to which a treatment is implemented as intended, and (2) treatment differentiation, the degree to which two or more study arms differ along critical dimensions (Borrelli, 2011). Monitoring of treatment fidelity enhances both the internal validity (the treatment is delivered as intended) and external validity (the treatment can be replicated and applied in real-world settings) (Borrelli, 2011). Treatment fidelity allows for the early detection of errors to prevent protocol deviations from becoming widespread and long lasting, which can potentially affect the study's ultimate conclusion. Furthermore, higher levels of treatment fidelity are associated with better treatment outcomes (Barry, Kuosmanen, & Dowling, 2018)

Outcome evaluation is designed to assess what has been achieved and whether the objectives set have been reached (Ewles & Simnett, 2003). Outcomes can be divided into immediate (output), intermediate (outcome) or long term (impact). The outcome evaluation of a health promotion programme is important for several reasons: as means of developing good practice, to make best use of limited resources, to provide feedback to stakeholders, and to inform policy development (Watt, Fuller, Harnett, Treasure, & Stillman-Lowe, 2001). Examples of outcome measures in dentistry include assessing the levels of oral health status, oral health behaviours, oral health attitudes, OHL and oral health related quality of life (OHRQoL). Although outcome measures can reveal if a programme has worked well (or does not work), they are neither intended nor designed to reveal why or how a programme works. The combination of process evaluation with indicators of short- and long-term outcome measures will provide the range of information needed to assess and understand the impact of health promotion initiatives, and make appropriate programme decisions and improvement if necessary (World Health Organization, 1998).

2.10.2 Focus Group Discussion as a method of data collection

The focus group discussion (FGD) is a type of data collection used in the qualitative study (Krueger, 2014). A focus group is a special type of group in terms of purpose, size, composition and procedures. A FGD is a good way to gather together people from similar backgrounds or experiences to discuss a specific topic of interest. The purpose of conducting FGD is to understand how people feel or think about an issue, idea, product, or service. Through FGD, the opinions are gathered by the researcher (Krueger, 2014). FGD generates in-depth understanding rather than quantifiable measurements (Krishna, Maithreyi, & Surapaneni, 2010). The FGD can be used to explore the meanings of survey findings that cannot be explained statistically, the range of opinions or views on a topic of interest and to collect a wide variety of local terms (Morgan, 2002).

FGD is a qualitative research technique and data collection procedure where a group of selected people will be given a topic to discuss in depth, aided by a professional external moderator (van Eeuwijk & Angehrn, 2017). The FGD is closely similar with other methods to gather information in qualitative study namely an individual qualitative interview, and regular meetings. The characteristic differences between FGD, individual qualitative interview, and a regular meeting are summarised in **Table 2.6** below.

During FGD, a moderator or group facilitator will introduce the topics for discussion and guide the group discussion and helps the group to participate in a lively and natural discussion amongst themselves (Krueger, 2014). The moderator must not overshadow the group and voice his or her own judgments. The moderator must be open, alert, and encourage all FGD participants to take part in the discussion. If possible, instead of relying on the moderator to address and interview participants one by one, the moderator should be able to establish a group dynamic where participants discuss topics from the discussion guide among themselves (Silverman, 2006). During FGD, a single train of thought must be avoided and participants are encouraged to interact socially and create group cohesiveness. The moderator should support for generation of ideas as well as self-disclosure (Green & Thorogood, 2018).

Table 2.6: Characteristics of different qualitative data collection techniques (van Eeuwijk & Angehrn, 2017)

	FGD	**Individual qualitative interview**	**Regular meetings**
Participants	Multiple participants who share one (some) common characteristic(s) that is (are) meaningful from the research perspective.	One individual interviewee who represents a very personal and distinct characteristic of importance from the research perspective.	Multiple participants who gather at the same place and have certain knowledge of the study subject
Mode of conduct	Semi-structured; carefully planned and cautiously executed.	Ranging from semi structured to unstructured; well planned and executed	Unstructured, without clear roles assigned to participants; no clear-cut scenario
Scope insight	Often a large spectrum of opinions, notions, and/or experiences; added focus on social interaction between participants.	Small spectrum of opinions, notions and/or experiences but provides deep individual insights	Often a large but scattered spectrum of opinions, notions, and/or experiences.
Levels of focus	High level of focus on the given topic(s).	Level of focus varies depending on the degree of structuring	Level of focus largely uncontrollable.
Degree of participation	When accurately and adequately moderated, all participants contribute equally to the discussion	The whole interview is dedicated to the knowledge, attitudes, opinions and experiences of one person	Usually, one or a few participants dominate and shape the discussion

In health studies, FGDs can be utilised in four different phases of the study, each with differing purpose, function and objective: (1) Exploration: at early phase of an investigation, FGD is performed to learn more about a given topic or field and to gather important pilot issues regarding the theme of the study; (2) Monitoring: in the middle of an on-going study activities, a FGD may be conducted to control or supervise the corresponding processes and dynamics of the study and to understand them better; (3) Evaluation: a FGD with the most important target group of the study, the FGD for this phase is conducted at the end or in the course of the phasing-out stage of a research programme, with the intention to verify, disprove, change or differentiate the study's provisional finding; (4) Gathering and assessing outcomes: conducted sometime after completion of a study, a FGD is performed to produce new findings about potential changes or processes within a target population and the health impacts (van Eeuwijk & Angehrn, 2017).

2.10.3 Precede-Proceed Framework in the evaluation of a programme

Evaluation of health promotion activities contributes to the accountability and development of evidence-based practice (Naidoo & Wills, 2016). During research planning, researchers should identify the most suitable framework to use for evaluation of their programme. The PRECEDE-PROCEED framework **(Figure 2.2)** is a comprehensive planning system that starts with extensive research to assess needs at multiple levels with an ecological perspective (L. W. Green & Kreuter, 1991).

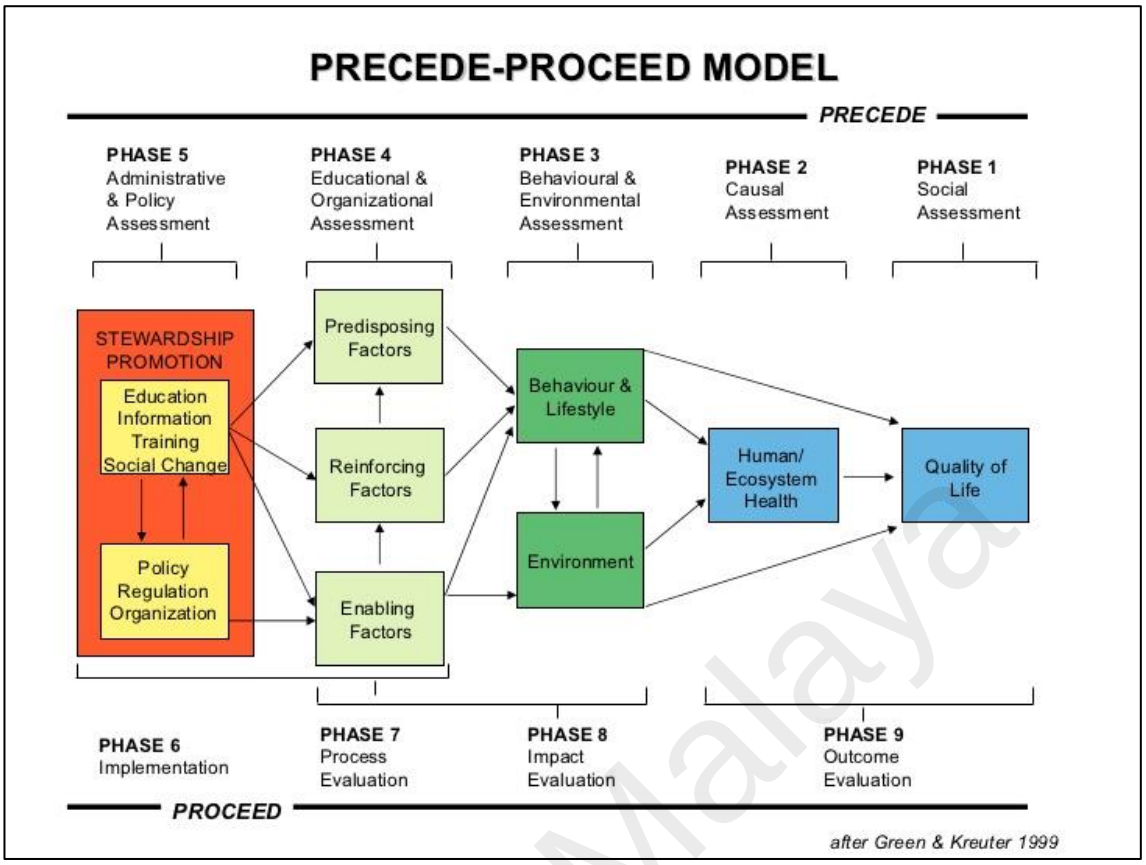

Figure 2.2: The PRECEDE-PROCEED framework

This framework is suitable to be applied in an interventional study because the purpose of the PRECEDE/PROCEED model is to direct initial attention to outcomes rather than inputs. The Precede model is a framework for the process of systematic development and evaluation of health education programmes. An underlying premise of this model is that health education is dependent on voluntary cooperation and participation of the client in a process which allows personal determination of behavioural practices and that the degree of change in knowledge and health practice is directly related to the degree of active participation of the client. Therefore, in this model, appropriate health education is considered to be the intervention or treatment for a properly diagnosed problem in a target population (L. W. Green & Kreuter, 1991).

Since this model is multidimensional, it can be applied in the social and behavioural sciences, epidemiology, administration, and education. Admitting the fact

that health and health behaviours have numerous causes, all must be evaluated in order to assure appropriate intervention based on this model. The Precede model have a comprehensive nature that can be applied in various settings such as school health education, patient education, community health education, and direct patient care settings (L. W. Green & Kreuter, 1991).

In acknowledgment of the need for health promotion interventions that go beyond conventional educational approaches to change unhealthy behaviours, the Proceed is added to the model. Proceed model components require the practitioner to go beyond educational interventions and to include necessary political, managerial, and economic actions to make environments in the social systems more conducive for healthy lifestyles and a more complete state of physical, mental, and social well-being for all.

This framework is widely taught and used for health promotion practice, with well over 1000 published applications (Porter, 2016). A local study in Johor used the Precede-Proceed model to evaluate its intervention programme in a quasi-experimental study involving preschool aged children, their parents and their siblings. The aim of this study was to explore the impact of Family Dental Wellness Programme (FDWP) on the caries incidence of preschool children and their, as well as on their mothers' OHL. From the evaluation using the Precede-Proceed model, the results showed children and siblings in the intervention group had a significantly lower net caries increment compared to the control group with caries prevented fraction for FDWP was 68% for the younger siblings and 63.6% for the older children. At three-year follow-up, there were significant increments in the OHL scores of mothers in the intervention group compared to the control group (Ismail, 2016).

This framework will be applied in the present study to evaluate the SIMSP. The types of evaluation will consist of: Process Evaluation, Impact Evaluation and Outcome

Evaluation. Implementation fidelity monitoring will be part the of process evaluation (phase 6) as well as the FGD among DTs to assess the implementation of SIMSP from the DTs' perspectives (Breitenstein et al., 2010). Improvement in oral health status and OHL as a result of the programme will also be assessed as part of Impact evaluation (phase 7). Due to the limited research period, outcome evaluation (phase 9) is not feasible for the SIMSP.

2.11 Summary

The literature review provides evidence on the related topics on oral health promotion for young children in the preschool age. Since oral health of preschool children is influenced by multifactorial factors, evidence showed that a combination of multiple methods of intervention is needed in order to get positive effects on preschool children's oral health. To invent new oral health intervention programmes, various factors need to be considered to ensure full participation from the stakeholders, capitalise use of limited resources and establish intervention fidelity. New interventions should utilise technological developments such as the digital media to conform to the ever-changing interests of the target group. Even the use of CRA can provide better clinical prevention and management output.

The literature has also shown multiple intervention programmes that gave positive outcomes on preschool children's oral health and OHB. Since good OHL is associated with better oral health outcomes, it is paramount for parents / caregivers to have good OHL because children are unable to make their own health decisions. Therefore, interventions should not only focus on the children but must include their parents / caregivers as well. With the active participation of parents / caregivers in oral health promotion, the incidence of dental caries, gingivitis, and poor oral hygiene would be reduced.

Besides that, teachers can provide a huge influence on preschool children's oral health as well. Since teachers are well trained to teach and provide knowledge suitable for preschool children's cognitive level, it is wise to include the teachers in oral health promotion programme. Good collaboration between the oral health services and preschool teachers will be beneficial to the community as a whole.

The SIMSP has been developed to improve the existing POHP due to poor involvement of parents and teachers in preschool children's oral health. This research will assess the effectiveness of SIMSP on preschool children's oral hygiene level, oral health and related behaviours, parents' OHL, and to assess the process evaluation of SIMSP based on the Precede-Proceed framework.

CHAPTER 3: METHODOLOGY

3.1 Introduction

This chapter describes the research methods which had been done in accordance with the extension of CONSORT Statements on reporting pragmatic trials and cluster randomised trials (Campbell, Elbourne, & Altman, 2004; Zwarenstein et al., 2008). The study protocol was registered with the Clinicaltrials.gov (NCT04339647).

3.2 Study area

Figure 3.1: Map of Peninsular Malaysia

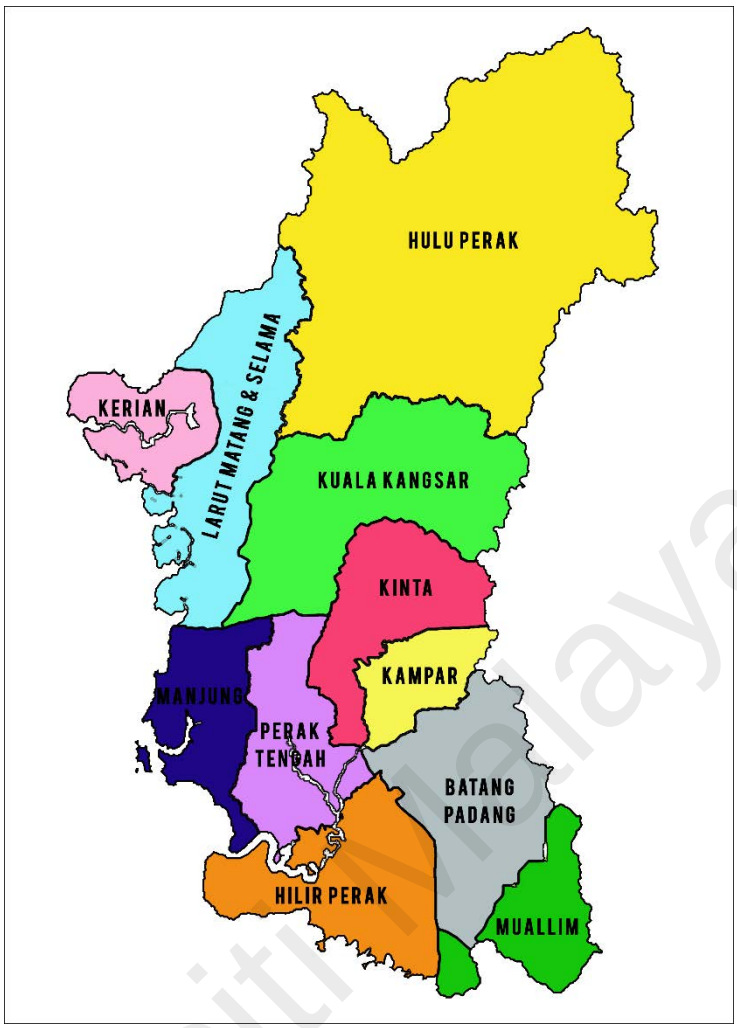

Figure 3.2: Map of Perak State

This study was conducted in the Kampar District which is situated in the state of Perak, Peninsular Malaysia (Figures 3.1 and 3.2). Kampar is a small district in Perak with a total area of 1038 kilometres square and the estimated population of 104,100 comprising of Malays (33%), Chinese (52%), Indians (11%) and others (4%) (Department of Statistics Malaysia, 2020). It has a mix of urban and rural areas with the majority of the population settling in the Kampar Town. There are three government dental clinics in Kampar District where 2 are located in the urban areas and one in the rural area.

In 2019, there were a total of 53 government preschools and 23 private preschools with total enrolment of 1940 preschool children in the district of Kampar. For this study, the sample was recruited from preschool children attending government funded

preschools that consists of 3 types, i.e. KEMAS, Perpaduan and Prasekolah, which are under the care of Kampar District Oral Healthcare Service.

3.3 Study design

The study design was a pragmatic, cluster-randomised, parallel-group, matched pair, controlled trial with a 1:1 allocation ratio. The clusters were government-funded preschools attended by children aged 5-6 years in the Kampar district. Preschools were the unit of randomisation.

In this study, the pragmatic study design was preferred to increase the external validity so that the research findings can be generalised to the preschool setting in the Kampar district. As the government-funded preschool education and the oral healthcare services in Malaysia are standardised, the findings may also be generalised to many other similar settings in the country (Zwarenstein et al., 2008).

3.4 Study population, sampling, and randomisation

3.4.1 Study population

The study population was 5-6-year-old preschool children in the Kampar district. Once selected, their parents and preschool teachers were also included in the study.

3.4.2 The inclusion and exclusion criteria

(a) Inclusion criteria for preschool

The inclusion criteria for preschool were government-funded preschools, and preschools that received the POHP.

(b) Inclusion criteria for participants

The inclusion criteria for participants were:

i. Healthy children aged 5-6 years. Children with chronic medical conditions, dental/oral developmental conditions, long term medication, and physical disability were excluded.

ii. Parents who can speak and write in the Malay language.

iii. Teachers who teach at the preschool on daily basis.

3.4.3 Sample size calculation

Sample size calculation was based on the effect of SIMSP on mean plaque score decrement of the children compared to the POHP after 6 months with a small effect size, dz = 0.30, alpha α value = 0.05, and desired power = 0.8. Using G*Power version 3.1.9.2 software (Cunningham & McCrum-Gardner, 2007), the sample size calculated was n = 352 (176 per group). **Table 3.1** shows estimation of sample size prior to 20% increment and design effect based on the impact of SIMSP on the outcome measures over and above the POHP over 6 months. This number was increased by 20% to account for non-respondents (Aday & Cornelius, 1996) giving the final sample size of 423.

The design of the study was cluster RCT. Due to some potential similarities among clustered subjects, there was a potential net loss of independent data within clustered subjects. Therefore, **effective sample size** (ESS) was calculated. The ESS is the sample size in clustered samples compared with the number of subjects actually enrolled. Based on the intracluster correlation coefficient of 0.026 from a pilot study, the design effect (correction factor in cluster sampling) was calculated using the formula **DE= 1 + ρ(m-1), w**here m = number of subjects in a cluster and ρ = intra cluster correlation coefficient (Killip, Mahfoud, & Pearce, 2004). Based on the average number of children in a preschool (n = 20), the DE = 1 + 0.026(19) = 1.494 = 1.50. Therefore, the ESS = 423 * 1.50 = **634 (317 children per group).**

Table 3.1: Estimation of sample size

Outcome(s)	Objective(s)	Basis of calculation	Software and test used	Sample size per group and total
Oral cleanliness	To assess the impact of SIMSP over and above the existing POHP in 6 months in terms of children's oral hygiene level	Effect size, d = 0.3 (small) α = 0.05 Power : 80% Df = 6	GPower ver. 3.1.9.2 Mean comparison (independent two groups)	IG: 176 CG:176 Total: 352
Oral health and related behaviours	To assess the impact of SIMSP over and above the existing POHP in 6 months in terms of children's oral health and related behaviours (all items)	Effect size, d = 0.2 (small) α = 0.05 Power : 80% Df = 6	GPower ver. 3.1.9.2 X^2 Test (independent two groups)	IG = 171 CG = 171 Total = 342
Parental OHL	To assess the impact of SIMSP over and above the existing POHP in 6 months in terms of parents' OHL	Effect size, d = 0.3 α: 0.05 Power : 80%	GPower ver. 3.1.9.2 T- test (difference between 2 independent means)	IG: 176 CG: 176 Total: 352

3.4.4 Sampling and randomisation of preschools into intervention and control

Prior to randomisation, matching of the eligible preschools were carried out to increase precision and minimise imbalance across treatment and control groups. This study involved 2 levels of randomisation. The randomisation sequence was carried out by the statistician employed at the Faculty of Dentistry, University of Malaya.

At the first level, in order to increase precision and minimise imbalance across treatment and control groups, the 53 eligible government funded preschools in Kampar district were paired according to location, type of preschool, and preschool characteristics, e.g. number of children, teachers, and the available facilities into 24 pairs. Five preschools were not paired as they were located far away from each other and thus were excluded from the study. **Figure 3.3** illustrates the flow diagram of the matching process. The preschool match-pairs were randomly selected until the sample size was met. At this level, 14 preschool match-pairs were randomly selected.

At the second level of randomisation, using computer generated random numbers, the preschools in each of the matched-pair were randomly allocated to the SIMSP intervention group or POHP control group. In total 28 preschools were randomly divided into IG and CG (14 preschools per group). The intervention group received the SIMSP while the control group received the current POHP. The CONSORT flowchart of the study is illustrated in **Figure 3.4 (page 109).**

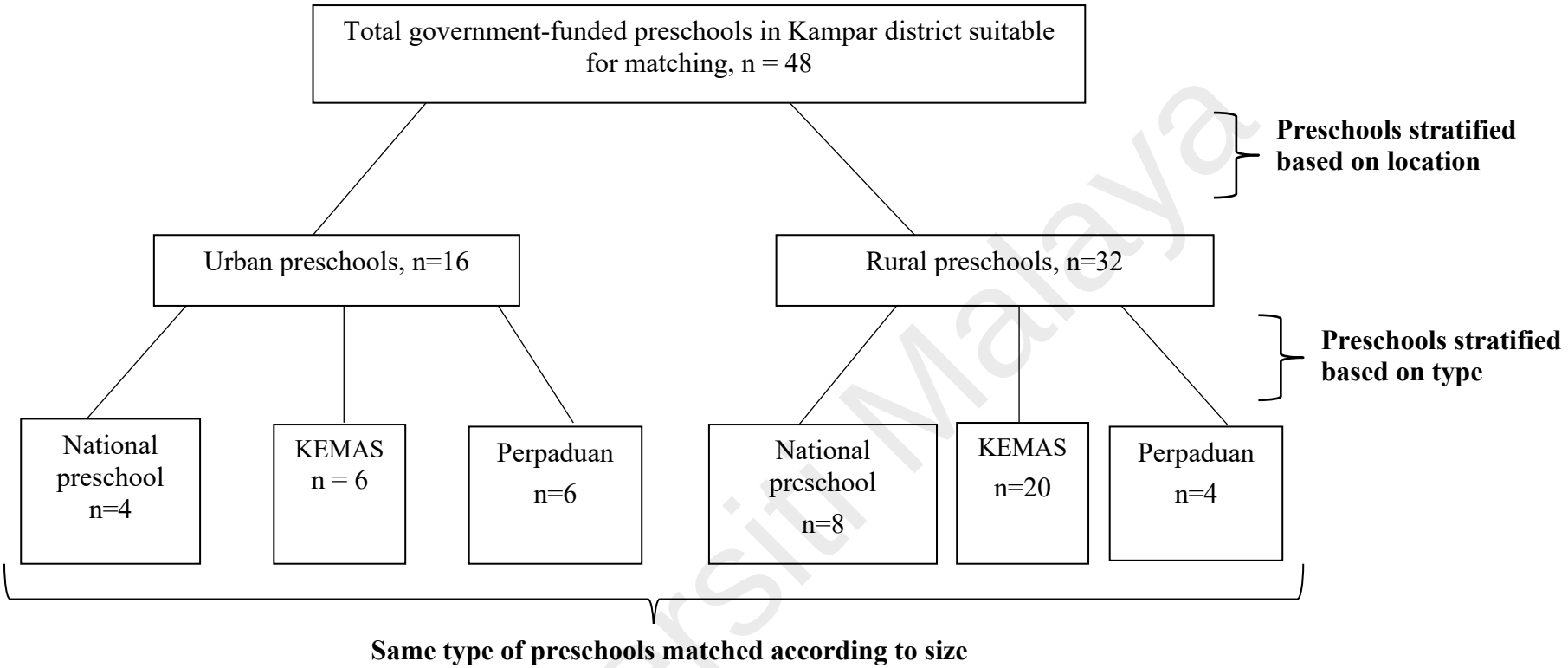

Figure 3.3: Flow diagram for matching of preschools

3.4.5 Allocation concealment

The allocation was based on clusters, and allocation concealment was at the cluster level. In this study, allocation concealment was achieved by having a senior dental officer in the Kampar dental clinic who was not involved in the cluster identification and recruitment to keep the allocation sequence in a brown envelope. The brown envelope was kept in a safe box in the Kampar dental clinic until the preschool pairs were recruited into the study.

The allocation sequence was generated by the statistician employed at the Faculty of Dentistry, University of Malaya using computer generated tables. The information was kept confidential until the interventions were assigned to the preschools. The investigators with the help of the DT team enrolled and assigned the clusters into intervention and control groups. All children in the preschools who fulfilled the inclusion/exclusion criteria were included in the study (complete enumeration). Informed consent from parents were sought after randomisation.

Table 3.2 enlists the preschools involved in the study.

Table 3.2: List of preschools involved in the study

	Intervention Group (SIMSP)	Enrolment	Control Group (POHP)	Enrolment
1	SK Gopeng	50	SK Gopeng Jalan Ilmu	50
2	SK Kuala Dipang	25	SK Sahom	25
3	SK Malim Nawar	25	SK Gunung Panjang	35
4	SK Tualang Sekah	59	SK Sentosa	50
5	KEMAS Taman Cahaya	19	KEMAS Taman Sentosa	17
6	KEMAS Kopisan Baru	18	KEMAS Kg Kepayang	15
7	KEMAS Pos Dipang	26	KEMAS Kuala Dipang	23
8	KEMAS Pulau Begading	20	KEMAS Bina Jaya	24
9	KEMAS Ulu Pili	25	KEMAS Jelintoh	31
10	KEMAS Itam Labu	20	KEMAS Tg Bangkung	20
11	KEMAS Stesen	20	KEMAS Bukit Pekan	12
12	Perpaduan Taman Ros	25	Perpaduan Mambang Di Awan	22
13	Perpaduan Taman Sentosa	24	Perpaduan Aston Settlement	20
14	Perpaduan Jeram	15	Perpaduan Lawan Kuda	15
	Total	371		359

3.5 Interventions

3.5.1 The SIMSP

The SIMSP was developed based on feedback from experts in dental public health (DPH) discipline, findings from the NOHPS 2015 (Oral Health Division, 2017), senior dental officers in the Ministry of Health, preschool curriculum experts in the Ministry of Education, preschool teachers, a child psychologist, and parents. The concept of the SIMSP is that improvement in preschool children's oral hygiene would require the combined efforts of DTs, preschool teachers, and parents working together on children's

oral health.

The SIMSP's target groups are preschool children and their parents. It is designed to be delivered at the individual and cluster levels. The SIMSP consists of the following package:

1) Preschool children:

a. Oral examination, OHE, TBD, FVA containing 22,600 part-per-million fluoride (ppmF) twice/year, and restorative treatment by DTs (this is the usual care/POHP).
b. Use of CRA to identify individual caries risk levels
c. In-class oral health lessons by teacher including worksheets and colouring activities based on the teacher's OHE booklet over a period of 6 months;
d. In-school daily toothbrushing with fluoride toothpaste (1450 ppmF) after morning break supervised by class teacher using horizontal scrubbing technique for 6 months;
e. Home toothbrushing at night supervised by parents/guardians.

2) Parents/guardians:

a. Attend a parent-DT meeting at school in the beginning of the year to discuss on child's oral health status and child's caries risk assessment (CRA) (F. Ramos-Gomez et al., 2010; F. J. Ramos-Gomez et al.)
b. Received OHE and diet advice from DTs based on child's CRA levels (low/medium/high);
c. Received free toothbrush and fluoride toothpaste (1450 ppmF) for child home toothbrushing after toothbrushing demonstration by DTs using horizontal scrubbing technique;

d. Received 10, 2-weekly oral health infographics from DTs sent via electronic messaging application (WhatsApp) for a duration of 6 months (printed versions for parents without a smartphone).

Teacher's OHE booklet

A teacher's OHE booklet (Appendix J) was developed for teaching oral health-related lessons to 5-6-year-old children by class teacher at school. The content was drafted by DPH specialists based on review of dental literature. It consists of 11 topics covering 6 domains as listed in **Table 3.2** below.

Table 3.3: List of domains and topics in the OHE booklet

Domains	Topics
1. Basic knowledge about teeth and dentition	i. Your teeth - small but functional ii. Healthy and strong teeth are useful iii. Milk teeth and permanent teeth iv. Why is my tooth loose?
2. Toothbrushing	Toothbrushing is fun
3. Dental caries	Dental caries / tooth decay / a hole in the tooth
4. Dental plaque	Dental plaque
5. Diet	Good choice of foods and drinks
6. Self-motivation	i. You are in charge ii. Visiting the dentist iii. Beautiful smile for all

The OHE booklet was content validated by a paediatric dentist, a periodontist, and a general dentist. The delivery method and the level of language used were assessed and verified by a child psychologist. Subsequently, preschool teachers' feedback were sought on the overall appearance of the booklet and the suitability of the worksheets for

preschool children's use. The booklet was tested on a group of preschool children who were not involved in the main study to assess its utility as a teaching tool before it was finalised. It was subsequently endorsed by the Committee on Preschool Curriculum from the Ministry of Education who were experts in preschool pedagogy and assessment before being used in the study.

Teachers in the SIMSP will deliver in-class oral health lessons based on the OHE booklet every 2 weeks for 6 months. Each lesson will take approximately 20 to 30 minutes. At the end of each lesson, a revision in the form of a colouring worksheet will be distributed to the children as part of the learning activities.

Parent oral health infographics

The parents/caregivers' oral health infographics (Appendix K) were developed prior to the study. The oral health infographics for parents/guardians consist of 10 topics covering 5 domains related to oral health. The list of domains and topics are listed below in **Table 3.3.**

Table 3.4: List of domains and topics of oral health infographics

Domains	**Topics**
1. Basic knowledge about teeth and dentition	Information about tooth structure & tooth eruption
2. Oral health related habits	i. Good oral health habits & parents' role to maintain good oral health ii. Poor oral health related habits
3. Oral diseases	i. Dental caries & relation between caries and sugar intake ii. Periodontal problems.
4. Toothbrushing and fluoride	i. Introduction to dental plaque & importance of toothbrushing ii. Introduction to fluoride and fluoridated toothpaste

5. Dental treatment	i.	Introduction to fluoride varnish
	ii.	Introduction to dental sealant
	iii.	Types of dental treatment & Sources for oral health related information.

The content was developed by DPH specialists and validated by a paediatric dental specialist and a periodontist. The infographics were further assessed by a social media expert for the overall appearance and content. The infographics were face validated by a group of preschool parents before they were finalised with some changes. The messages are delivered to parents every 2 weeks for a period of 5 months.

CRA form

The CRA form (Appendix I) used in this study was adapted from the CRA template used by experts during the Malaysia Early Caries Expert Workshop 2014 (F. J. Ramos-Gomez et al., 2010) It was modified to suit the preschool setting in Malaysia that included clinical, environmental, and behavioural factors when assessing caries risk in young children, including factors associated with the primary caregivers (Fontana, 2015).

The CRA form consists of 4 steps.

a) Step 1 - Current Caries Experience Assessment: the child's number of teeth with ICDAS score is recorded.
b) Step 2 - Risk Factor Assessment: the 6 risks listed are visible plaque, use of fluoridated toothpaste, crowding / deep fissures, sugary snacks / drinks between meals, bottle feeding at night, and mother / siblings with caries. Visible plaque and crowding / deep fissures are identified during charting while other risk factors are determined from an interview with the parents during the parent-DT meeting at school.

c) Step 3 - Caries Risk Indicator: child's caries risk is identified as low, medium or high based on the information retrieved in Step 1 and Step 2.

d) Step 4 - Caries Management Recommendation: this step provides individual treatment plan for the child based on his / her caries risk indicator. For the intervention group, the DT use this form as reference during consultation with parents to inform them of their child's oral health status and the recommended caries management based on the caries risk levels.

3.5.2 The POHP

Preschool children in the POHP will receive the usual care delivered by DTs. These are an oral examination, toothbrushing drill, OHE, TBD, FVA (22,600 ppmF) twice/year, and restorative treatment by DTs.

3.6 Conduct of study

3.6.1 Implementation of the SIMSP intervention

The SIMSP intervention was delivered for a period of 6 months. It consisted of 3 phases:

Phase 1: DTs' first visit to SIMSP preschools

DTs visited the preschools in the beginning of the year to conduct an oral examination with the children to assess for caries and dental plaque. The presence of crowding/deep fissures was also assessed for inclusion in the CRA form. A self-administered questionnaire for parents were sent to parents through class teacher.

Phase 2: DTs' second visit to SIMSP preschools

This visit took place 2 weeks after the first visit. DTs conducted OHE and TBD with the children followed by FVA (22,600 ppmF) on their teeth. At this visit, DTs met with parents to discuss their child's oral health status and completed the child's CRA

form. During the DT-parent meeting, instead of focusing on information giving, the DTs were trained to be patient-centred which is one of the components of motivational interviewing (MI). Since MI provides a collaborative and goal-oriented style of communication, this interviewing method focused on building intrinsic motivation for change by exploring and resolving uncertainties about oral health among the parents (Borrelli, Tooley, & Scott-Sheldon, 2015). Oral health information and dietary advice were given to the parents based on their child's CRA levels (low/medium/high). The parents took home OHE and dietary advice pamphlets (Appendix L and M) for further reading. A set of free toothbrush and fluoride toothpaste (1450 ppm F) was distributed to parents for child home toothbrushing along with instructions. Parental agreement to receive 10 oral health infographics sent by DTs via WhatsApp every 2 weeks over the next 5 months was sought.

With regards to teachers, they were given the teacher's OHE booklet as a teaching aid for delivering in-class oral health lessons over 6 months (24 weeks). Teachers were also given supplies of toothbrush and fluoride toothpaste (1450 ppm F) for children's daily toothbrushing for 6 months (24 weeks) and a teeth model and toothbrushing instructions to help with the supervision.

Phase 3: DTs' third visit to SIMSP preschools

This visit took place 24 weeks after the second visit. An oral examination was carried out to assess for dental plaque. In this phase, DTs carried out treatment using ART technique if required followed by the second application of FVA (22,600 ppmF). A post intervention self-administered questionnaire for parents were sent through class teacher.

3.6.2 Implementation of the POHP

The control group received the existing POHP which was conducted in 2 phases.

Phase 1: DTs' first visit to control preschools

In the first visit, an oral examination was carried out to assess for caries and dental plaque. Then, DTs conducted OHE, TBD, and FVA (22,600 ppmF) on the children's teeth. A self-administered questionnaire for parents were sent through class teacher.

Phase 2: DTs' second visit to control preschools

The second visit was scheduled after 6 months from the first visit. An oral examination was carried out to assess for dental plaque. In this phase, DTs carried out treatment using atraumatic restorative treatment technique (ART) if required followed by the second application of FVA (22,600 ppmF). A post intervention self-administered questionnaire for parents were sent through class teacher.

3.7 Outcomes of the study

The primary outcome variable was the mean decrement of plaque score in children after 6 months assessed using the Oral Cleanliness Index (Bearn et. al., 1996; Public Health England, 2015).

The secondary outcomes were: (1) changes in the children's oral health and related behaviours after 6 months, and (2) mean increment of parental OHL score (domain score and total score) after 6 months.

In this study, the implementation fidelity of the SIMSP protocol was also assessed. In addition, qualitative data on the process implementation of the SIMSP using the perspectives of the dental team were also collected. Qualitative methodology is described at the end of the chapter.

3.7.1 Study variables

Based on the objectives of the study, the following variables were collected **(Table 3.4)**.

Table 3.5: Study variables

Variable	Operational Definition	Scale	Unit of measurement
1. Children's oral cleanliness score (Oral Cleanliness Index) (Bearn et al., 1996; Public Health England, 2015).	Highest score among reference teeth (53 to 63)	Ordinal & continuous	0 = teeth appear clean 1 = a little plaque visible 2 = substantial amount of plaque visible 9 = assessment cannot be made
2. Daily toothbrushing	Daily toothbrushing frequency	Ordinal	1 = 2 or more times daily 2 = 1 time daily 3 = Once every 2 days 4 = 1 to 3 times a week 5 = Don't brush teeth
3. Parents' monitoring of children's toothbrushing activity at home	Frequency of parents to monitor children's toothbrushing activities	Nominal	1 = Daily 2 = Infrequent 3 = Never
4. Use of fluoridated toothpaste	Daily toothbrushing with fluoridated toothpaste	Ordinal	1 = 2 or more times daily 2 = 1 time daily 3 = Once every 2 days 4 = 1 to 3 times a week 5 = Don't brush teeth
5. Use of bottle feeding	Frequency of using bottle	Nominal	1 = Daily 2 = Infrequent 3 = Never
6.Use of bottle feeding at night	Frequency of using bottle at night	Nominal	1 = Daily 2 = Infrequent 3 = Never
7. Daily sugar intake	Total sugar intake daily	Nominal	1 = 4 times daily or less 2 = 5 times daily or more
8. Carbonated drinks intake	Frequency of carbonated drinks intake	Nominal	1 = Daily 2 = 1-3 times weekly 3 = Never

Table 3.4: Study variables (continued)

Variable	Operational Definition	Scale	Unit of measurement
9. History of dental visits	Children's latest visit to dental clinic (excluding school dental visit)	Nominal	1 = Less than 1 year ago 2 = Between 1-2 years ago 3 = More than 2 years ago 4 = Never visited dental clinic
10. Reasons for dental visit	Reasons for latest visit to dental clinic	Nominal	1 = Dental check up 2 = Tooth restoration 3 = Scaling 4 = Toothache 5 = Trauma 6 = Other reasons
11. Parent's OHL (knowledge domain)	Sum of score	Continuous and ordinal	Poor = Score 0 – 3 Moderate = Score 4 – 8 Good = Score 9-12
12. Parent's OHL (comprehension domain)	Sum of score	Continuous and ordinal	Poor = Score 0 – 4 Good = Score 5
13. Parent's OHL (skills and motivation domain)	Sum of score	Continuous and ordinal	Poor = Score 0 – 12 Moderate = Score 13 – 25 Good = Score 26-39
14. Parent's Total OHL scores	Sum of score from 3 domains	Continuous	Score 0 – 56
15. Level of parent's oral health literacy	Category of oral health literacy scores of OHL questionnaires adapted from Ludke et al. (2010)	Ordinal	Poor = Score 0-18 Moderate = Score 19-37 Good = Score 38 – 56

3.8 Data collection and study instruments

Data collection took place at baseline and after 6 months in the intervention and control group. The methods of data collection were:

a) An oral examination to record preschool children's oral health status

b) A self-administered questionnaire answered by parents/caregivers

3.8.1 Oral examination

The preschool children underwent an oral examination to assess dental caries and plaque score at baseline. After 6 months, follow-up examinations were done for plaque score only. These examinations were conducted by 2 calibrated dental officers who were blinded to the intervention group throughout the study.

The examiners assisted each other to record the charting and to hold the headlight throughout the data collection process. The preschool children were examined at the respective preschool at an area designated by the teacher. The examiner sat on a chair and the preschool children laid on supine position while placing their head on the examiner's lap. The oral examination was carried out with the aid of a headlight (LED bulb with 50 lumens). The oral examination was conducted before morning break. The teeth were dried using a manual air blower, i.e. a chip syringe. A disposable dental probe and a mouth mirror were used to examine the teeth. A dental probe was only used to remove excessive plaque on the occlusal surfaces of the teeth for caries assessment. It was applied gently on the teeth surfaces to ensure that it did not damage nor introduce a cavity into the teeth. No dye or colouring agent was applied on teeth surfaces to examine plaque. The same procedure was carried out after 6 months.

Caries status

The International Caries Detection and Assessment System (ICDAS) was used to assess caries status of the children. ICDAS is a clinical scoring system, which allows for the detection and assessment of caries activities (A. I. Ismail et al., 2007). The ICDAS score was recorded in the validated ICDAS charting sheet (Mohd Nor, Chadwick, Farnell,

& Chestnutt, 2019) (Appendix H). The ICDAS score was charted at surface and tooth levels. The scores ranged from 0 to 6. The description for each score is shown below (Gugnani et al., 2011):

- 0: Sound tooth surface: no evidence of caries after 5 seconds of air drying.
- 1: First visual change in enamel: opacity or discolouration (white or brown) is visible at the entrance to the pit or fissure seen after prolonged air drying.
- 2: Distinct visual change in enamel visible when wet, lesion must be visible when dry.
- 3: Localised enamel breakdown (without clinical visual signs of dentinal involvement) seen when wet and after prolonged drying.
- 4: Underlying dark shadow from dentine.
- 5: Distinct cavity with visible dentine.
- 6: Extensive (more than half the surface) distinct cavity with visible dentin.

In addition, teeth with no decay or filling, or teeth with filling without decay were considered as sound (ICDAS = 0). Only 1-digit caries coding was used in this study. Although caries was not one of the outcome measures, its assessment was done as proxy to determine if both groups were equal in terms of oral disease level at baseline.

Plaque score

Plaque score was examined using the Oral Cleanliness Index (Appendix H) which is a simple measure based on modifications of the Silness and Low Index for the assessment of plaque (Bearn et al., 1996; Public Health England, 2015). Assessment for the presence of visible plaque involved examining the labial surfaces of upper anterior teeth segments from upper right to upper left primary canines. Each surface was recorded using the following codes: 0 - teeth appear clean, 1 - presence of plaque around the labial

cervical margins and covering less than ½ of labial tooth surface, 2 - plaque covering more than ½ of labial tooth surfaces, and 9 - assessment cannot be made.

0 = teeth appear clean	Labial tooth surfaces appear clean. Do not probe pellicle
1 = a little plaque visible	Existence of plaque around the labial cervical margins and covering less than ½ of labial tooth surfaces
2 = substantial amount of plaque Visible	Plaque covering ≥ ½ the labial tooth surfaces
9 = assessment cannot be made	Apply this code where relevant: • There are no teeth in both anterior segments for plaque assessment • There are roots in anterior segments, and plaque levels assessment cannot be undertaken, or • The child is uncooperative

3.8.2 Self-administered questionnaire

The questionnaire consisted of 3 sections (Appendix G):

Section A: consists of questions on demographic characteristics of the respondents which included parents/guardians age, type of relation with the child, education level, total household income, and family status.

Section B: consists of preschool children's oral health and related behaviours such as tooth brushing habit, use of fluoridated toothpaste, bottle feeding, and frequency of consuming sweet food and drinks.

Section C: consists of the Malay version of Dental Health Literacy Assessment Instrument (DHLAI) that was adapted from (Ludke et al., 2008) and validated by Ismail et al (2018). This section of the questionnaire consisted of 3 domains; oral health

knowledge domain, comprehension and skill domain, and motivation domain with 12, 5 and 39 items, respectively.

Section A of DHLAI assessed parents' oral health knowledge on the different components of OHL which included the mother's basic dental knowledge, knowledge on oral health promotion, oral health protection, disease prevention and system navigation (understanding the available free dental services and knowledge about the first dental visit). Section B tested the parents' ability to understand healthcare instructions using their comprehension skill. It measured the domain of healthcare maintenance. Section C assessed the parents' perception on their skills and motivation with the children's oral healthcare. The details are shown in **Table 3.5.**

Table 3.6: Contents of the Malay DHLAI (Ismail, Razak, & Ab-Murat, 2018) to assess parents' OHL

	Domain (Question)	**Domains**	**Total**
1.	Domain A (Question 2 & 12)	Oral health knowledge: Oral Health promotion	2
2.	Domain A (Question 5)	Oral health knowledge: Oral Health protection	1
3.	Domain A (Question 3,7,8, 9,11)	Oral health knowledge: Disease prevention	5
4.	Domain A (Question 10)	Oral health knowledge: System navigation	1
5.	Domain A (Question 1,4,6)	Oral health knowledge: Basic dental knowledge	3
6	Domain B (Question 1 to 5)	Heath care maintenance Comprehension skill	5
7.	Domain C (Question 1 to 39)	Perception on motivation and skill of oral health care of children	39
	Total question		56

3.8.3 Calibration and standardisation of examiners

It was necessary to assess the consistency of each individual examiner when examining at different times (intra-examiner reliability), as well as the variations between examiners (inter-examiner reliability) when examining same individuals. Prior to conducting the clinical examinations, the two examiners had undergone calibration and standardisation for caries assessment using the ICDAS (Pitts, 2004), and oral cleanliness assessment using the Oral Cleanliness Index (Bearn et al., 1996; Public Health England, 2015).

The researcher (NH) and 2 examiners (DO1 & DO2) underwent calibration and standardisation of ICDAS with a paediatric dental specialist. For the Oral Cleanliness Index, the researcher (NH) underwent calibration and standardisation with a periodontal specialist, and the examiners (DO1 & DO2) underwent standardisation for the Oral Cleanliness Index with the researcher (NH). Calibration was done at Tadika KEMAS Taman Sentosa, Kampar. In this study, the examiners had undertaken inter- and intra-examiner reliability assessment in order to validate the findings for the ICDAS and plaque score chartings.

Kappa score was used to compare agreement between examiners and within examiner (Cohen, 1962). The interpretation of agreement for Kappa are shown below in **Table 3.6.** Kappa score were compared and Kappa score below 0.60 indicates inadequate agreement among the examiners (Cohen, 1962).

Table 3.7: Interpretation of Cohen's Kappa (Cohen, 1962)

Value of Kappa	Level of agreement
< 0	Less than chance agreement
0.01 - 0.20	Slight agreement
0.21 - 0.40	Fair agreement
0.41 - 0.60	Moderate agreement
0.61 - 0.80	Substantial agreement
0.81 - 0.99	Almost perfect agreement

The results of the calibration and standardisation exercise are shown in **Table 3.7** and **Table 3.8.**

Table 3.8: Inter- and intra-examiner reliability analysis for the oral cleanliness score

Dental officer	Plaque score (Kappa score)	
	Inter examiner	Intra examiner
NHA	0.723	0.766
DO1	0.732	0.832
DO2	0.799	0.938

Table 3.9: Inter- and intra-examiner reliability analysis for the ICDAS

Dental officer	ICDAS (Kappa score)	
	Inter examiner	Intra examiner
NHA	0.746	0.763
DO1	0.721	0.840
DO2	0.796	0.691

3.8.4 Blinding

This study used a single-blinding strategy to reduce bias where the examiners were blinded to the intervention group.

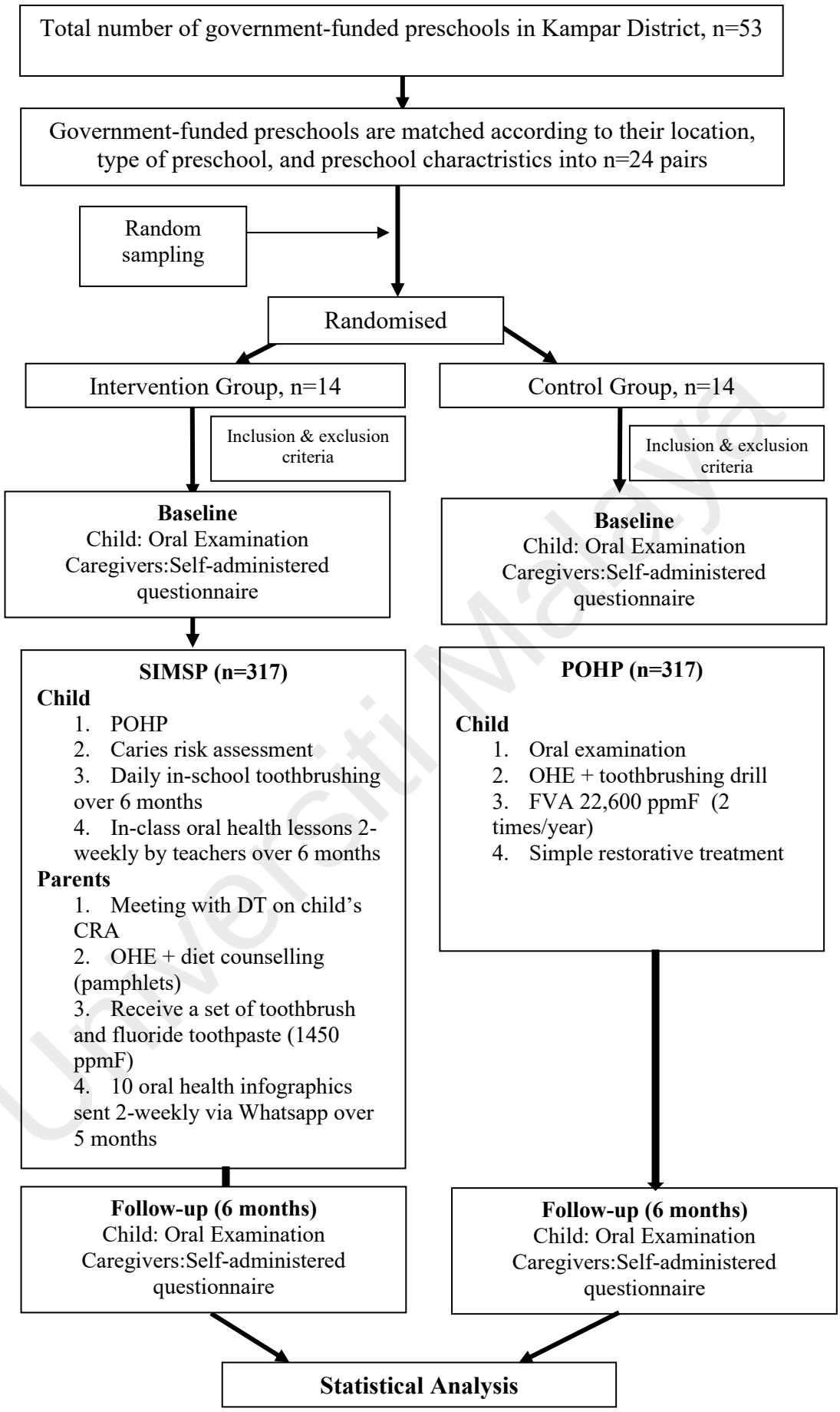

Figure 3.4: The Consort flowchart of the study

3.9 Monitoring the implementation fidelity of SIMSP

Monitoring the implementation fidelity of the study was a crucial element of the process evaluation of the SIMSP intervention (Breitenstein et al., 2010). The researchers observed the implementation fidelity of the SIMSP to ensure that it was delivered as planned throughout the 6-month period.

The researchers visited every preschool 3 times over the 6-month period to monitor the implementation fidelity at each preschool. During these visits, the researcher observed how the in-class OHE was conducted, preschool children's responses, and the conduct of toothbrushing drill as well. Variations in the implementation process between preschools were minimised through discussion, facilitation, and support.

The researcher (NH) attended all parent-DT meetings to observe the conduct of the intervention. Following every parent-DT meeting, the researcher conducted post-mortem discussion with the DTs to identify any issues that may have arisen and directly discussed the solutions. Frequent communications between the researcher and the DTs were crucial to ensure the smooth delivery of the SIMSP.

Data on implementation fidelity were self-reported by DTs and teachers through various methods; the in-class lessons by filling in lesson dates in the OHE booklet by teacher, in-school toothbrushing by completing a toothbrushing diary by teacher, parents' meeting with DTs by completing the attendance list by DTs, and infographics sent to parents by completing a standardised form by DTs.

3.10 Quantitative data analysis

In this study, analyses were carried out at individual/general level. There were 2 reasons for this. First, the estimated intracluster correlation coefficient was very small (< 0.03) indicating the clustering effect was insignificant, therefore, independence of data was

highly likely (Galbraith, Daniel, & Vissel, 2010). Second, the number of cluster in our study was higher than the average number of subjects within each cluster. The number of subjects per cluster varied ranging from 5 to 50 subjects (with 15 of the 28 clusters (53.6%) have < 20 subjects each). Therefore, the number of subjects in many clusters were too few for cluster effect to take place or to be accounted in the analysis.

All data were entered into and analysed using Statistical Package for the Social Science Software (SPSS) version 21.0 for windows. The data on preschool children's dental plaque, oral health and related behaviours, and parents' OHL were analysed to answer the primary objective and the first of the secondary objectives.

Intention to treat analysis (ITT) was carried out to all intervention outcomes, where all participants after randomisation remained in their allocated group for analysis (McCoy, 2017). ITT is a method for analysing results in a prospective randomised study where all participants who were randomised are included in the statistical analysis and analysed according to the group they were originally assigned, regardless of what treatment (if any) they received. This method allows the researcher to draw unbiased conclusions regarding the effectiveness of an intervention. This method preserves the benefits of randomisation, which cannot be assumed when using other methods of analysis such as per protocol analysis. In this study, participants who did not return for the follow-up, the baseline data for oral hygiene levels, OHB and OHL were used as the follow-up data.

The Pearson Chi-square test and McNemar test was used to analyse significant differences between SIMSP and POHP. The demographic characteristics of the sample were analysed using descriptive statistics.

The effect size of the study was calculated using repeated measures test in general linear model (GLM) analysis. Cohen (1988) suggested general conventions for effect sizes as d=0.20 is considered small, d=0.50 is medium, and d=0.80 is large (Cohen, 1988).

Impact of SIMSP over and above POHP was tackled through calculation of the effect size of the study outcomes. The effect size indicated the magnitude of excess difference between SIMSP and POHP.

Retrospective calculation of power of study using GLM was conducted at data analysis stage.

(i) Analysis of data on preschool children's dental plaque.

Between-group differences in mean item and total scores were assessed using Independent sample t test. Within-group comparison after 6 months was assessed using Paired sample T test. Between-group differences in the proportion of children with plaque at baseline and after 6 months were assessed using Pearson Chi-square test. The level of significance was set at $p < 0.05$.

Mean plaque score increment or decrement after 6 months was calculated for the SIMSP and POHP. Between-group comparison of mean plaque score increment or decrement was assessed using Independent sample T test. Within-group comparison of mean plaque score increment was assessed using Paired sample T test. The level of significance was set at $p < 0.05$.

(ii) Analysis of data on preschool children's oral health and related behaviours.

Differences in the proportion between the groups was analysed using Chi-square test at baseline and after 6 months. Within-group comparisons were assessed using McNemar test. The level of significance was set at $p < 0.05$.

(iii) Analysis on parents' OHL

In assessing parents' oral health knowledge in section A, any correct answers provided was given one point. The total score was categorised into three categories; "Poor" (0-3), "Moderate" (4-8) and "Good" (9-12).

For assessing comprehension in section B, respondents were asked whether the statements given were "True" or "False" and one point was given for the correct answer. The total scores were dichotomized into two categories: "Poor" (0-4) and "Good" (all correct answers for 5 questions).

For section C, respondents were asked to indicate the extent of their agreement or disagreement on perceptions of skill and motivation for the oral health care of their children. A five-point Likert scales ranging from "Strongly agree" to "Strongly disagree" was used. The answers were grouped into "Agree" and "Disagree". One point was given to every positive statement with "Agree" answer which reflects a positive perception. For positive statement, "Strongly Agree" and "Agree" were recoded as 1, while "Not sure", "Disagree" and "Strongly Disagree" were recoded as 0. One point was given to every negative statement with "Disagree" answer (recoded from "Disagree" and "Strongly Disagree" responses) for items SM 4, SM 6, SM 8, SM 9, SM 10, SM 12, SM 13, SM 14, SM 15, SM 17, SM 19, SM 22, SM 23, SM 29, SM 34, SM 35, which also reflects a positive perception.

Item and total scores of the three sections in the intervention and control groups were described in mean and standard deviation if the data were normally distributed or in median if the data were non-normally distributed. For each section, total score was calculated by adding all item scores. The total scores for Section A, B and C ranging from 0 to 12, 0 to 5, and 0 to 39, respectively. Thus, the total scores for parents' oral health

literacy ranging from 0 to 56. Higher score indicating better oral health literacy among parents.

Between-group differences for the 3 domains and the overall scores were assessed using Independent sample t test for normally distributed data, and Mann Whitney test for skewed data at baseline and after 6 months. Between-group differences in the proportion of OHL levels were analysed using Pearson Chi-square test at baseline and follow-up. The level of significance was set at $p < 0.05$.

Mean score increment after 6 months was calculated for both groups. Between-group comparison of OHL score increment was assessed using Independent sample T test. Within-group comparison of OHL score increment was assessed using Paired sample T test. The level of significance was set at $p < 0.05$.

3.11 Qualitative Study

This part of study was qualitative, explorative, descriptive and contextual in nature. It was conducted to address the study's secondary objective number 3.

3.11.1 Study design

It was a qualitative study using focus group discussions (FGD) as the method for data collection (Krueger, 2014). The FGD was conducted to explore other potential associated environmental factors which might influence the programme implementation and the outcome. FGD could also provide a broader range of information about a topic and offer an opportunity for clarifying or supporting the outcomes of quantitative data in the present study (Krueger, 2014).

The FGD sessions were conducted among DTs and HAs to get their opinions on the following aspects of the SIMSP: appropriateness, effectiveness, facilitators, barriers and suggestions for improvement.

3.11.2 Population and sampling

The population consisted of all DTs and HAs who implemented the SIMSP. Purposive sampling method was used. Each FGD session consisted of 4 to 5 participants.

3.11.3 Data collection

The summary of data collection is outlined below:

a) Interview protocol

Questions posed for the participants were tailored to explore their personal experience being part of the team to implement the SIMSP.

b) Interview procedure – The participants took part in the FGD at a location prepared by the researcher. The participants were informed of the purpose of this research which was to explore the implementation of SIMSP and the researcher acted as the moderator in the FGD. The FGD sessions were conducted right after the intervention was completed.

A topic guide with open-ended questions was used to obtain the opinions of the participants about the SIMSP (Appendix N). Topics for discussion included the perceived appropriateness, effectiveness, facilitators, barriers, and suggestions for improvement of the SIMSP. The researcher, who facilitated the discussion, used this topic guide to ask and probe questions (Wong, 2008). Five open-ended questions were asked in the FGD in relation to the SIMSP. The list of domains and leading open-ended questions are listed below in **Table 3.10.**

Table 3.10: List of domains and open ended questions for FGD

Domain	Open ended question
Appropriateness	What are your opinions about the appropriateness of the SIMSP for preschool OH programme?
Effectiveness	What are your opinions about the benefits of the SIMSP?
Feasibility - facilitators	What are the factors that facilitate or help you to implement or run the SIMSP?
Feasibility- barriers	What are the factors that make it difficult (or act as barriers) for you to implement or run the SIMSP?
Suggestions for improvement	In your opinion, what are your suggestions to improve the SIMSP in the future.

A voice recorder was used to record the FGD and later used for data transcriptions and reference.

The FGD proceeded as follows:

The discussion started with an 'ice-breaker', i.e. self-introduction by the moderator and each participant. The rules and regulations of the FGD were explained. Afterwards, the moderator introduced the topic for discussion. The questions were asked to the group one at a time to obtain their feedback. Participants were free to give their views. The discussions were held without interrupting the natural flow of the discussion and were considered completed when no further opinions were put forward by the participants or repeating answers or opinions were given by the participants. If the discussion was held back by lack of input, the moderator would ask probing questions to guide and promote participations. The moderator would also monitor the group dynamics such as levels of participation, the presence of dominant participants, levels of interest, and voice tones of the participants. Finally, when the FGD was over, the moderator thanked all the participants.

3.11.4 Rigour of data from the FGD

The validity and reliability of qualitative analysis was described as trustworthiness (Elo et al., 2014). The terms credibility, transferability, dependability, and confirmability are used in qualitative research to explain the reliability and validity of data and contribute to appraise the findings of qualitative research (Golafshani, 2003). The rigour of data in the FGD was established by following the criteria for data trustworthiness (Lincoln & Guba, 1999). The following steps were undertaken to ensure the rigour of data in this study:

a) Credibility: To ensure data credibility was achieved, the following strategies were undertaken, i.e. prolonged engagement, persistent observations, and triangulation (Lincoln & Guba, 1999).

   i. Prolonged engagement: a few minutes were spent with the participants to understand and develop good rapport with them. This was to ensure that participants felt comfortable to give their opinions based on the questions asked.

   ii. Persistent observation: identifying those characteristics and elements that are most relevant to the questions under study. The sessions were observed carefully in terms of group dynamics, i.e. levels of participation in the presence of more senior DTs, presence of dominant participants (vocal participants), and level of interest to answer the questions. The group dynamics were monitored by the moderator closely. In addition to this, prolonged engagement with the data involved reading and re-reading of the transcripts, re-analysed, and revised the themes from the FGD.

   iii. Triangulation: triangulation aims to enhance the process of qualitative research by using multiple approaches (Sim & Sharp, 1998). In this study, triangulation was achieved using different data sources, investigator, and methods of data collection (Lincoln & Guba, 1999).

- Data triangulation: the data were obtained by conducting two sessions of FGD at different places and different times.
- Investigator triangulation: investigator triangulation was achieved by involving two researchers as research team members, and involving them in addressing the organisational aspects of the study and the process of analysis. Data were analysed by two different researchers. The investigator triangulation was done by employing a colleague from the same field, i.e. the researcher (NH) and another researcher in the same department who had experience in qualitative research. Both investigators were supplied with the voice recordings from the FGD and went through the data transcriptions independently. If there were differences in opinions about the emerging themes, these were resolved through discussions. The two researchers held regular meetings during the process of data analysis (after analysing every third data set). In addition, regular analytical sessions were held with the research team.
- Method triangulation: The findings from the qualitative part of the study would be useful to support findings from the quantitative part of the study.

b) Transferability: the aim is to ensure the data obtained from the FGD can be generalised to all dental staffs that are involved in POHP. All DTs and HAs involved in the FGD were universally selected due to limited number involved in SIMSP. These participants had experience with both SIMSP and POHP. Therefore, transferability can be achieved.

c) Dependability and confirmability: the accuracy of the data was assured by relying on the audio recorder and field notes during transcription and data checking. All FGDs were performed in the same manner using a focus group guide, which using this method had supported the consistency of data collection.

3.11.5 Data analysis

The discussions were digitally recorded, and the verbatim transcript of the entire discussion was produced. The transcript was complemented with field notes taken during the FGD. The final level of analysis involved the comprehension of the possible themes and demonstrate how those themes emerged. The framework method analysis was used to analyse the FGD data (Furber, 2010; Galel, Heath, Cameron, Rashid, & Redwood, 2013). In this method, the semi structured (open ended) questionnaire prepared by the researcher contained specific domains. The procedures for analysing the qualitative data in this study followed the framework method analysis:

a) Transcription: A verbatim (word-for-word) transcription of the FGD data was done into the Malay language and later translated into English. Transcripts were done with large margins and adequate line spacing for later coding and note making. The transcription was done by the researcher (NH) and an external transcriptor (NS) by sending the audio-recording to the person. All transcriptions were manually checked and thorough discussions between the two parties (NH and NS) were held by comparing the results of each transcription. At the final discussion, it was agreed that there were no differences in the 2 sets of the transcriptions.
b) Familiarisation: The researcher familiarised herself with the FGD data by listening to the audio recorder immediately after the discussion took place for several times, and also later by reading the transcriptions. The familiarisation process took about 1 week for each FGD. In addition, the transcriptions and contextual or field notes that were recorded during the FGD were read and used to complement the audio-recording to understand the content better. The process continued until the researcher had become familiar with most of the responses and could imagine the possible themes that would emerge from the transcriptions. The whole process took about 2 weeks. The transcripts were entered into NVivo software.

c) Coding: After data familiarisation, the transcript was read carefully line by line, applying a paraphrase or label (a 'code') that described what the researcher had interpreted from the passage. At this stage 'open coding' takes place, i.e. coding anything that might be relevant from as many different perspectives as possible. Coding aims to classify the data so that they could be compared systematically with other parts of the data set. Coding was done with the help from 2 dental colleagues and another person from the public. Inputs from the public person would offer alternative viewpoints thus ensuring that one particular perspective did not dominate.

d) Developing a working analytical framework: After coding the first few transcripts, the researcher (NH) and the supervisors met together to discuss and compare the codes that were applied, and agreed on a set of codes to be applied to subsequent transcripts.

e) Applying the analytical framework: The working analytical framework was applied by indexing subsequent transcripts using the existing categories and codes using Nvivo software. Each code was assigned with the full name of the code and written directly onto the transcripts.

f) Charting data into the framework matrix: A spreadsheet was used to generate a matrix and matrix and the data were 'charted' into the matrix. The charting involved summarising the data by category from each transcript retrieved from the Nvivo software. The chart included references to interesting quotations.

g) Interpreting the data: Impressions, ideas and early interpretations of the data also was note down as additional data. Observation during FGD was also note down such as group theme, group dynamics, voice tone, etc. The findings that generated through the process can go beyond description of particular cases to explanation of, for example, reasons for the emergence of a phenomena, predicting how an organisation, or identifying areas that are not functioning well within an organization or system.

The final results of the FGD were presented in tables including the domains, themes, and verbatim explanation to support the emerging themes.

The full data collection flowchart is illustrated in **Figure 3.5.**

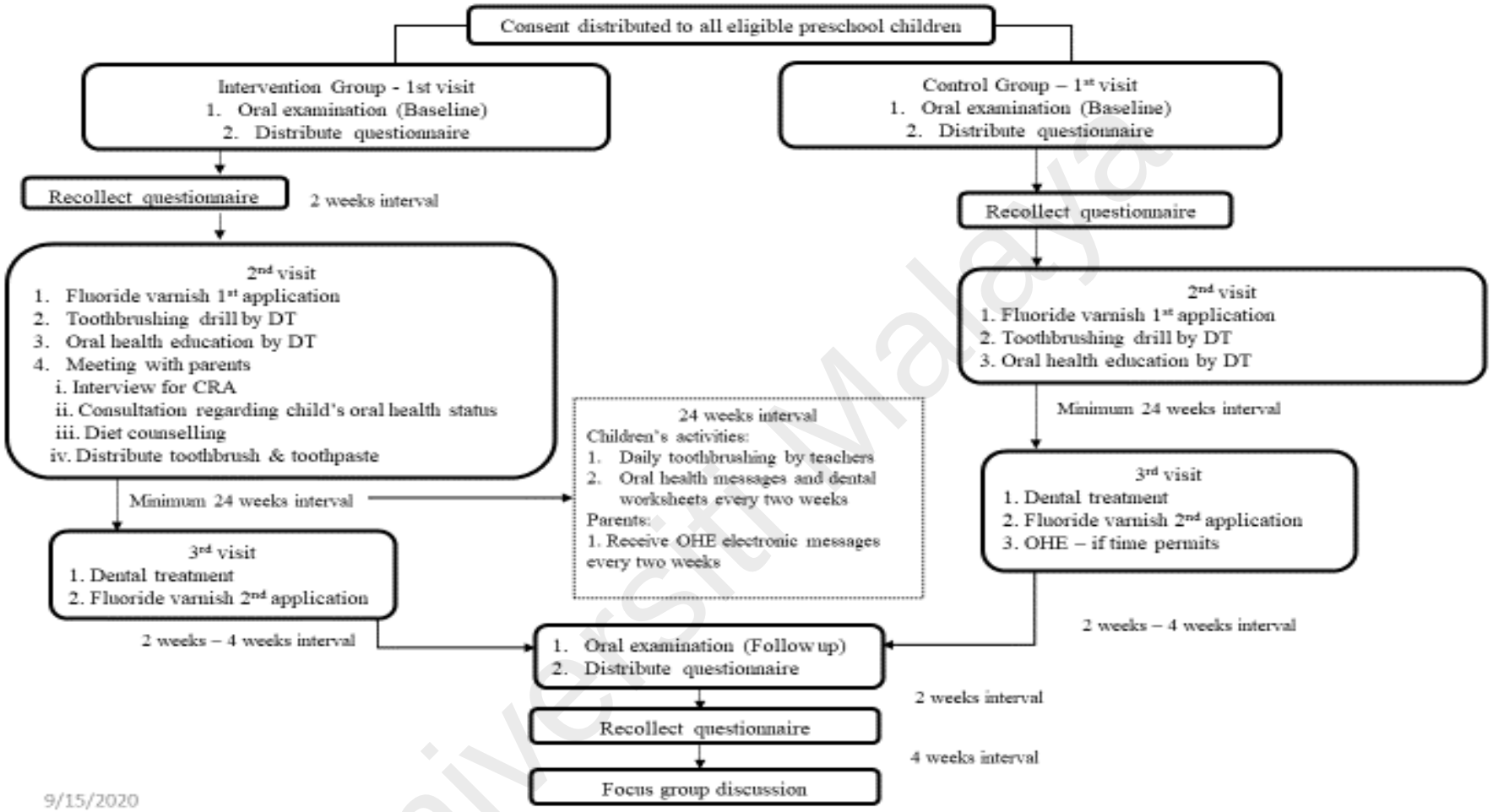

Figure 3.5: Data collection flowchart

3.12 Ethical approval for the study

The study had been approved by the Medical Ethics Committee, Faculty of Dentistry, University of Malaya [Ref: DF C01904/0004(P)] (Appendix A). Permissions to conduct the study were obtained from the Oral Health Division, Ministry of Health [Ref: KKM.600-55/7/2 Jld.5(43)] (Appendix B), Ministry of Education [Ref: KPM.600-3/2/3-eras(2834)] (Appendix C), Perak State Education Department [Ref: JPNK.SPS.UPP.600-1 Jld.2(40)] (Appendix D), Department of National Unity [Ref: JPNIN.PK.900-2/18 Jld.5(25)] (Appendix E) and Department of Community Development [Ref: PK100-11/1 JLD.61(44)] (Appendix F). The study was conducted in compliance with the principles of the Declaration of Helsinki. A written informed consent was obtained from parents/caregivers before the study began and a verbal agreement was sought from children before oral examination.

CHAPTER 4: RESULTS

4.1 Introduction

The results presented in this chapter follow the study objectives and are divided into primary objective and secondary objectives. In general, the details of the results are as follows:

i. response rate and demographic characteristics of the preschool children and their parents

ii. Primary objective: to assess the effect of the SIMSP over and above the existing POHP in improving the oral hygiene level among 5-6-year-old children in the Kampar District over 6 months

iii. Secondary objectives:

1. To assess the impact of the SIMSP over and above the existing POHP in 6 months in terms of:
    a) Children's oral health and related behaviours
    b) Parents' OHL
2. To assess the implementation fidelity of the SIMSP protocol in terms of:
    a) Parents' compliance in attending the parent-DT meeting at school.
    b) Teachers' compliance in delivering in-class OHE, dental worksheets, and supervising daily toothbrushing with the preschool children.
    c) DT's compliance in sending oral health infographics to parents via Whatsapp application (or paper infographics).
3. To undertake a process evaluation of the SIMSP by exploring the perspectives of DT on the following factors:
    a) Appropriateness of the SIMSP
    b) Effectiveness of the SIMSP

c) Facilitators to implement the SIMSP

d) Barriers to implement the SIMSP

e) Suggestions for improving the SIMSP

4.2 Response rate

The number of children who fulfilled the inclusion and exclusion criteria and consented to participate in this study was 730. **Table 4.1** shows the number of children at baseline and at 6-month follow-up. At baseline, of the 730 children, 77 were absent during data collection day. Therefore, the total number of children who underwent an oral examination was 653 with 89.5% response rate. After 6 months, 130 children had not attended the oral examination due to various reasons; 19 changed schools and 111 were absent during follow-up oral examination. The response rate at 6-month follow-up was 80.1%.

After the oral examination at baseline, the parental questionnaire was distributed to parents through the schoolteacher. Of the 653 questionnaires distributed, 517 were returned with 79.2% response rate. At 6-month follow-up, 517 questionnaires were distributed to parents, of whom 446 returned the questionnaire with 86.3% response rate as shown in **Table 4.2**.

Based on the intention to treat (ITT) analysis, data from 653 children and 517 questionnaires were analysed. The Consort flow chart of the study is presented in **Figure 4.1 (page 131).**

Table 4.1: Response rate of the sample for oral examinations by group

		Intervention	Control
i.	Initial sample size	366	364
ii.	Preschool children who were absent during data collection at baseline	22	55
		Baseline	
iii.	Number of preschool children with baseline oral examination	344	309
iv.	Response rate	94.0%	84.9%
Overall response rate		653 (89.5%)	
		Follow-up	
v.	Number of preschool children attended oral examination	287	236
vi.	Number of children who missed the oral examination	57	73
vii.	Response rate	83.4%	76.4%
Overall response rate		80.1%	
Inclusion in ITT analysis		344 (100%)	309 (100%)

Table 4.2: Response rate of the sample for self-administered questionnaire by group

		Intervention	Control
		Baseline	
i.	Number of questionnaires distributed to parents	344	309
ii.	Numbers of questionnaires not returned by parents	86	50
iii.	Number of questionnaires returned by parents	258	259
iv.	Response rate	(75.0 %)	(83.8%)
Overall response rate		517 (79.2%)	

Table 4.2: Response rate of the sample for self-administered questionnaire by group (continued)

		Follow-up	
v.	Number of questionnaires distributed to parents	258	259
vi.	Numbers of questionnaires not returned by parents	22	49
vii.	Response rate	236 (91.5%)	210 (81.1%)
Overall response rate		446 (86.3%)	
viii.	Inclusion in ITT analysis	258 (100%)	259 (100%)

Table 4.3 shows the results of retrospective power analysis calculation. It was observed that the observed power of study for the outcome measures were 1.00.

Table 4.3: Retrospective power analysis calculation

Outcome	**Effect size [a]**	**Observed power [a]**
Oral hygiene level	0.51	1.00
Oral health behaviours	0.86	1.00
OHL	0.97	1.00

[a] General linear model

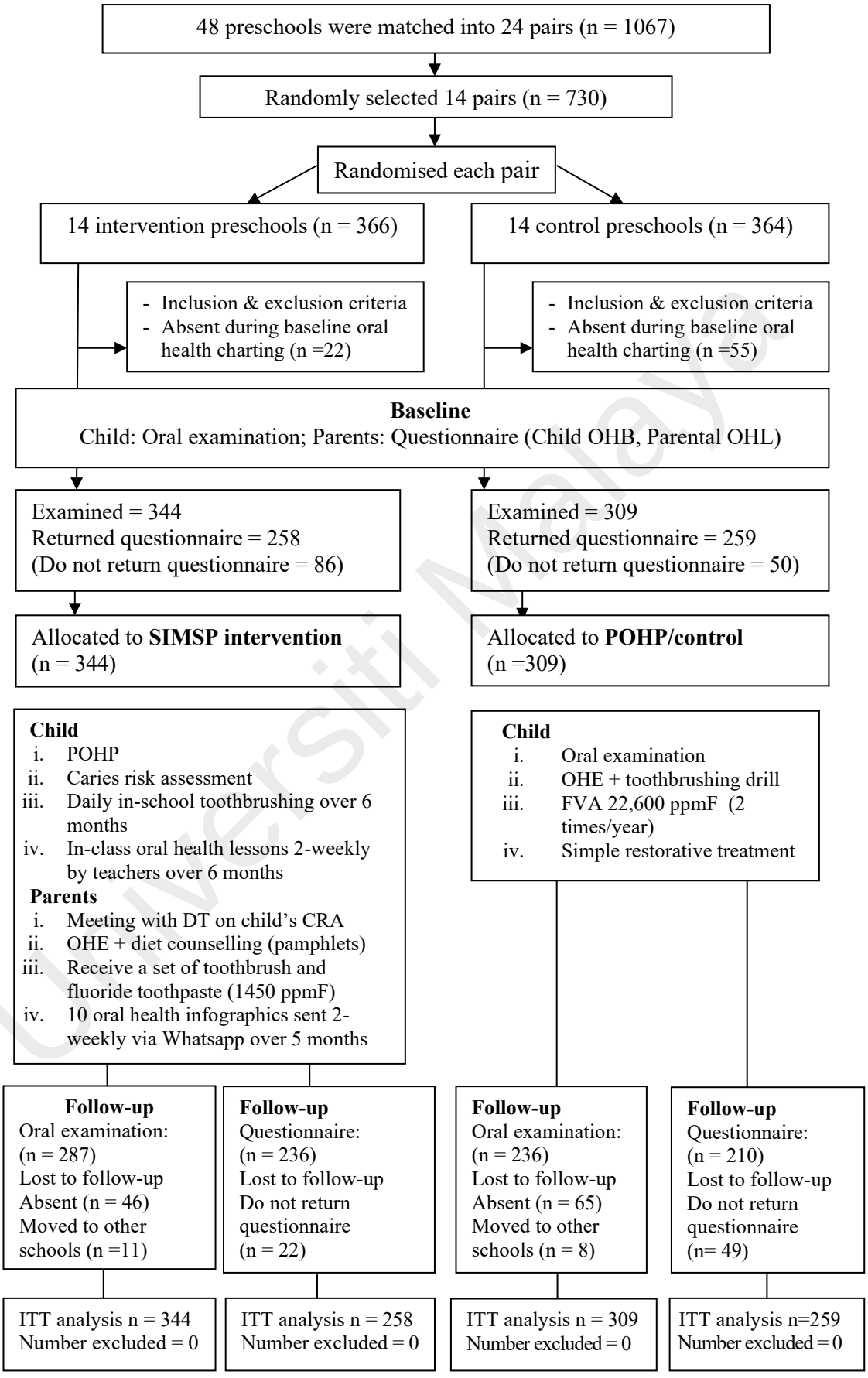

Figure 4.1: The Consort flow chart of the study

4.3 Demographic characteristics of the sample

Table 4.4 shows the demographic characteristics of the sample at baseline. Significantly more children in the intervention were male (53.5% vs 45.0%) than children in the control group. The parental questionnaire was answered mostly by mothers of preschool children. There was a significant difference in father's education level between groups, with more fathers with STPM or College diploma in the POHP group and significant number of fathers with no formal education and primary school education in the SIMSP group. There were no between-group differences in terms of parental age, types of preschool, mother's or carer's highest education level, household income and family status.

Table 4.4: Sociodemographic of children (N=653) and parents (N=517) at baseline by group

Variable	Overall, N (%)	Intervention n (%)	Control n (%)	p value [a]
Gender of child				
Male	323 (49.5)	184 (53.5)	139 (45.0)	**0.030**
Female	330 (50.5)	160 (46.5)	170 (55.0)	
Type of preschool				
National preschool	286 (43.8)	147 (42.8)	139 (45.0)	
KEMAS	258 (39.5)	135 (39.2)	123 (39.8)	0.615
Perpaduan	109 (16.7)	62 (18.0)	47 (15.2)	
Relation with child (n=517)[1]				
Mother	397 (76.8)	209 (81.0)[α]	188 (72.6)	**0.029**
Father	100 (19.3)	38 (14.7)	62 (23.9)[α]	
Caregiver	20 (3.9)	11 (4.3)	9 (3.5)	
Age category (n=497)*				
<19	3 (0.6)	0	3 (1.2)	0.504
20-29	61 (12.3)	30 (12.1)	31 (12.4)	
30-39	305 (61.4)	156 (62.9)	149 (59.8)	
40-49	115 (23.1)	56 (22.6)	59 (23.7)	
>50	13 (2.6)	6 (2.4)	7 (2.8)	

Table 4.4: Sociodemographic of children (N=653) and parents (N=523) at baseline by group (continued)

Variable	Overall, N (%)	Intervention n (%)	Control n (%)	p value [a]
Mother's / carer's highest education level (n =516)*				
No formal education	19 (3.7)	14 (5.4)	5 (1.9)	0.245
Primary school	28 (5.4)	15 (5.8)	13 (5.0)	
Secondary school	289 (56.0)	143 (55.4)	146 (56.6)	
STPM/College diploma	116 (22.5)	58 (22.5)	58 (22.5)	
University degree	64 (12.4)	28 (10.9)	36 (14.0)	
Father's highest education level (n = 507)*				
No formal education	12 (2.4)	11 (4.4) [α]	1 (0.4)	**0.001**
Primary school	40 (7.9)	28 (11.1) [α]	12 (4.7)	
Secondary school	303 (59.8)	148 (58.7)	155 (60.8)	
STPM/College diploma	112 (22.1)	46 (18.3)	66 (25.9) [α]	
University degree	40 (7.9)	19 (7.5)	21 (8.2)	
Household income (n =516)*				
No fixed monthly income	54 (10.5)	29 (11.2)	25 (9.7)	0.161
< 1000	77 (14.9)	48 (18.6)	29 (11.2)	
1001 – 1999	163 (31.6)	77 (29.8)	86 (33.3)	
2000 – 3999	125 (24.2)	63 (24.4)	62 (24)	
4000 – 4999	43 (8.3)	19 (7.4)	24 (9.3)	
> 5000	54 (10.5)	22 (8.5)	32 (12.4)	
Family status (n =516)*				
Traditional family	482 (93.4)	242 (93.8)	240 (93.0)	0.723
Divorced / single parent	34 (6.6)	16 (6.2)	18 (7.0)	

[a] Pearson Chi Square; [1] This information is derived from the questionnaire (N = 517); *sample did not equal to 517 due to missing data; [α] Z score >1.96 indicating significant difference; figure in bold indicates p<0.05

4.4 Baseline caries status of the children

Table 4.5 shows no significant difference in caries prevalence (by person) of primary teeth between the SIMSP and POHP groups at baseline.

Table 4.5: Caries prevalence at baseline at person level by group (N=653)

	Overall, n (%)	Intervention n=344, n (%)	Control n=309, n (%)	p value[a]
Sound / Non cavitated teeth ($ICDAS_{0-2}$)	29 (4.4)	13 (3.8)	16 (5.2)	0.386
Cavitated teeth ($ICDAS_{3-6}$)	624 (95.6)	331 (96.2)	293 (94.8)	

[a] Pearson Chi square

Table 4.6 shows no significant difference in caries prevalence (by teeth) of primary teeth between the SIMSP and POHP groups at baseline.

Table 4.6: Prevalence of caries at baseline at teeth level by group (N=12940)

	Overall, n (%)	Intervention n (%)	Control n (%)	p value[a]
Sound teeth ($ICDAS_{0}$)	2617 (20.2)	1393 (20.4)	1224 (19.9)	0.221
Non cavitated caries ($ICDAS_{1-2}$)	6095 (47.1)	3163 (46.5)	2932 (47.7)	
Cavitated caries ($ICDAS_{3-6}$)	4266 (32.9)	2283 (33.4)	1983 (32.3)	
	12940	6839	6139	

[a] Pearson Chi square

4.5 To assess the effect of the SIMSP over and above the existing POHP in improving oral hygiene level among 5-6-year-old children in the Kampar District over 6 months (Primary Objective)

This section describes the findings of the primary objective. Table 4.7 shows the proportions of schoolchildren with visible dental plaque on the labial surfaces of upper anterior teeth from 53 to 63 by group.

At baseline, there was no significant difference in the proportions of children with plaque between groups. However, at follow-up there was a significant difference ($p < 0.05$) between groups with significantly more children in the SIMSP (43.9%) had "teeth appear clean" compared to children in the POHP (35.6%).

Alternatively, the SIMSP (56.1%) had a significantly lower proportion of preschool children with "presence of plaque" compared to the POHP (64.4%) ($p < 0.05$). For within-group comparison, the SIMSP showed a significant change ($p < 0.001$) where the proportion of preschool children with "teeth appear clean" had increased from 31.1% at baseline to 43.9% after 6 months.

Table 4.7: Proportions of children with visible dental plaque at baseline and follow-up by group (N=653)

	Overall	**Intervention**	**Control**	**p value[a]**
Baseline	n=653	n = 344	n = 309	
Teeth appear clean, n (%)	206 (31.5)	107(31.1)	99 (32.0)	0.798
Presence of plaque, n (%)	447 (68.5)	237 (68.9)	210 (68.0)	
Follow-up	n=523	n = 287	n = 236	
Teeth appear clean, n (%)	261 (40.0)	151 (43.9)	110 (35.6)	**0.031**
Presence of plaque, n (%)	392 (60.0)	193 (56.1)	199 (64.4)	
p-value[b]		**<0.001**	0.222	

[a] Pearson Chi Square for between-group comparison; [b] McNemar test for within-group comparison; figure in bold indicates $p<0.05$

Table 4.8 shows changes in mean plaque score between baseline and follow-up after 6 months. At baseline there was no significant difference in mean plaque score between the SIMSP and the POHP. At follow-up, the p-value was significant (p = 0.046) with mean plaque score in the SIMSP was lower than that in the POHP. For mean plaque decrement score, the SIMSP showed higher mean decrement score (mean = -0.26, SD = 0.84) than that in POHP (mean = -0.19, SD = 0.69). The effect size was + 0.64 which represents medium effect size. For within-group comparison, both the SIMSP and POHP showed significant reduction in mean plaque score.

Table 4.8: Changes in mean plaque score at baseline and follow-up by group (N=653)

		Overall (n=653)	**Intervention (n=344)**	**Control (n=309)**	**p value[a]**	**Effect size**	**Effect size descriptor**
Plaque score	Baseline score Mean (± SD)	1.05 (0.83)	1.03 (0.81)	1.07 (0.84)	0.489		
	Follow-up Mean (± SD)	0.82 (0.78)	0.76 (0.78)	0.89 (0.77)	**0.046**		
	Mean increment score (±SD)	-0.23 (0.77)	-0.26 (0.84)	-0.19 (0.69)	0.201	0.64	Medium
	p-value[b]	**<0.001**	**<0.001**	**<0.001**			
	Effect size		0.12	0.07			
	Effect size descriptor		small	small			

[a] Independent sample T-test; [b] Paired sample T test; SD = standard deviation; ES = effect size; figure in bold indicates $p < 0.05$

Table 4.9 shows the proportions of children with overall plaque score changes, either decrement, increment or no change, between the groups over 6 months. At follow-up, there was a significant difference between the SIMSP and POHP where a significantly higher proportion of children in the SIMSP (9.0%) had an overall plaque score decrement from score 2 to 0 than children in the POHP (3.2%). Also, a significantly higher proportion of children in the POHP (14.9%) had an overall plaque score decrement from score 2 to 1 compared to children in the SIMSP (9.9%).

Table 4.9: Plaque score change after 6 months by group

	Overall n=653, n (%)	**Intervention n (%)**	**Control n (%)**	**p value[a]**
Decrement				
2 – 1	80 (12.3)	34 (9.9)	46 (14.9) [α]	**0.002**
1 – 0	70 (10.7)	41 (11.9)	29 (9.4)	
2- 0	41 (6.3)	31 (9.0) [α]	10 (3.2)	
Increment				
0 – 1	48 (7.4)	21 (6.1)	27 (8.7)	0.059
1 – 2	22 (3.4)	14 (4.1)	8 (2.6)	
0 - 2	7 (0.1)	6 (1.7)	1 (0.3)	
No change				
0-0	149 (22.8)	78 (22.7)	71 (23.0)	0.246
1-1	113 (17.3)	62 (18.0)	51 (16.5)	
2-2	115 (17.6)	51 (14.8)	64 (20.7)	

[a] Pearson Chi square test; [α]Z score >1.96 indicating significant difference;
bold figure indicating $p < 0.05$

Table 4.10 shows the proportions of anterior teeth with overall plaque score changes, either decrement, increment or no change, between the groups over 6 months. At follow-up, there was a significant difference between the SIMSP and POHP where a significantly higher proportion of children in the SIMSP (7.9%) had an overall plaque score decrement from score 1 to 0 than children in the POHP (4.4%). Also, a significantly higher proportion of children in the POHP (3.4%) had an overall plaque score increment from score 0 to 1 compared to children in the SIMSP (3.0%).

Table 4.10: Plaque score change in anterior teeth after 6 months by group (n = 3541)

	Overall	**Intervention**	**Control**	**p value[a]**
Plaque changes				
Decrement				
2 – 1	166 (4.69)	67 (1.89)	99 (2.80)	**<0.001**
1 – 0	433 (12.23)	278 (7.85) [α]	155 (4.38)	
2- 0	178 (5.03)	123 (3.47)	55 (1.55)	
Increment				
0 – 1	226 (6.38)	106 (2.99)	120 (3.39) [α]	**<0.001**
1 – 2	45 (1.27)	29 (0.82)	16 (0.45)	
0 - 2	46 (1.30)	36 (1.02)	10 (0.28)	
No change				
0-0	1647 (46.51)	849 (23.98) [α]	798 (22.54)	**<0.001**
1-1	541 (15.28)	232 (6.55)	309 (8.73)	
2-2	259 (7.31)	116 (3.28)	143 (4.04)	

[a]Pearson Chi square test; [α] Z score >1.96 indicating significant difference; bold figure indicating $p < 0.05$

Table 4.11 shows proportions of schoolchildren with 'teeth appear clean', 'a little plaque' and 'substantial amount of plaque' on the labial surfaces of upper anterior teeth from 53 to 63 by group.

At baseline, all teeth showed no significant differences between the SIMSP and POHP in terms of dental plaque levels. However, at follow-up, significant differences in dental plaque levels were seen on 52, 62, 63 where higher proportions of children in the SIMSP had 'teeth appear clean' than children in the POHP.

Table 4.11: Proportions of anterior teeth (53 to 63) with dental plaque levels at baseline and follow-up by group (n=653)

		Baseline				Follow-up			
		Overall* n (%)	**Intervention n (%)**	**Control n (%)**	**p value[a]**	**Overall**	**Intervention n (%)**	**Control n (%)**	**p value[a]**
53	Teeth appear clean	268 (41.6)	144 (42.5)	124 (40.5)	0.754	332 (51.5)	188 (55.5)	144 (47.1)	0.076
	A little plaque	223 (34.6)	118 (34.8)	105 (34.3)		220 (34.1)	103 (30.4)	117 (38.2)	
	Substantial amount of plaque	154 (23.9)	77(22.7)	77 (25.2)		93 (14.4)	48 (14.2)	45 (14.7)	
52	Teeth appear clean	319 (54.9)	159 (53.7)	160 (56.1)	0.496	388 (66.8)	213 (72.0)$^{\alpha}$	175 (61.4)	**0.014**
	A little plaque	182 (31.3)	99 (33.4)	83 (29.1)		147 (25.3)	60 (20.3)	87 (30.5)$^{\alpha}$	
	Substantial amount of plaque	80 (13.8)	38 (12.8)	42(14.7)		46 (7.9)	23 (7.8)	23 (8.1)	
51	Teeth appear clean	373 (68.3)	194 (69.3)	179 (67.3)	0.876	409 (74.9)	220 (78.6)	189 (71.1)	0.077
	A little plaque	122 (22.3)	61 (21.8)	61 (22.9)		104 (19.0)	43 (15.4)	61 (22.9)	
	Substantial amount of plaque	51 (9.3)	25 (8.9)	26 (9.8)		33 (6.0)	17 (6.1)	16 (6.0)	

[a] Pearson Chi Square for between group comparison; *sample did not equal to 653 due to missing data ; $^{\alpha}$Z score >1.96 indicating significant difference; figure in bold indicates $p < 0.05$

Table 4.11: Proportions of anterior teeth (53 to 63) with dental plaque levels at baseline and follow-up by group (n=653) (continued)

		Baseline				Follow-up			
		Overall* n (%)	**Intervention n (%)**	**Control n (%)**	**p value[a]**	**Overall**	**Intervention n (%)**	**Control n (%)**	**p value[a]**
61	Teeth appear clean	372 (67.3)	195 (67.7)	177 (66.8)	0.568	422 (76.3)	229 (79.5)	193 (72.8)	0.130
	A little plaque	125 (22.6)	61 (21.2)	64 (24.2)		102 (18.4)	44 (15.3)	58 (21.9)	
	Substantial amount of plaque	56 (10.1)	32 (11.1)	24 (9.1)		29 (5.2)	15 (5.2)	14 (5.3)	
62	Teeth appear clean	321 (55.5)	161 (53.8)	160 (57.3)	0.699	391 (67.6)	218 (72.9) [α]	173 (62.0)	**0.006**
	A little plaque	160 (27.7)	86 (28.8)	74 (26.5)		127 (22.0)	50 (16.7)	77 (27.6) [α]	
	Substantial amount of plaque	97 (16.8)	52 (17.4)	45 (16.1)		60 (10.4)	31 (10.4)	29 (10.4)	
63	Teeth appear clean	257 (40.2)	135 (40.3)	122 (40.1)	0.847	316 (49.5)	183 (54.6) [α]	133 (43.8)	**0.010**
	A little plaque	222 (34.7)	119 (35.5)	103 (33.9)		236 (36.9)	106 (31.6)	130 (42.8) [α]	
	Substantial amount of plaque	160 (25.0)	81 (24.2)	79 (26.0)		87 (13.6)	46 (13.7)	41 (13.5)	

[a] Pearson Chi Square for between group comparison; *sample did not equal to 653 due to missing data; [α]Z score >1.96 indicating significant difference; figure in bold indicates $p < 0.05$

Table 4.12 shows the proportions of children with the presence of plaque, i.e. 'teeth appear clean' or 'teeth with presence of plaque' on the anterior surfaces on 53 to 63. At baseline, there was no significant difference in the proportions of children with dental plaque on 53 to 63 between the SIMSP and POHP. At follow-up, significant differences ($p<0.05$) were seen on 53, 52, 51, 62, and 63 where higher proportions of children in the SIMSP had 'teeth appear clean' than children in the POHP.

Table 4.12: Proportions of anterior teeth (53 to 63) with presence of plaque at baseline and follow-up by group

		Baseline				Follow-up			
		Overall* n (%)	**Intervention n (%)**	**Control n (%)**	**p value[a]**	**Overall* n (%)**	**Intervention n (%)**	**Control n (%)**	**p value[a]**
53	Teeth appear clean	268 (41.6)	144 (42.5)	124 (40.5)	0.615	332 (51.5)	188 (55.5)	144 (47.1)	**0.033**
	Presence of plaque	377 (58.4)	195 (57.5)	182 (59.5)		313 (48.5)	151 (44.5)	162 (52.9)	
52	Teeth appear clean	319 (54.9)	159 (53.7)	160 (56.1)	0.557	388 (66.8)	213 (72.0)	175 (61.4)	**0.007**
	Presence of plaque	262 (45.1)	137 (46.3)	125 (43.9)		193 (33.2)	83 (28.0)	110 (38.6)	
51	Teeth appear clean	373 (68.3)	194 (69.3)	179 (67.3)	0.617	409 (74.9)	220 (78.6)	189 (71.1)	**0.043**
	Presence of plaque	173 (31.7)	86 (30.7)	87 (32.7)		137 (25.1)	60 (21.4)	77 (28.9)	
61	Teeth appear clean	372 (67.3)	195 (67.7)	177 (66.8)	0.819	422 (76.3)	229 (79.5)	193 (72.8)	0.065
	Presence of plaque	181 (32.7)	93 (32.3)	88 (33.2)		131 (23.7)	59 (20.5)	72 (27.2)	
62	Teeth appear clean	321 (55.5)	161 (53.8)	160 (57.3)	0.397	391 (67.6)	218 (72.9)	173 (62.0)	**0.005**
	Presence of plaque	257 (44.5)	138 (46.2)	119 (42.7)		187 (32.4)	81 (27.1)	106 (38.0)	
63	Teeth appear clean	257 (40.2)	135 (40.3)	122 (40.1)	0.966	316 (49.5)	183 (54.6)	133 (43.8)	**0.006**
	Presence of plaque	382 (59.8)	200 (59.7)	182 (59.9)		323 (50.5)	152 (45.4)	171 (56.3)	

[a] Pearson Chi Square for between group comparison; *sample did not equal to 653 due to missing data; figure in bold indicates $p < 0.05$

Table 4.13 shows changes in mean plaque score for anterior teeth (53 to 63) after 6 months by group. At baseline, all teeth showed no significant difference in mean plaque score between the SIMSP and POHP. At follow-up, between-group results showed a significant difference in mean plaque score for 52 and 62. For 52, children in the SIMSP had lower mean plaque score (mean = 0.35, SD = 0.61) than children in the POHP (mean = 0.44, SD = 0.62) ($p = 0.013$). While for 62, children in the SIMSP had lower mean plaque score (mean = 0.36, SD = 0.66) than children in the POHP (mean = 0.48, SD = 0.68) ($p = 0.047$). At the same time, there were significant differences in mean plaque decrement score for 52 and 62 between the SIMSP and POHP. The effect size for 52 and 62 was 0.42 each which represents small effect size. The range of effect sizes for differences in mean plaque decrement score between the groups were small (0.31) to medium (0.55 for tooth 56) favouring the SIMSP.

Over the period of 6 months, within-group comparison showed all teeth had a significant decrement in mean plaque score for both groups. However, the magnitude of improvement in terms of effect sizes were consistently higher in the SIMSP group.

Table 4.13: Changes in mean plaque score for anterior teeth (53 to 63) after 6 months by group

Tooth		Overall	Intervention	Control	p value[a]	Effect size	ES descriptor
53	Baseline Mean (+ SD)	0.82 (0.79)	0.80 (0.78)	0.84 (0.80)	0.493		
	Follow-up Mean (+ SD)	0.63 (0.72)	0.58 (0.72)	0.67 (0.72)	0.071		
	Mean increment (+ SD)	-0.13 (1.01)	-0.17 (1.01)	-0.09 (1.00)	0.377	0.55	Medium
	p value[b]	**<0.001**	**<0.001**	**<0.001**			
	Effect size		0.29	0.13			
	ES Descriptor		Small	Small			
52	Baseline Mean (+ SD)	0.59 (0.72)	0.59 (0.70)	0.57 (0.72)	0.774		
	Follow-up Mean (+ SD)	0.40 (0.62)	0.35 (0.61)	0.44 (0.62)	**0.013**		
	Mean increment (+ SD)	-0.182 (0.67)	-0.2396 (0.74)	-0.127 (0.58)	**0.040**	0.42	Small
	p value[b]	**<0.001**	**<0.001**	**<0.001**			
	Effect size		0.365	0.19			
	ES Descriptor		Small	Small			
51	Baseline Mean (+ SD)	0.41 (0.65)	0.39 (0.65)	0.41(0.67)	0.608		
	Follow-up Mean (+ SD)	0.30 (0.58)	0.27 (0.56)	0.33 (0.60)	0.060		
	Mean increment (+ SD)	-0.10 (0.62)	-0.13 (0.66)	-0.08(0.57)	0.389	0.31	Small
	p value[b]	**<0.001**	**0.002**	**0.029**			
	Effect size		0.25	0.13			
	ES Descriptor		Small	Small			

[b] Paired Sample T Test; [c] Mann Whitney test; SD = standard deviation; ES = effect size; figure in bold indicates $p < 0.05$

Table 4.13: Changes in mean plaque score for anterior teeth (53 to 63) after 6 months by group (continued)

Tooth		Overall	Intervention	Control	p value[c]	Effect size	ES descriptor
61	Baseline Mean (+ SD)	0.43 (0.67)	0.44 (0.69)	0.40 (0.65)	0.970		
	Follow-up Mean (+ SD)	0.28 (0.55)	0.25 (0.54)	0.30 (0.55)	**0.081**		
	Mean increment (+ SD)	-0.15 (0.64)	-0.18 (0.72)	-0.10 (0.54)	0.143	0.32	Small
	p value[b]	**<0.001**	**<0.001**	**0.003**			
	Effect size		0.31	0.17			
	ES Descriptor		Small	Small			
62	Baseline Mean (+ SD)	0.61 (0.76)	0.63 (0.44)	0.59 (0.75)	0.420		
	Follow-up Mean (+ SD)	0.43 (0.67)	0.36 (0.66)	0.48 (0.68)	**0.014**		
	Mean increment (+ SD)	-0.19 (0.75)	-0.26 (0.82)	-0.11 (0.65)	**0.010**	0.42	Small
	p value[b]	**<0.001**	**<0.001**	**0.007**			
	Effect size		0.48	0.15			
	ES Descriptor		Small	Small			
63	Baseline Mean (+ SD)	0.85 (0.79)	0.83 (0.79)	0.84 (0.80)	0.778		
	Follow-up Mean (+ SD)	0.63 (0.70)	0.59 (0.72)	0.68 (0.68)	**0.026**		
	Mean increment (+ SD)	-0.209 (0.73)	-0.25 (0.78)	-0.16 (0.66)	0.137	0.56	Medium
	p value[b]	**<0.001**	**<0.001**	**<0.001**			
	Effect size		0.32	0.22			
	ES Descriptor		Small	Small			

[b] Paired Sample T Test; [c] Mann Whitney test; SD = standard deviation; ES = effect size; figure in bold indicates $p < 0.05$

Table 4.14 shows between group changes in mean plaque score at baseline and follow-up by different facial sides. At baseline, both right and left sides had no significant difference in mean plaque score between the SIMSP and POHP. At follow-up, between-group results showed a significant difference in mean plaque score (p=0.016) for left side (61-63). At follow up, for teeth 51-53, children in the SIMSP had higher mean plaque score decrement (mean = 0.59, SD = 1.77) than children in the POHP (mean = 0.35, SD = 1.42) (p = 0.013). As for 61-63, mean plaque score decrement in SIMSP was higher (mean = 0.69, SD = 1.97) than children in the POHP (mean = 0.34, SD = 1.42) and the difference was statistically significant (p = 0.019). The effect size for both sides were 0.50 which represents medium effect size.

Table 4.14: Between group changes in mean plaque score at baseline and follow-up by different facial sides

	51-53						61-63					
	Overall	Intervention	Control	*p*-value [a]	ES	ES descriptor	Overall	Intervention	Control	*p*-value [a]	ES	ES descriptor
Baseline Mean (+ SD)	1.76 (1.87)	1.75 (1.85)	1.77 (1.88)	0.869			1.84 (2.00)	1.84 (1.96)	1.84 (1.95)	0.983		
Follow-up Mean (+ SD)	1.29 (1.61)	1.16 (1.58)	1.43 (1.64)	0.052			1.32 (1.65)	1.16 (1.64)	1.50 (1.65)	**0.016**		
Mean increment (+ SD)	-0.47 (1.61)	-0.59 (1.77)	-0.35 (1.42)	0.78	0.50	Medium	-0.52 (1.74)	-0.69 (1.97)	-0.34 (1.42)	**0.019**	0.50	Medium
p value[b]	**<0.001**	**<0.001**	**<0.001**				**<0.001**	**<0.001**	**<0.001**			

[a] Independent sample T-test; [b] Paired sample T-test; SD = standard deviation; ES= Effect size; figure in bold indicates $p < 0.05$

Table 4.15 shows stratification of plaque score change based on caries risk group in the SIMSP group by proportion. A significant association was observed between plaque score change and CRA levels after 6 months. A significantly higher proportion of preschool children in the high CRA level had a decrement in plaque score after 6 months than children in the moderate or low CRA levels. A significantly higher proportion of children in the moderate CRA level group had no change in plaque score after 6 months than children in the high or low CRA level groups.

Table 4.15: Stratification of overall plaque score change based on caries risk group in the SIMSP

Plaque score change	**Overall**	**CRA levels, n (%)**			
		Low	**Moderate**	**High**	**p value[a]**
Increment	42 (12.2)	2 (50.0)	10 (15.9)	30 (10.9)	**<0.001**
Decrement	106 (31.4)	0	5 (9.5)	101 (37.0) [α]	
No change	192 (56.4)	2 (50.0)	47 (74.6) [α]	143 (52.2)	
Total, n (%)	340 (100)	4 (1.5)	62 (18.3)	274 (80.2)	

[a] Pearson Chi Square test; [α] Z score >1.96 indicating significant difference, bold figure indicating $p < 0.05$

Table 4.16 shows stratification of mean plaque score change based on caries risk group in the SIMSP group. A significant within group mean decrement was observed ($p<0.001$) among preschool children in the high CRA after 6 months than children in the moderate or low CRA levels.

Table 4.16: Mean plaque score based on caries risk group in the SIMSP at baseline and follow-up

Mean plaque score	Overall	CRA levels			
		Low	Moderate	High	p value[a]
Baseline, Mean (+SD)	1.03 (0.81)	0.25 (0.50) $^{\alpha}$	0.24 (0.53) $^{\beta}$	1.22 (0.75) $^{\alpha, \beta}$	**<0.001**
Follow-up, Mean (+SD)	0.76 (0.78)	1.0 (1.16)	0.35 (0.63) $^{\alpha}$	0.85 (0.78) $^{\alpha}$	**<0.001**
Increment, Mean (+SD)	-0.23 (0.77)	0.75 (0.96) $^{\alpha}$	0.11 (0.73) $^{\beta}$	-0.36 (0.83) $^{\alpha, \beta}$	**<0.001**
p value[b]	**<0.001**	0.215	0.226	**<0.001**	

[a] One-way Anova; [b] Paired sample T-test; bold figure indicating $p < 0.05$; $^{\alpha, \beta}$ Difference statistically significant (Tukey's Test)

Table 4.17 shows proportions of anterior teeth (53 to 63) with presence of plaque at baseline and follow-up stratified by caries risk levels for the SIMSP group. At baseline, a trend was observed that higher proportions of children from the high risk group had "substantial amount of plaque" on their anterior teeth. At follow-up, a trend was observed that higher proportions of children from high risk group that had "teeth appear clean" for all teeth compared to baseline. Significant change was not seen in children from low risk group.

Table 4.17: Proportions of anterior teeth (53 to 63) with presence of plaque at baseline and follow-up stratified by caries risk levels for SIMSP group (N=344)

Caries risk level	Baseline					Follow-up				
	n (%)	Teeth appear clean n (%)	A little plaque n (%)	Substantial amount of plaque n (%)	p value[a]	n (%)	Teeth appear clean n (%)	A little plaque n (%)	Substantial amount of plaque n (%)	p value[a]
53										
Low	4 (1.2)	3 (2.1)	1 (0.8)	0	**<0.001**	4 (1.2)	2 (1.1)	1 (1.0)	1 (2.1)	**0.004**
Moderate	62 (18.3)	51 (35.4) $^{\alpha}$	10 (8.5)	1 (1.3)		62 (18.3)	48 (25.5) $^{\alpha}$	11 (10.7)	3 (6.3)	
High	273 (80.5)	90 (62.5)	107 (90.7) $^{\alpha}$	76 (98.7) $^{\alpha}$		273 (80.5)	138 (73.4)	91 (88.3) $^{\alpha}$	44 (91.7)	
Total, n (%)	339*	144 (42.5)	118 (34.8)	77 (22.7)		339*	188 (55.5)	103 (30.4)	48 (14.1)	
52										
Low	4 (1.4)	3 (1.9)	1 (1.0)	0	**<0.001**	4 (1.4)	2 (0.9)	1 (1.7)	1 (4.3)	0.065
Moderate	58 (19.6)	49 (30.8) $^{\alpha}$	8 (8.1)	1 (2.6)		58 (19.6)	50 (23.5) $^{\alpha}$	6 (10.0)	2 (8.7)	
High	234 (79.0)	107 (67.3)	90 (90.9) $^{\alpha}$	37 (97.4) $^{\alpha}$		234 (79.0)	161 (75.6)	53 (88.3) $^{\alpha}$	20 (87.0)	
Total, n (%)	296*	159 (53.7)	99 (33.4)	38 (12.9)		296*	213 (72.0)	60 (20.3)	23 (7.8)	
51										
Low	4 (1.4)	4 (2.1)	0	0	**0.001**	4 (1.4)	2 (0.9)	1 (2.3)	1 (5.9)	**0.050**
Moderate	57 (20.4)	52 (26.8) $^{\alpha}$	3 (4.9)	2 (8.0)		57 (20.4)	52 (23.6) $^{\alpha}$	4 (9.3)	1 (5.9)	
High	219 (78.2)	138 (71.1)	58 (95.1) $^{\alpha}$	23 (92.0)		219 (78.2)	166 (75.5)	38 (88.4)	15 (88.2)	
Total, n (%)	280*	194 (69.3)	61 (21.8)	25 (8.9)		280*	220 (78.5)	43 (15.4)	17 (6.1)	

[a] Pearson Chi Square test; $^{\alpha}$Z score >1.96 indicating significant difference, * sample did not equal to 344 due to missing data; figure in bold indicates $p < 0.05$

Table 4.17: Proportions of anterior teeth (53 to 63) with presence of plaque at baseline and follow-up stratified by caries risk levels for SIMSP group (N=344)

Caries risk levels	Baseline					Follow-up				
	n (%)	Teeth appear clean n (%)	A little plaque n (%)	Substantial amount of plaque n (%)	p value[a]	n (%)	Teeth appear clean n (%)	A little plaque n (%)	Substantial amount of plaque n (%)	p value[a]
61										
Low	4 (1.4)	4 (2.1)	0	0	**<0.001**	4 (1.4)	2 (0.9)	1 (2.3)	1 (6.7)	**0.006**
Moderate	60 (20.8)	56 (28.7) [α]	3 (4.9)	1 (3.1)		60 (20.8)	57 (24.9) [α]	2 (4.5)	1 (6.7)	
High	224 (77.8)	135 (69.2)	58 (95.1) [α]	31 (96.9) [α]		224 (77.8)	170 (74.2)	41 (93.2) [α]	13 (86.7)	
Total, n (%)	288*	195 (67.7)	61 (21.2)	32 (11.1)		288*	229 (79.5)	44 (15.3)	15 (5.2)	
62										
Low	4 (1.4)	4 (2.5)	0	0	**<0.001**	4 (1.4)	2 (0.9)	0	2 (6.5) [α]	**0.004**
Moderate	58 (19.4)	51 (31.7) [α]	6 (7.0)	1 (1.9)		58 (19.4)	51 (23.4) [α]	4 (8.0)	3 (9.7)	
High	237 (79.3)	106 (65.8)	80 (93.0) [α]	51 (98.1) [α]		237 (79.3)	165 (75.7)	46 (92.0) [α]	26 (83.9)	
Total, n (%)	299*	161 (53.8)	86 (28.8)	52 (17.4)		299*	218 (72.9)	50 (16.7)	31 (10.4)	
63										
Low	4 (1.2)	4 (3.0) [α]	0	0	**<0.001**	4 (1.2)	2 (1.1)	1 (0.9)	1 (2.2)	**0.001**
Moderate	62 (18.5)	52 (38.5) [α]	9 (7.6)	1 (1.2)		62 (18.5)	49 (26.8) [α]	9 (8.5)	4 (8.7)	
High	269 (80.3)	79 (58.5)	110 (92.4) [α]	80 (98.8) [α]		269 (80.3)	132 (72.1)	96 (90.6) [α]	41 (89.1)	
Total, n (%)	335*	135 (40.3)	119 (35.5)	81 (24.2)		335*	183 (54.6)	106 (31.6)	46 (13.7)	

[a] Pearson Chi Square test; [α]Z score >1.96 indicating significant difference, * sample did not equal to 344 due to missing data; figure in bold indicates $p < 0.05$

Table 4.18 shows changes in mean plaque score for anterior teeth (53 to 63) after 6 months in SIMSP stratified by caries risk levels. Over the period of 6 months, results consistently showed larger decrement of mean plaque score in high risk group than those in low and moderate risk groups. The effect size for 52 and 62 was 0.521 and 0.540 respectively which represents medium effect size.

Table 4.18: Changes in mean plaque score for anterior teeth (53 to 63) after 6 months in SIMSP by caries risk levels

Tooth		Overall	Low	Moderate	High	p value[a]	Effect size	ES descriptor
53	Baseline Mean (+ SD)	0.77 (0.78)	0.25 (0.44) $^{\beta}$	0.19 (0.44) $^{\beta}$	0.92 (0.78) $^{\alpha, \beta}$	**<0.001**		
	Follow-up Mean (+ SD)	0.54 (0.70)	0.75 (0.85) $^{\alpha, \beta}$	0.26 (0.54) $^{\alpha, \beta}$	0.61 (0.72) $^{\beta}$	**0.001**		
	Mean increment (+ SD)	-0.23(0.77)	0.50 (0.51)	0.07 (0.63) $^{\beta}$	-0.31 (0.78) $^{\beta}$	**0.001**	0.521	Medium
	p value[b]	**0.018**	**<0.001**	**0.044**	**0.021**			
52	Baseline Mean (+ SD)	0.59 (0.71)	0.25 (0.44) $^{\alpha}$	0.17 (0.42) $^{\beta}$	0.70 (0.73) $^{\alpha, \beta}$	**<0.001**		
	Follow-up Mean (+ SD)	0.36 (0.62)	0.75 (0.85) $^{\alpha}$	0.17 (0.45) $^{\beta}$	0.40 (0.64) $^{\alpha, \beta}$	**0.021**		
	Mean increment (+ SD)	-0.23 (0.74)	0.50 (0.89)	-0.01 (0.48) $^{\beta}$	-0.30 (0.77) $^{\beta}$	**0.002**	0.424	Small
	p value[b]	**0.018**	**0.011**	0.823	**0.021**			
51	Baseline Mean (+ SD)	0.40 (0.65)	0.00 (0) $^{\alpha}$	0.12 (0.42) $^{\beta}$	0.48 (0.68) $^{\alpha, \beta}$	**0.001**		
	Follow-up Mean (+ SD)	0.27 (0.57)	0.75 (0.85) $^{\alpha}$	0.11 (0.36) $^{\beta}$	0.31 (0.59) $^{\alpha, \beta}$	**0.012**		
	Mean increment (+ SD)	0.12 (0.65)	0.75 (0.85) $^{\alpha}$	-0.02 (0.40) $^{\beta}$	-0.17 (0.69) $^{\alpha, \beta}$	**0.008**	0.299	Small
	p value[b]	**0.016**	**<0.001**	0.415	**0.019**			
61	Baseline Mean (+ SD)	0.44 (0.69)	0	0.08 (0.34) $^{\beta}$	0.54 (0.73) $^{\beta}$	**<0.001**		
	Follow-up Mean (+ SD)	0.26 (0.55)	0.75 (0.85) $^{\alpha}$	0.07 (0.31) $^{\alpha, \beta}$	0.30 (0.57) $^{\beta}$	**0.002**		
	Mean increment (+ SD)	-0.18 (0.71)	0.75 (0.85)	-0.02 (0.30) $^{\beta}$	-0.24 (0.76) $^{\beta}$	**0.003**	0.316	Small
	p value[b]	**0.017**	**<0.001**	0.274	**0.021**	**<0.001**		

[a] One-way Anova; [b] Paired sample T-test; bold figure indicating $p < 0.05$; $^{\alpha, \beta}$ Difference statistically significant (Tukey's Test)

Table 4.18: Changes in mean plaque score for anterior teeth (53 to 63) after 6 months in SIMSP by caries risk levels

Tooth		Overall	Low	Moderate	High	p value[a]	Effect size	ES descriptor
62	Baseline Mean (+ SD)	0.63 (0.76)	0	0.14 (0.39) $^{\beta}$	0.77 (0.78) $^{\beta}$	**<0.001**		
	Follow-up Mean (+ SD)	0.37 (0.66)	1.00 (1.02) $^{\alpha}$	0.17 (0.49) $^{\alpha, \beta}$	0.41 (0.68) $^{\beta}$	**0.007**		
	Mean increment (+ SD)	-0.26 (0.81)	1.00 (1.02) $^{\alpha}$	0.03 (0.52) $^{\alpha, \beta}$	- 0.36 (0.83) $^{\beta}$	**<0.001**	0.422	Small
	p value[b]	**0.019**	**<0.001**	0.298	**0.022**			
63	Baseline Mean (+ SD)	0.81 (0.78)	0 $^{\alpha}$	0.18 (0.43) $^{\beta}$	0.97 (0.76) $^{\alpha, \beta}$	**<0.001**		
	Follow-up Mean (+ SD)	0.56 (0.70)	0.75 (0.85)	0.27 (0.57) $^{\beta}$	0.63 (0.71) $^{\beta}$	**0.001**		
	Mean increment (+ SD)	-0.24 (0.77)	0.75 (0.85)	0.08 (0.64) $^{\beta}$	-0.34 (0.77) $^{\beta}$	**<0.001**	0.540	Medium
	p value[b]	**0.018**	**<0.001**	**0.013**	**0.020**			

[a] One-way Anova; [b] Paired sample T-test; bold figure indicating $p < 0.05$; $^{\alpha, \beta}$ Difference statistically significant (Tukey's Test)

4.6 To assess the impact of the SIMSP over and above the existing POHP in 6 months in terms of children's oral health and related behaviours (Secondary objective 1a)

Table 4.19 shows the oral health behaviours of the preschool children as reported by their parents or caregivers. There was a significant difference in the frequency of monitoring child's toothbrushing at follow-up where 3.9% of parents in the SIMSP reported they didn't monitor their children's toothbrushing compared to only 1.2% in the POHP.

There was a significant increase (p = 0.013) in the proportion of children in the SIMSP who used toothpaste 2 or more times daily when toothbrushing over 6 months where the increment was 7.7% compared to 4.2% in POHP.

For toothbrushing frequency two or more times daily, significant difference (p=0.011) was seen for the overall result where 74.9% reported of toothbrushing frequency more than two times daily at follow-up compared to baseline with 69.8%. For between group comparison, no statistically significant difference was seen between SIMSP and POHP. However, frequency two or more times daily increased by 5.9% in SIMSP versus 2.2% in POHP.

There was a difference in the proportion of children who used Colgate toothpaste after 6 months between the groups. The difference was approaching a statistical significance. More than half of children from the SIMSP (52.3%) used Colgate toothpaste after 6 months compared to children in the POHP (42.2%) (p = 0.055).

Table 4.19: Oral health behaviour items by group at baseline and follow-up (N=517)

Variable	Overall n (%)		Intervention (n = 258) n (%)		Control (n = 259) n (%)		p value [a]
Toothbrushing	Yes	No	Yes	No	Yes	No	
Baseline, n = 517	514 (99.4)	3 (0.6)	256 (99.2)	2 (0.8)	258 (99.6)	1 (0.4)	0.560
Follow-up, n = 517	512 (99.0)	5 (1.0)	254 (98.4)	4 (1.6)	258 (99.6)	1 (0.4)	0.176
p value[b]	0.727		0.668		1.000		
Toothbrushing frequency	2 or more times daily	Less than 2x daily	2 or more times daily	Less than 2x daily	2 or more times daily	Less than 2x daily	
Baseline, n = 517	361 (69.8)	156 (30.2)	174 (67.4)	84 (32.6)	187 (72.2)	72 (27.8)	0.139
Follow-up, n = 517	387 (74.9)	130 (25.1)	189 (73.3)	69 (26.7)	198 (76.4)	61 (23.6)	0.231
p value[b]	**0.011**		0.730		0.091		
Frequency to monitor child's toothbrushing	Monitor daily / Infrequent	Do not monitor	Monitor daily / Infrequent	Do not monitor	Monitor daily / Infrequent	Do not monitor	
Baseline, n = 517	500 (96.7)	17 (3.3)	246 (95.3)	12 (4.7)	254 (98.1)	5 (1.9)	0.067
Follow-up, n = 517	504 (97.5)	13 (2.5)	248 (96.1)	10 (3.9)	256 (98.8)	3 (1.2)	**0.043**
p value[b]	0.454		0.774		0.625		

[a] Pearson Chi Square for between-group comparison; [b] McNemar test for within-group comparison; figure in bold indicates $p < 0.05$

Table 4.19: Oral health behaviour items by group at baseline and follow-up (N = 517)

Variable	Overall, n (%)		Intervention (n = 258) n (%)		Control (n = 259) n (%)		p value [a]
Frequency of using toothpaste when toothbrushing	2 or more times daily	Less than 2x daily	2 or more times daily	Less than 2x daily	2 or more times daily	Less than 2x daily	
Baseline, n = 517	353 (68.3)	164 (31.7)	170 (65.9)	88 (34.1)	183 (70.7)	76 (29.3)	0.142
Follow-up, n = 517	384 (74.3)	133 (25.7)	190 (73.6)	68 (26.4)	194 (74.9)	65 (25.1)	0.743
p value[b]	**0.002**		**0.013**		0.100		
Use of fluoridated toothpaste at home	Yes	No	Yes	No	Yes	No	
Baseline, n = 517	427 (82.6)	90 (17.4)	212 (82.2)	46 (17.8)	215 (83.0)	44 (17.0)	0.446
Follow-up, n = 517	451 (87.2)	66 (12.8)	224 (86.8)	34 (13.2)	227 (87.6)	32 (12.4)	0.441
p value[b]	**0.011**		0.105		0.067		

[a] Pearson Chi Square for between-group comparison; [b] McNemar test for within-group comparison; figure in bold indicates $p < 0.05$

Table 4.19: Oral health behaviour items by group at baseline and follow-up (N = 517)

Toothpaste brand (n = 480)	**Baseline, n = 480***			**Follow-up, n = 480***			
	Overall	Intervention n (%)	Control n (%)	p value[a]	Overall	Intervention n (%)	Control n (%)	p value[a]
Colgate	199 (38.6)	108 (42.2)	91 (35.1)	0.391	231 (45.0)	134 (52.3)[α]	97 (37.8)	0.055
Kodomo Lion	122 (23.7)	51 (19.9)	71 (27.4)		115 (22.3)	43 (16.8)	72 (27.8)	
Darlie	85 (16.5)	41 (16.0)	44 (17.0)		71 (13.8)	31 (12.1)	40 (15.5)	
Safi	20 (3.9)	12 (4.7)	8 (3.1)		20 (3.9)	11 (4.3)	9 (3.5)	
Raiya∞	8 (1.5)	5 (1.9)	3 (1.2)		7 (1.4)	2 (0.8)	5 (1.9)	
Fresh and White	5 (1.0)	3 (1.2)	2 (0.8)		5 (1.0)	4 (1.6)	1 (0.4)	
Pepsodent	3 (0.6)	1 (0.4)	2 (0.8)		0	0	0	
Amway Glister kids	1 (0.2)	0	1 (0.4)		1 (0.2)	0	1 (0.2)	
Mukmin∞	14 (2.7)	8 (3.1)	6 (2.3)		15 (2.9)	6 (2.3)	9 (3.5)	
Tesco	3 (0.6)	1 (0.4)	2 (0.8)		1 (0.2)	1 (0.4)	0	
Morning Kiss∞	5 (1.0)	1 (0.4)	4 (1.5)		1 (0.2)	1 (0.4)	0	
Jordan	2 (0.4)	0	2 (0.8)		2 (0.4)	0	2 (0.8)	
Pureen∞	2 (0.4)	1 (0.4)	1 (0.4)		0	0	0	
Halagel∞	0	0	0		2 (0.4)	1 (0.4)	1 (0.4)	
Others	6 (1.2)	4 (1.6)	2 (0.8)		8 (1.6)	5 (2.0)	3 (1.2)	
Don’t use toothpaste	5 (1.0)	2 (0.8)	3 (1.2)		1 (0.2)	1 (0.4)	0	

[a] Pearson Chi Square, between-group comparison; * sample did not equal to 517 due to missing data, ∞ Non-fluoridated toothpaste;

[α]Z score >1.96 indicating significant difference

Table 4.20 shows the oral health related behaviours of the preschool children as reported by their parents or caregivers. At follow-up, there was a significant reduction in the proportion of children who used bottle feeding in both groups ($p<0.001$).

At baseline, there was a significant difference between the groups in terms of preschool children who used bottle feeding daily where the proportion of children in the SIMSP was significantly higher (84.8%) than children in the POHP (71.3%). However, at follow-up the number of children who used bottle feeding daily in the SIMSP had reduced a lot and the difference between the groups was no longer statistically significant at follow-up.

For within-group comparison, there was a significant reduction ($p<0.001$) in bottle feeding usage in both groups at follow-up. There was also a significant reduction in daily bottle feeding use at night in the POHP at follow-up ($p = 0.013$).

For sugar intake during dinner, there was a significant within-group difference in the POHP between baseline and follow-up where the proportion of children who took sugars at dinner time was significantly less at follow-up than at baseline ($p = 0.026$).

In terms of carbonated drinks intake frequency at follow-up, there was a significant difference between groups where a higher proportion of children in the POHP took carbonated drinks daily (2.7%) compared to those in the SIMSP (0.4%) ($p = 0.033$).

No other significant difference in oral health related behaviours was observed between the groups.

Table 4.20: Oral health related behaviours of children at baseline and follow-up by group (N = 517)

Variable	Overall N (%)		Intervention (n = 258), n (%)		Control (n = 259), n (%)		p value [a]
Bottle feeding	No	Yes	No	Yes	No	Yes	
Baseline, n = 517	324 (62.7)	193 (37.3)[a]	166 (64.3)	92 (35.7)	158 (61.0)	101 (39.0)	0.735
Follow-up, n = 517	369 (71.4)	148 (28.4)[b]	186 (72.4)	72 (27.6)	183 (70.7)	76 (29.3)	0.666
p value[b]	**<0.001**		**0.001**		**<0.001**		
Bottle feeding frequency	Daily	Infrequent	Daily	Infrequent	Daily	Infrequent	
Baseline (n = 193) (n from [a])	150 (77.7)	43 (22.3)	78 (84.8)	14 (15.2)	72 (71.3)	29 (28.7)	**0.024**
Follow-up (n = 148) (n from [b])	104 (70.3)	44 (29.7)	55 (76.4)	17 (23.6)	49 (64.5)	27 (35.5)	0.177
p value[b]	**<0.001**		**<0.001**		**<0.001**		
Bottle feeding at night	No	Yes	No	Yes	No	Yes	
Baseline, n = 516*	343 (66.3)	173 (33.5)[c]	171 (66.5)	86 (33.5)	172 (66.4)	87 (33.6)	0.975
Follow-up, n = 516*	385 (74.5)	131 (25.3)	193 (75.1)	64 (24.9)	192 (74.1)	67 (25.9)	0.801
p value[b]	**<0.001**		**<0.001**		**0.001**		

[a] Pearson Chi Square, between-group comparison; [b] McNemar test for within group comparison;

* sample did not equal to 517 due to missing data, figure in bold indicates $p < 0.05$

Table 4.20: Oral health related behaviours of children at baseline and follow-up by group (N = 517) (continued)

	Overall N (%)		**Intervention (n = 258), n (%)**		**Control (n = 259), n (%)**		**p value [a]**
Bottle feeding frequency at night (n from [c])	**Daily**	**Infrequent / Nil**	**Daily**	**Infrequent / Nil**	**Daily**	**Infrequent / Nil**	
Baseline (n=173)	135 (78.0)	38 (22.0)	69 (80.2)	17 (19.8)	66 (75.9)	21 (24.1)	0.488
Follow-up (n=173)	85 (64.9)	46 (35.1)	45 (70.3)	19 (29.7)	40 (59.7)	27 (40.3)	0.203
p value[b]	**<0.001**		0.570		**0.013**		
Sugar intake							
At breakfast	Yes	No	Yes	No	Yes	No	
Baseline, n=516*	254 (49.2)	262 (50.7)	128 (49.8)	129 (50.2)	126 (48.6)	133 (51.4)	0.793
Follow-up, n=516*	275 (53.2)	242 (46.8)	138 (53.5)	120 (46.5)	137 (52.9)	122 (47.1)	0.893
p value[b]	0.159		0.435		0.254		
Morning snack	Yes	No	Yes	No	Yes	No	
Baseline, n=516*	289 (55.9)	227 (43.9)	114 (56.0)	113 (44.0)	145 (56.0)	114 (44.0)	0.991
Follow-up, n=516*	277 (53.6)	239 (46.2)	141 (54.7)	117 (45.3)	136 (52.7)	122 (47.3)	0.659
p value[b]	0.420		0.837		0.402		

[a] Pearson Chi Square, between-group comparison; [b] McNemar test for within group comparison;

* sample did not equal to 517 due to missing data, figure in bold indicates $p < 0.05$

Table 4.20: Oral health related behaviours of children at baseline and follow-up by group (N = 517) (continued)

	Overall N (%)		Intervention (n = 258), n (%)		Control (n = 259), n (%)		p value [a]
Lunch	Yes	No	Yes	No	Yes	No	
Baseline, n=516*	251 (48.6)	265 (51.3)	126 (49.0)	131 (51.0)	125 (48.3)	134 (51.7)	0.862
Follow-up, n=516*	221 (42.7)	296 (57.3)	110 (42.6)	148 (57.4)	111 (42.9)	148 (57.1)	0.959
p value[b]	**0.025**		0.118		0.136		
Afternoon tea	Yes	No	Yes	No	Yes	No	
Baseline, n=516*	327 (63.2)	189 (36.6)	173 (67.3)	84 (32.7)	154 (59.5)	105 (40.5)	0.064
Follow-up, n=516*	319 (61.7)	198 (38.3)	165 (64.0)	93 (36.0)	154 (59.5)	105 (40.5)	0.293
p value[b]	0.596		0.456		1.000		
Dinner	Yes	No	Yes	No	Yes	No	
Baseline, n=516*	203 (39.3)	313 (60.7)	98 (38.1)	159 (61.9)	105 (40.5)	154 (59.5)	0.576
Follow-up, n=516*	172 (33.3)	345 (66.7)	86 (33.3)	172 (66.7)	86 (33.2)	173 (66.8)	0.975
p value[b]	**0.012**		0.213		**0.026**		

[a] Pearson Chi Square, between-group comparison; [b] McNemar test for within group comparison;

* sample did not equal to 517 due to missing data, figure in bold indicates $p < 0.05$

Table 4.20: Oral health related behaviours of children at baseline and follow-up by group (N = 517) (continued)

Variable	Overall N (%)		Intervention (n = 258), n (%)		Control (n = 259), n (%)		p value [a]
Supper	Yes	No	Yes	No	Yes	No	
Baseline, n=516*	40 (7.7)	476 (92.1)	23 (8.9)	234 (91.1)	17 (6.6)	242 (93.4)	0.311
Follow-up, n=516*	43 (8.3)	474 (91.7)	24 (9.3)	234 (90.7)	19 (7.3)	240 (92.7)	0.418
p value[b]	0.795		1.000		0.845		
Total sugar intake daily	≤4 times daily	≥ 5 times daily	≤4 times daily	≥ 5 times daily	≤4 times daily	≥ 5 times daily	
Baseline, n=517	443 (85.7)	74 (14.3)	222 (86.0)	36 (14.0)	221 (85.3)	38 (14.7)	0.816
Follow-up, n=517	456 (88.2)	61 (11.8)	225 (87.2)	33 (12.8)	231 (89.2)	28 (10.8)	0.485
p value[b]	0.160		0.760		0.100		
Carbonated drinks intake	No intake	Daily / irregular intake	No intake	Daily / irregular intake	No intake	Daily / irregular intake	
Baseline, n=516*	263 (50.9)	253 (48.9)	138 (53.7)	119 (46.3)	125 (48.3)	134 (51.7)	0.217
Follow-up n=516*	249 (48.3)	267 (51.7)	127 (49.2)	131 (50.8)	122 (47.3)	136 (52.7)	0.660
p value[b]	0.239		0.215		0.791		

[a] Pearson Chi Square, between-group comparison; [b] McNemar test for within group comparison;
* sample did not equal to 517 due to missing data, figure in bold indicates $p < 0.05$

Table 4.20: Oral health related behaviours of children at baseline and follow-up by group (N = 517) (continued)

Variable	Overall N (%)		Intervention (n = 258), n (%)		Control (n = 259), n (%)		p value [a]
Carbonated drinks intake frequency	Daily	1-3 times per week / less	Daily	1-3 times per week / less	Daily	1-3 times per week / less	
Baseline, n=517	5 (1.0)	512 (99.0)	2 (0.8)	256 (99.2)	3 (1.2)	256 (98.8)	0.656
Follow-up, n=517	8 (1.5)	509 (98.5)	1 (0.4)	257 (99.6)	7 (2.7)	252 (97.3)	**0.033**
p value[b]	0.508		1.000		0.219		

[a] Pearson Chi Square, between-group comparison; [b] McNemar test for within group comparison;

* sample did not equal to 517 due to missing data, figure in bold indicates $p < 0.05$

Table 4.20: Oral health related behaviours of children at baseline and follow-up by group (N = 517) (continued)

	Baseline				Follow-up			
	Overall	**Intervention**	**Control**	**p value[a]**	**Overall**	**Intervention**	**Control**	**p value[a]**
Last visit to the dentist, n=516*								
Less than 1 year	123 (23.8)	53 (20.6)	70 (27.0)	0.176	161 (31.2)	78 (30.4)	82 (32.0)	0.157
Between 1-2 years ago	69 (13.4)	33 (12.8)	36 (13.9)		63(12.2)	25 (9.7)	38 (14.8)	
More than 2 years ago / Never visited dental clinic	324 (62.8)	171 (66.5)	153 (59.1)		292 (56.6)	154 (59.9)	138 (53.3)	
Reason for last dental visit; n=516*								
Check up	195 (37.8)	95 (37.0)	100 (38.6)	0.401	193 (37.5)	85 (32.9)	108 (42.0)	0.440
Restoration	31 (6.0)	15 (5.8)	16 (6.2)		31 (6.0)	18 (7.0)	13 (5.1)	
Scaling	5 (1.0)	5 (1.9)	0		7 (1.4)	5 (1.9)	2 (0.8)	
Toothache / oral pain	28 (5.4)	12 (4.7)	16 (6.2)		51 (9.9)	27 (10.5)	24 (9.3)	
Trauma	3 (0.6)	1 (0.4)	2 (0.8)		2 (0.4)	1 (0.4)	1 (0.4)	
Others	9 (1.7)	5 (1.9)	4 (1.5)		14 (2.7)	8 (3.1)	6 (2.3)	
Never visit dentist	245 (47.5)	124 (48.2)	121 (46.7)		218 (42.1)	114 (44.2)	104 (40.1)	

[a] Pearson Chi Square, between-group comparison ;* sample did not equal to 517 due to missing data

4.7 To assess the impact of the SIMSP over and above the existing POHP in 6 months in terms of parents' OHL (Secondary objective 1b)

Table 4.21 shows the mean scores for parents' OHL and by domain at baseline and follow-up. At baseline, there was a significant difference in the knowledge domain mean scores between groups where parents in the SIMSP had a significantly lower mean score. However, at follow-up, the difference was no longer significant. For knowledge domain, the mean increment score was higher in the SIMSP and the difference between groups was statistically significant. The effect size was 0.92 which represents a large effect size.

For comprehension domain, overall, there was a significant reduction in mean score at follow-up for both groups. However, no significant difference in the mean scores was observed between groups.

For skills and motivation domain, there was no significant difference in the findings between groups. However, the mean increment score was higher in the SIMSP at follow-up compared to the POHP but the difference was not statistically significant. The effect size of the SIMSP on the domain compared to the POHP was 0.97 which represents a large effect size. For total OHL score, there was a significant increase in total OHL mean score in the SIMSP between baseline and follow-up where the total OHL mean score was significantly higher at follow-up. The effect size of the difference in mean total OHL scores between the SIMSP and POHP was 0.97 which represents a large effect size.

Table 4.21: OHL mean scores at baseline and follow-up by domain and group (N = 517)

	Variables	Score range	Overall	Intervention (n=258)	Control (n=259)	p value[a]	Effect Size	Effect Size descriptor
Knowledge	Baseline score Mean (±SD)	0 – 12	6.96 (2.52)	6.73 (2.54)	7.19 (2.48)	**0.039**		
	Follow-up score Mean (±SD)		7.24 (2.52)	7.27 (2.58)	7.209 (2.48)	0.791		
	Increment score Mean (±SD)		0.28 (2.60)	0.54 (2.75)	0.02 (2.42)	**0.024**	0.92	Large
	p value[b]		**0.014**	**0.002**	0.878			
	Effect size			0.20	0.01			
	ES descriptor		Small	Small	Small			
Comprehension	Baseline score Mean (±SD)	0 - 5	4.07 (1.09)	4.04 (1.09)	4.09 (1.09)	0.962		
	Follow-up score Mean (±SD)		4.025 (1.21)	4.00 (1.24)	4.050 (1.18)	0.453		
	Increment score Mean (+SD)		-0.04 (1.24)	-0.39 (1.25)	-0.04 (1.23)	0.858[c]	0.06	Small
	p value[b]		0.457	0.620	0.580			
	Effect size		**0.005**	0.03	0.04			
	ES descriptor		Small	Small	Small			

[a] Independent sample T test; [b] Paired sample T test; [c] Mann Whitney test, SD = standard deviation; ES= Effect size; figure in bold indicates $p < 0.05$

Table 4.21: OHL mean scores at baseline and follow-up by domain and group (N = 517)

	Variables	Range	Overall	Intervention	Control	p value[a]	Effect Size	Effect size descriptor
Skills and motivation	Baseline score Mean (±SD)	0 – 39	28.42 (5.99)	28.00 (6.44)	28.83 (5.53)	0.085		
	Follow-up score Mean (±SD)		28.98 (6.08)	28.75 (5.91)	29.20 (6.26)	0.634		
	Increment score Mean (+SD)		0.56 (6.49)	0.753 (6.72)	0.37 (6.27)	0.506	0.97	Large
	p value[b]		0.054	0.077	0.352			
	Effect size		0.05	0.12	0.06			
	ES descriptor		Small	Small	Small			
Total OHL score	Baseline score Mean (+SD)	0 - 56	39.11 (8.64)	38.72 (8.56)	39.90 (8.14)	0.116		
	Follow-up Mean (+SD)		40.44 (8.00)	40.30 (7.90)	40.573 (8.11)	0.699		
	Increment score Mean (±SD)		1.12 (8.67)	1.575 (8.78)	0.675 (8.55)	0.242	0.97	Large
	p value[b]		**0.004**	**0.005**	0.209			
	Effect size		0.16	0.19	0.08			
	ES descriptor		Small	Small	Small			

[a] Independent sample T test; [b] Paired sample T test; [c] Mann Whitney test, SD = standard deviation; ES = effect size; figure in bold indicates $p < 0.05$

Table 4.22 shows the OHL levels by domain at baseline and follow-up. For all domains, there was no significant difference between groups at baseline and follow-up. However, the SIMSP had a higher increase in the proportions of parents with 'good' level of OHL at follow-up for the knowledge and skills and motivation domains than the POHP. For the knowledge domain, the increase was 9.3% for SIMSP in the "good" level compared to a decrease by 2.3% in the POHP. For the skills and motivation domain, there was an 8.3% increase for 'good' level in the SIMSP compared to POHP with 3.1% increase. For comprehension domain, majority of parents from both groups had 'poor' levels at baseline and follow-up with no significant difference between the groups.

For overall OHL levels, there was no significant difference between the groups at baseline and follow-up. However, SIMSP had 10.2% increase in the proportions of parents with 'good' level of OHL at follow-up than the POHP with 6.6%.

Table 4.22: OHL levels by domain at baseline and follow-up between the groups (N = 517)

OHL Domain	Level	Baseline				Follow-up			
		Overall n (%)	Intervention n (%)	Control n (%)	p value[a]	Overall n (%)	Intervention n (%)	Control n (%)	p value[a]
Knowledge	Poor	53 (10.3)	32 (12.4)	21 (8.1)	0.590	44 (8.5)	23 (8.9)	21 (8.1)	0.651
	Moderate	306 (59.2)	158 (61.2)	148 (57.1)		297 (57.4)	143 (55.4)	154 (59.5)	
	Good	158 (30.6)	68 (26.4)	90 (34.7)		176 (34.0)	92 (35.7)	84 (32.4)	
Comprehension	Poor	278 (53.8)	139 (53.9)	139 (53.7)	0.516	270 (52.2)	139 (53.9)	131 (50.6)	0.453
	Good	239 (46.2)	119 (46.1)	120 (46.3)		247 (47.8)	119 (46.1)	128 (49.4)	
Skills and motivation	Poor	16 (3.1)	10 (3.9)	6 (2.4)	0.206	14 (2.8)	4 (1.6)	10 (3.9)	0.206
	Moderate	113 (22.1)	63 (24.6)	50 (19.6)		87 (17.2)	47 (18.7)	40 (15.7)	
	Good	382 (74.8)	183 (71.5)	199 (78.0)		406 (80.1)	201 (79.8)	205 (80.4)	
Overall	Poor	18 (3.5)	11 (4.3)	7 (2.7)	0.480	15 (3.0)	6 (2.4)	9 (3.5)	0.713
	Moderate	170 (32.9)	88 (34.1)	82 (31.7)		127 (25.0)	65 (25.8)	62 (24.3)	
	Good	329 (63.6)	159 (61.6)	170 (65.6)		365 (72.0)	181 (71.8)	184 (72.2)	

[a] Pearson Chi Square; *sample did not equal to 517 due to missing data

4.8 To assess the implementation fidelity of the SIMSP protocol (Secondary objective 2)

This section describes the findings for the secondary objective 2 which was to assess the implementation fidelity of the SIMSP protocol in terms of:

a. Parents' compliance in attending the parent-DT meeting at school.
b. Teachers' compliance in delivering in-class OHE, dental worksheets, and supervising daily toothbrushing with the preschool children.
c. DT's compliance in sending oral health infographics to parents via Whatsapp application (or paper infographics).

Table 4.23 shows the implementation fidelity of the SIMSP. Overall, majority of parents (83.1%) attended the parent-DT meeting at preschools. The compliance rate of teachers in delivering the in-class oral health lessons and dental worksheets was 96.8% each. The teachers' compliance rate in supervising daily toothbrushing at school was 93.7%. The compliance rate of DTs to deliver oral health infographics to parents over the period of 6 months was 100%.

Table 4.23: Implementation fidelity of the SIMSP protocol

Preschool	Number of children (N =344)	Parents' attendance at meeting (N = 344) n (%)	Teacher's oral health lessons (N = 11) n (%)	Children's worksheets (N = 11) n (%)	Daily tooth-brushing at school (N=98 days) n (%)	Delivery of 10 e-infographics to parents n (%)
SK Gopeng	50	40 (80.0)	11 (100)	11 (100)	98 (100)	10 (100)
SK Tualang Sekah	59	46 (78.0)	11 (100)	11 (100)	98 (100)	10 (100)
Sk Malim Nawar	18	18 (100)	11 (100)	11 (100)	98 (100)	10 (100)
SK Kuala Dipang	20	16 (80.0)	9 (81.0)	9 (81.0)	73 (74.5)	10 (100)
KEMAS Ulu Pili	25	25 (100)	11 (100)	11 (100)	98 (100)	10 (100) $^{\infty}$
KEMAS Pos Dipang	26	24 (92.3)	11 (100)	11 (100)	98 (100)	10 (100) $^{\infty}$
KEMAS Taman Cahaya	19	12 (63.2)	11 (100)	11 (100)	98 (100)	10 (100)
KEMAS Kg Itam Labu	14	13 (92.9)	11 (100)	11 (100)	80 (81.6)	10 (100)
KEMAS Jalan Stesen	20	15 (75.0)	10 (90.9)	10 (90.9)	98 (100)	10 (100)
KEMAS Kg Pulai Bergading	20	18 (90.0)	11 (100)	11 (100)	98 (100)	10 (100)
KEMAS Kopisan Baru	11	7 (63.6)	11 (100)	11 (100)	98 (100)	10 (100)
Perpaduan Jeram	13	11 (84.6)	9 (81.0)	9 (81.0)	98 (100)	10 (100)
Perpaduan Taman Ros	25	22 (88.0)	11 (100)	11 (100)	98 (100)	10 (100)
Perpaduan Taman Sentosa	24	19 (79.2)	11 (100)	11 (100)	54 (55.1)	10 (100)
Overall	344	286 (83.1)	149 (96.8)	149 (96.8)	92 (93.7)	10 (100)

4.9 Results of Focus Group Discussion

This section describes the findings for secondary objective number 3: To undertake a process evaluation of the SIMSP by exploring the perspectives of the dental on the following factors:

a) Appropriateness of the SIMSP

b) Effectiveness of the SIMSP

c) Facilitators to implement the SIMSP

d) Barriers to implement the SIMSP

e) Suggestions for improving the SIMSP

Table 4.24 shows the profile of the FGD participants. In total, 5 DTs and 4 HAs participated in the FGD which was conducted in two sessions.

Table 4.24: Profiles of FGD participants

Gender	Dental therapist, n (%)	Health assistant, n (%)	Total, n (%)
Female	5 (55.6)	3 (33.3)	8 (88.9)
Male	0	1 (11.1)	1 (11.1)
Total	5	4	9 (100)

The findings are presented in 5 domains that are divided further to different themes.

4.9.1 Perspectives of the dental team on the appropriateness of the SIMSP in the preschool settings (Secondary objective 3a)

a) Parental involvement in child's oral health

Various responses were elicited from the participants regarding this issue as they opined that parents have a huge role in preschool children's oral health. Participants felt that the SIMSP was very appropriate to be implemented in preschool setting because this programme included parents' involvement in their children's oral health. The participants were aware that the POHP needs to include parents' participation. With the SIMSP, they now have the idea how to tackle the issue.

*We need to have a suitable event to tackle the parents. The SIMSP gave us an idea how to do it. (*All participants)

All participants agreed that the SIMSP was suitable at preschool level. Their major standpoint was parents' involvement in preschool programme activities had increased since the intervention of the SIMSP.

Preschool programmes must include parents. Before this, we hardly get parents' involvement. But with this programme, parental involvement increased. (Participant 4, DT)

The SIMSP gave the dental team a new experience on how to get parents to participate in dental programme at preschool.

Throughout my working experience, there is never a preschool programme that gives attention to parents. (Participant 7, HA)

The DTs were able to inform the parents of their children's oral health status directly through the meeting with parents. Before this programme, the parents were informed through letters and there was no meeting.

If the preschool children needs restorative treatment using high speed instruments, we can inform the parents directly and tell them to bring their children to the clinic for treatment. (Participant 3, DT)

In the participants' opinion, the SIMSP was more comprehensive as it involved all party that was involved in preschool children's oral health.

The SIMSP has a more comprehensive plan that incorporates everyone involved in preschool children's oral health. So everyone has their own responsibility. (Participant 8, HA)

b) Address individual dental problems

The DTs expressed their views regarding giving customised OHE and diet advice to individual preschool children and their respective parents.

The common approach before the SIMSP was to give talk to parents and preschool children in a general setting with no focus on individual dental problems.

Before this programme, we gave talk to parents in general, with no focus on individual dental problems. (Participant 1, DT).

However, in the SIMSP, the participants perceived that through their meetings with parents, the DTs could provide individual consultation to the parents. Guided by the CRA form, the DTs gained oral health related information of the child from the parents and customised the OHE messages to parents based on their children's oral health

problems. By doing so, parents were more interested to listen and take note of the advice given to them by the DT.

In this SIMS programme we will meet parents one by one. By doing so we can find out what the problem is. Especially the children with dental problem. So, from there we know what the problem is, can guide the parent, tell parents how to deal with it. So I think the programme is kind of good (Participant 4, DT)

4.9.2 Perspectives of the dental team on the effectiveness of the SIMSP in the preschool settings (Secondary objective 3b)

The SIMSP was effective to increase parents' and teachers' participation to promote preschool children's oral health. The improved participation may lead to increased awareness and improved their OHK. As for the preschool children, the SIMSP may have improved their toothbrushing habits, toothbrushing method and effectiveness, and oral hygiene level. Overall, the participants perceived that the SIMSP was effective to improve preschool children's oral health and related behaviour.

a) Increase parents' oral health awareness

Through the meeting with DTs, parents were expected to have better awareness, and more knowledge about their children's oral health, the risk factors that can cause caries and the preventive strategies. Since DTs were advised to perform ART technique on preschool children, those that required more complex treatment are referred to the dental clinic for treatment. With increased awareness among parents, participants perceived that parents will be more sensitive to their children's oral health needs including taking their child for a preventive visit to the dental clinic.

*Hopefully through individual meeting with parents, it will give the parents awareness to take their children to the clinic. (*Participant 2, DT)

*If the parents have awareness, they will take the child to the clinic for treatment no matter if they are busy at work. (*Participant 1, DT)

b) Improve children's toothbrushing habits

Participants shared their experience witnessing an improvement in toothbrushing habits of the preschool children in the intervention group. They saw children brushed their teeth after meals without waiting for their teacher's instruction. It was good that the children have inculcated good oral health habits through this programme.

*At the intervention preschools, I witnessed the children will immediately brushed their teeth after meal. (*Participant 6, HA)

The participants perceived that maybe through daily toothbrushing practice conducted by their teachers, preschool children have developed better discipline to care for their teeth and helped to develop positive oral health behaviours. This in the long term will impact positively on gingival health and reduce caries.

*They have better discipline; they know what to do after eating at school. That is to brush their teeth. (*Participant 3, DT)

c) Improve parents' oral health knowledge

All participants acknowledged that parents need to have good OHK in order for them to improve their family members' oral health. However, in this scenario, the best information to give to parents should be related to their preschool children. So it was a good approach to relate the use of CRA and OHE to parents. This way, they will be more attentive and can relate to the OHE given to them.

We can guide parents to improve their children's oral health by identifying the cause of their problems through CRA (Participant 5, DT)

Through the meeting, the DTs can emphasize on important OHE messages such as toothbrushing before bed, sugar intake and other oral health related habits suitable for the preschool children. Parents also have the chance to ask questions. This 2-way communication is good to improve the stakeholder's engagement.

Before this maybe parents didn't know the importance of good oral health habit such as toothbrushing before going to bed. When we meet face to face, they can get the information and directly ask us if they don't understand. (Participant 3, DT)

ECC is a major problem in the Kampar district and most of preschool children are at high risk of developing dental caries. DTs took advantage of the meeting session to explain about caries, from the causal factor to its development process and caries prevention.

We can tell parents about caries in detail, for example how it started and how to prevent it. (Participant 4, DT)

The main aim of the SIMSP was to improve oral health and oral health related behaviours among preschool children in order to prevent decay in future permanent dentition. Hence, all DTs agreed that the SIMSP is best implemented during preschool years as this is the erupting age for first molars. For preschool children with permanent molars, the DTs will show those teeth to the parents and emphasise on the importance to brush well. For most parents, the meeting gave them knowledge about permanent teeth and their eruption dates as well as the correct oral hygiene care for their children.

Many parents were surprised to find out that permanent molars have erupted in their children's mouth. Before this, they do not know about it and are motivated to keep those teeth caries free (Participant 2, DT).

d. Improve oral hygiene of preschool children

All the DTs agreed that generally preschool children in the intervention group have cleaner teeth compared to the children in the control group. This opinion is parallel with their observation that shows preschool children have better toothbrushing discipline in school.

In general, we found children in the intervention programme have cleaner teeth. Makes it easier for us to apply fluoride varnish. (Participant 3, DT).

The DTs are trained to interview parents to identify caries risk factors by using the CRA form. Afterwards, the parents will use that information to improve their preschool children's oral health. They perceived that this practice can improve the preschool children's oral health because parents have better knowledge, able to better understand the information given and have better skills and motivation to improve their children's oral health.

From the CRA form, we can somehow identify the children's risk factor for caries. From there, we know what to advice the parents and their children (Participant 4, DT*)*

4.9.3 Perspectives of the dental team on the facilitators of implementing the SIMSP in the preschool settings (Secondary objective 3c)

Participants expressed many factors that facilitated the implementation of the SIMSP. Most responses were related to the support given by dental service administrators, parents and preschool teachers.

a) Support from dental administrators

The participants expressed their administrators' aspiration to carry out a dedicated team for preschool children. However, the administrators did not have a clear guideline on how to implement the programme. Therefore, they were supportive of the SIMSP and were enthusiastic to know its outcome.

Our bosses really want us to run a dedicated team for preschool children, but they do not have a clear idea how it should be done. They are keen on the SIMSP outcome and asked us for feedbacks. (Participant 3, DT)

Even though the DTs and HAs were required to wear their formal uniform during working hours, the administrators had given the SIMSP team an exemption regarding this matter during the meeting with parents. The DTs and HAs were allowed to wear plain clothes. The reason was the informal attire will provide an informal setting for the meeting and to reduce anxiety among the preschool children and parents.

*During meeting with parents for the SIMSP, our boss allowed us (the DTs and HAs) to wear normal clothes. Children sometimes get afraid and cry when they see us in white uniforms. (*Participant 5, DT).

Many DTs expressed concerns about the difficulty for working parents to attend the meeting during working hour. As a way to attract and facilitate working parents to attend the meetings, the dental administration team has agreed that time slips can be issued to parents upon request if they were taking time off work to attend the meeting.

*We were allowed to issue time slips for working parents who attended the meeting. So those parents can request for time slips if they need them and show it to their employers. (*Participant 2, DT)

b) Parental support

The participants felt motivated to conduct the SIMSP due to good support from the parents. The participants perceived that high parents' attendance to preschools for consultation meeting was an indicator for good parental support.

Before this, we hardly got parents' participation in our POHP. But with the SIMSP, they were willing to join and parental involvement increased. We're happy because it looks good in our work record. (Participant 3, DT)

c) Informal setup for meeting

The participants admitted that the informal setup of the meetings provided a conducive environment for them to engage with the parents in a relax and unthreatening manner.

We met parents in a relaxed and less formal environment, therefore we find that the parents and their children were more responsive. (Participant 3, DT)

Plus, when the children saw their parents there, the kids got excited. They sat with their parents and listened to our advice. (Participant 5, DT)

d) Simple OHE messages

In order to deliver OHE messages to the parents, the participants said they referred to the SIMSP pamphlets provided. They felt the messages in the pamphlet were precise, simple and informative. It was easy for them to explain to the parents because the OHE were written in layman terms.

*The OHE messages are simple and easy for us to understand, and easy for us to deliver. The content of the pamphlet is simple, and we can use it to explain to parents the reasons for tooth decay in easy terms. (*Participant 5, DT)

During consultation, the DTs were trained and advised to avoid medical jargons when delivering OHE messages to parents. This was to avoid misunderstanding and misinterpretation by the receiver.

The delivery method was simple, it's easy for us to deliver the oral health messages and easy for the parents to understand. (Participant 4, DT).

e. OHE tools and materials

Participants shared positive feedback regarding the use of the caries risk assessment (CRA) form. Despite this being their first exposure to CRA, they found it to be user-friendly and was very helpful to inform parents about their children's oral health status, caries risk, and steps to be taken to reduce the risks for caries and its prevention in their children.

The CRA form is new to us, however through training we know how to use it as a consultation tool. It was very helpful to identify the child's problems and cause of tooth decay. From there we can give suitable advice. (Participant 1, DT)

As part of the intervention, parents were given OHE pamphlets, fluoridated toothpaste, toothbrushes, and toothbrushing chart for home use. The participants perceived the oral health materials as a show of appreciation for parents' cooperation and support. The tokens were also meant to help and motivate their children to brush their teeth at home.

Parents were very happy to receive the pamphlets, toothpaste, toothbrushes, and toothbrushing chart. At least they don't go home empty handed (Participant 2, DT).

The participants perceived that the exposure to this programme and the SIMSP booklet for teachers had improved preschool teachers' awareness about the importance of oral health.

*The teachers were more responsive and cooperative because they understand the importance of the oral health through reading the SIMSP booklet. (*Participant 2, DT).

f) Good support from teachers

All participants agreed that preschool teachers' support and cooperation was a major factor for the SIMSP's success. Teachers played an important role as a mediator between the DTs, the preschool children and parents.

In order to invite parents to the preschool, we definitely need the teacher's help and I don't think this programme is a burden to the teachers. (Participant 1, DT)

The participants highlighted the teacher's cooperation during the SIMSP. This improvement was maybe due to increased awareness among the teachers after their involvement in the SIMSP.

The teachers were very cooperative. Before this, the teachers were quite reluctant to invite parents to preschool during our dental visit. However, during the SIMSP, they were very helpful. Maybe this was due to increased awareness among the teachers

This programme might have improved teacher's awareness on oral health. Therefore, all teachers involved in the SIMSP were willing to help and support the programme (Participant 4, DT)

Participants spoke about the influence of teachers on preschool children. They perceived that teachers could help the preschool children to achieve good oral health status by conducting daily toothbrushing as part of daily school activity.

Teachers play a huge role to run this programme. So far, they are very cooperative. Almost all of them conduct toothbrushing drill (Participant 8, HA)

4.9.4 Perspectives of the dental team on the barriers to implementing the SIMSP in the preschool settings (Secondary objective 3d)

a) High workload of DT

In general, the main barrier to the SIMSP implementation was the DTs' high workload in other aspects of their work. The DT's current job scope is very broad and demanding. Their job scope required them to be involved in many other dental programmes such as in primary and secondary school oral health programmes, toddlers' programme, other oral health promotion programmes, and many others. Therefore, their schedules are full. In their opinion, they can deliver the SIMSP well if they focus solely on the preschool programme.

If we can focus solely on the preschool programme, we think we can improve the POHP. (All DTs)

*But if we really want to run the SIMSP, maybe we should just focus on the government preschools first. There are too many private preschools, I'm worried we won't be able to include them all. (*Participant 4, DT)

b) Lack of full parental attendance

To get all parents to be involved in the existing POHP has been a long-standing problem to the dental service. The participants were aware of the POHP guideline recommendation for parents' attendance during dental visit at preschool. However, the DTs were not able to meet this recommendation. Proactive action is needed to improve the POHP.

*It's not easy to get parents to come for dental consultation. To tackle them, we need to be creative. (*All DT)

Even with the SIMSP, not all parents could attend the meetings. Ideally, all parents should attend the meetings with the DTs. However, parents' participation had increased a lot more compared to before.

*We can wish to get 100% attendance from the parents (*Participant 4, DT)

c) Limited resources

Majority of the participants were concerned about the continuity of the SIMSP due to limited resources. The resources include DT workforce, dental materials and transportation. They hoped that the state dental administrators will be able to resolve this problem in the future such as by collaboration of the SIMSP with relevant industries.

*To continue the SIMSP after this, we will need special allocation for it. For now, even to get transportation to preschool can be a problem (*Participant 3, DT).

For this research, the SIMSP team consisted of 5 DTs and 4 HAs. Since the delivery of the SIMSP dependent on advanced planning especially for meeting with parents, everybody's commitment was crucial.

Teamwork is important to ensure success in any programme. For that, we need everyone to be responsible and always stick to plan (Participant 6, HA)

4.9.5 Perspectives of the dental team on the suggestions for improving the SIMSP (Secondary objective 3e)

a) Include dental officer as part of the dedicated team

All participants were happy with the SIMSP. However, they did voice out several issues to improve the programme. All participants agreed that the SIMSP's dedicated team should include at least one dental officer. Based on their experience, some parents may enquire questions which the DTs were not confident to answer. A DT recalled an incident when she was asked about fluorosis and she was reluctant to answer because of limited knowledge on her part. A dental officer may be able to facilitate and provide answers to the parent.

I think it's good to have a dental officer as part of the team. Some parents ask difficult questions which we (the DTs) are unsure of the answers. We don't know if we can be ready to answer all inquiries from the parents and teachers, that's why we need a dental officer to back us up. (Participant 3, DT)

The participants perceived that parents and preschool teachers would be more interested to attend the meeting if a dental officer is present.

Parents are more confident if they see a doctor around. (Participant 7, HA)

Besides providing supervision during dental consultations, dental officers are needed to issue and sign time slips to parent upon request.

We need the dental officer to supervise and sign the time slips as well. (Participant 5, DT)

The participants suggested for the delivery of the electronic oral health infographics to be done by a dental officer. In addition, it is best if the administrators can provide a sim card purposely for the SIMSP usage. They felt using a personal phone number is unsafe and unprofessional.

I think for OHE blasts through electronic messaging, it is best done by a dental officer. If the receivers have any enquiries, they can directly ask the doctor. (Participant 2, DT)

b) Input from parents of the SIMSP

In unison, all participants agreed that the SIMSP is better than the current POHP. They perceived that the SIMSP is a beneficial programme to the preschool children. However, they did have concerns about other stakeholders' opinion especially the parents.

I think this programme is good but must get opinion from parents as well. What does the parents say about this programme? (Participant 3, DT)

Through observation, the dedicated team perceived that parents were happy with the SIMSP. Even so, they suggested for the researcher to get parents' opinion regarding this matter.

The parents seem happy during the meetings, but we need to get their opinion. (Participant 9, HA)

c. Incorporate the SIMSP into existing POHP

Even though the POHP had been established since 30 years ago, this programme failed to address factors that could influence preschool children's oral health such as

parental influence, sugars intake, bottle feeding and many others. The participants realised that the SIMSP was formulated to include parents and preschool teachers as agent of change for preschool children's oral health. So, all participants unanimously suggested to incorporate the SIMSP into the current POHP.

The SIMSP should be introduced in preschools. When the children enter primary school, it's too late to get parents involvement. (Participant 2, DT)

For now, the SIMSP is conducted as part of a community trial and everything seems to be working out well. However, the participants were concerned whether the SIMSP can be carried out and sustainable. Therefore, they suggested for a pilot study to test the SIMSP in a different work setting.

First of all, it is necessary to create a dedicated team for POHP and try to incorporate the SIMSP in the real work setting. (Participant 1, DT)

d. Training to improve delivery of the SIMSP

All participants agreed that continuous training is needed to improve their knowledge and communication skills for the SIMSP.

We hope to get more training and improve our knowledge on fluorosis, fluoride and some other topics. (Participant 2, DT)

e. Obtain funding from industries

Referring to a yearly school dental programme for year 1 children in primary school which is sponsored by Colgate, the participants suggested the programme to be shifted to preschool level. They perceived that it will be more beneficial to the children.

We need special allocation for the SIMSP. Maybe we can ask for sponsorship for preschool programme. We can send our pictures to dental company like Colgate. I suggest changing Colgate's primary school programme to preschool. If we can incorporate that programme just within this district, it will be good enough. This is because it is too late to get parents involvement in Primary School (Participant 2, DT)

Table 4.25 summarises the emerged themes from the FGD sessions based on domains.

Table 4.25 : Results of the FGD according to discussion domains

Domain	Themes	Verbatim
1. Appropriateness	a. Parental involvement in child's health	• *We need to have an event suitable to tackle the parents. This programme gave us an idea how to do it* *All participants* • *Preschool programmes must include parents. Before, we hardly get parents' involvement. But with this programme, parental involvement increased.* *P4, DT* • *Throughout my working experience, there is never a preschool programme that gives attention to parents* *P7, HA* • *If the preschool student needs restorative treatment using high speed instruments, we can inform the parents directly and tell them to bring their children to the clinic for treatment* *P3, DT* • *The SIMS programme has a more comprehensive plan that incorporates everyone involved in preschool children's oral health. So everyone has their own responsibility* • *P8, HA*

Table 4.25: Results of the FGD according to discussion domains (continued)

Domain	Themes	Verbatim
1. Appropriateness	b. Address individual dental problems	• *So in this the SIMS programme we will meet parents one by one. By doing so we can find out what the problem is. Especially the children with dental problem. So from there we know what the problem is, can guide the parent, tell parents how to deal with it. So I think the programme is kind of good* *P4, DT* • *Before this programme, we gave talk to parents in general, with no focus on individual dental problems.* *P1, DT*
2. Effectiveness	a. Increase parents' oral health awareness	• *Hopefully through individual meeting with parents, it will give the parents awareness to take their children to the clinic* *P2, DT* • *If the parents have awareness, they will take the child to the clinic for treatment no matter if they are busy at work* *P2, DT*
	b. Improve children's toothbrushing habits	• *At the intervention preschools, I witnessed the children will automatically brush their teeth after meal* *P6, HA*

Table 4.25: Results of the FGD according to discussion domains (continued)

Domain	Themes	Verbatim
2. Effectiveness	b. Improve children's toothbrushing habits	• *They have better discipline; they know what to do after eating at school. That is to brush their teeth* *P3, DT*
	c. Improve parents' oral health knowledge	• *We can guide parents to improve their children's oral health by identifying the cause of their problems through CRA* *P5, DT* • *Before this maybe parents didn't know the importance of good oral health habit such as toothbrushing before going to bed. When we meet face to face, they can get the information and directly ask if they don't understand.* *P3, DT* • *Many parents are surprised to find out that permanent molars have erupted in their children's mouth. Before this, they do not know about it and are motivated to keep those teeth caries free* *P2, DT*

Table 4.25: Results of the FGD according to discussion domains (continued)

Domain	Themes	Verbatim
2. Effectiveness	c. Improve parents' oral health knowledge	• *We can tell parents about caries in detail, for example how it started and how to prevent it* *P4, DT*
	d. Improve preschool children's oral health	• *In general, we find children in the intervention programme have cleaner teeth. Makes it easier for us to apply fluoride varnish* *P3, DT* • *From the CRA form, we can identify the preschool children's problems. From there, we know what to advice the parents and their children* *P4, DT*
3. Facilitators	a. Support from administrators	• *Our bosses really want us to run a dedicated team, but they do not have a clear idea how it should be done. They are keen on the SIMS programme outcome and asked us for feedbacks* *P3, DT*

Table 4.25: Results of the FGD according to discussion domains (continued)

Domain	Themes	Verbatim
3. Facilitators	a. Support from administrators	• *During meeting with parents for the SIMS programme, our boss allowed us (the DTs and HAs) to wear normal clothes. Children sometimes get afraid and cry when they see us in white uniforms* *P5, DT* • *We were allowed to issue timeslips for working parents who attended the meeting. So those parents can request for timeslip if the need them* *P2, DT*
	b. Parental support	• *Before this, we hardly get parents' participation in our POHP. But with the SIMS programme, they are willing to join and parental involvement increased. We're happy because it looks good in our work record. . (Participant 3, DT).* *P5, DT*
	c. Less formal set up for meeting	• *We met parents in a relaxed and less formal environment, therefore we found that the parents and their children were more responsive.* *P3, DT* • *Plus, when the children saw their parents there, the kids get excited. They sit with their parents and listen to our advice.* *P5, DT*

Table 4.25: Results of the FGD according to discussion domains (continued)

Domain	Themes	Verbatim
3. Facilitators	d. Simple oral health messages	• *The OHE messages are simple and easy for us to understand, and easy for us to deliver. The content of the pamphlet is simple, and we can use it to explain reasons for tooth decay in easy terms.* *P5, DT* • *The delivery method is simple, it's easy for us to deliver the oral health messages and easy for the parents to understand.* *P4, DT*
	e. OHE tools and materials	• *The caries risk assessment form is new to us, however through training we know how to use it as a consultation tool. It is helpful to identify the patient's problems and cause for tooth decay. From there we can give suitable advice.* *P1, DT* • *Parents were very happy to receive the pamphlets, toothpaste, toothbrushes, and toothbrushing chart. At least they don't go home empty handed* *P2, DT*
	f. Good support from teachers	• *This programme might have improved teacher's awareness on oral health. Therefore, all teachers involved in the SIMS programme are willing to help and support the programme* *P4, DT*

Table 4.25: Results of the FGD according to discussion domains (continued)

Domain	Themes	Verbatim
3. Facilitators	f. Good support from teachers	• *In order to invite parents to the preschool, we definitely need the teacher's help and I don't think this programme is a burden to the teachers* *P1, DT* • *Maybe the teachers are more responsive and cooperative because they understand the importance of the oral health through reading the SIMS programme booklet.* *P2, DT* • *Ok, the teachers are very cooperative. Before this, the teachers are quite reluctant to invite parents to preschool during our dental visit. However, during The SIMS programme, they are very helpful. Maybe this is due to increased awareness among the teachers* *P6, HA* • *Teachers play a huge role to run this programme. So far, they are very cooperative. Many of them conduct toothbrushing drill* *P8, HA*

Table 4.25: Results of the FGD according to discussion domains (continued)

Domain	Themes	Verbatim
4. Barriers	a. High work burden	• *If we can focus solely on preschool programme, we think we can improve the POHP* *All DT*
	b. Parents involvement	• *It's not easy to get parents to come for dental consultation. To tackle them, we need to be creative* *All DT* • *We wish to get 100% attendance from the parents* *P4, DT*
	c. Limited resources	• *To continue the SIMSP after this, we will need special allocation for it. For now, even to get transportation to preschool is a problem* *P3, DT* • *Teamwork is important to ensure success in any programme. For that, we need everyone to be responsible and always stick to plan* *P6, HA*

Table 4.25: Results of the FGD according to discussion domains (continued)

Domain	Themes	Verbatim
5. Suggestions for improvement	a. Include dental officer as part of dedicated team	• *I think it's good to have a dental officer as part of the team. Some parents ask difficult questions which we (the DT) are unsure of the answers. We don't know if we can be ready to answer all inquiries from the parents and teachers, that's why we need a dental officer to back us up* *P3, DT* • *We need the dental officer to supervise and sign the timeslips* *P5, DT* • *Parents are more confident if they see a doctor around* *P7, HA* • *I think for OHE blasts through electronic messaging, it best done by dental officers* *P2, DT*
	b. Opinion from other stakeholders	• *I think this programme is good but must get opinion from parents as well. What does the parents say about this programme?* *P3, DT* • *The parents seem happy during the meetings, but we need to get their opinion* *P9, HA*

Table 4.25: Results of the FGD according to discussion domains (continued)

Domain	Themes	Verbatim
	c. Incorporate the SIMS programme in current POHP	• *When the children enter primary school, it's too late to get parents involved* *P2, DT* • *First of all, it is necessary to create a dedicated team for POHP and try to incorporate the SIMS programme in the real work setting.* *All DT*
	d. Training to improve delivery	• *We hope to get more training on certain matters such as fluorosis, fluoride and some other topics.* *P2, DT*
	e. Obtain funding from industry	• *We need special allocation for the SIMS programme. Maybe we can ask for sponsorship for preschool programme. We can send our pictures to dental company like Colgate. I suggest to change Colgate's primary school programme to preschool better. If we can incorporate the SIMS programme just within this district, it will be good enough. This is because it's too late to get parents involvement at Standard 1.* *P2, DT*

CHAPTER 5: DISCUSSION

5.1 Introduction

This study was a pragmatic, cluster-randomised, parallel-group, matched pair, controlled trial comparing the effect of SIMPS over and above the POHP on preschool children's oral health parameters and parents' OHL over 6 months in the Kampar district, Perak. Pragmatic trials are interventions tested within a real-world situation and they are felt to be better at evaluating the effectiveness of an intervention at the community level and help to promote the external validity of the research findings (Roland & Torgerson, 1998). This programme placed a great importance on parents' and teachers' involvement in preschool children's oral health by applying interventions that involved their active participation. This programme also explored opinions from DTs on the strategies used in the SIMSP in order to improve and strengthen the SIMSP in providing oral health care to the preschool children and OHE to parents/guardians.

This chapter will discuss the results of the present study, compare the results with relevant past studies, and discuss the research finding differences in the present study with other related studies in Malaysia and elsewhere.

5.2 Intention to treat (ITT) analysis

It was common for patients in clinical trials to not always adhere to the protocol. Excluding drop-out patients from the analysis can have significant implications that can impact the results and analysis of a study. In our study, ITT was carried out for the primary and secondary outcome measures (White, Horton, Carpenter, & Pocock, 2011). ITT analysis included 16.6% and 23.6% of non-respondents from the SISMP and POHP, respectively. ITT analysis was conducted for several reasons. The main reason for the ITT analysis in the study was to maintain the prognostic balance generated from the original random treatment allocation. Secondly, it was to overcome potential compliance

bias from the dropouts. Excluding the dropouts from analysis can result in biased outcomes. Thirdly, the researchers do not want to overestimate the study outcomes. Even though ITT analysis can potentially dilute the magnitude of potential effectiveness of a study, results from ITT analysis is more accurate with unbiased estimate. ITT is commonly used in data analysis in RCT and its use in our study was justified (McCoy, 2017). Per-protocol analysis was not conducted in this study for the reasons mentioned above.

5.3 Response rate

The response rates were considered acceptable at baseline and after 6 months. At baseline, the overall recruitment rate for oral examination was 89.5% (n=653/730), where the percentage in the SIMSP and POHP was 94.0% and 84.9%, respectively. The high recruitment rate could be attributed to the good collaboration and support provided by the preschool teachers as well as the support from the school and district administrations. In our study, the teachers helped to distribute the consent form to parents and informed them about the study. The consent forms were collected by the teachers and returned to the researcher before data collection began. The preschool teachers and their assistants also helped to ensure the preschool children followed the instructions given by the researcher and thereby reducing dental anxiety among them. In addition, the preschool children were captive groups during school days, therefore there were easily accessible on school days, thus, contributed towards the high recruitment rate in this research. After the oral examination at baseline, the parental questionnaire was distributed to parents through preschool teachers. Of the 653 questionnaires distributed, 517 were returned (response rate = 79.2%). The response rate was considered acceptable from a questionnaire distribution (Baruch,1999).

The overall response rate for oral examination after 6 months was 80.1% (n = 523/653), 83.4% in the SIMSP (n = 287/344), and 76.4% in the POHP (n = 236/309). The main reason for the reduced response rates was because some of the preschool children had moved to other schools. The number of schoolchildren who moved schools were 19 (SIMSP =11, POHP=8) as stated in Chapter 4. However, the majority of the dropouts were caused by the preschool children being absent (SIMSP = 46, POHP = 65) during the oral examination day since attendance was not compulsory unlike at primary and secondary schools. In addition, it was the raining season during the follow-up examinations which contributed towards the non-attendance of the preschool children. As the examiners were working in the government service, they were unable to return to the preschools multiple times as they had to adhere to strict work schedule and the study protocol. There were 28 preschools altogether and they could only spend a few days in each of the preschools for collecting data. This was considered appropriate to achieve maximum attendance for the oral examinations. Post intervention questionnaire was distributed to 517 parents, with 86.3% response rate. This response rate was considered acceptable for data collection using questionnaire (Baruch, 1999).

The number of preschool children who completed the oral examinations after 6 months were 523, which was approximately 20% less from the baseline. The response rate in our study was better than the response rate from a similar trial in Thailand, which was 24% (Poul Erik Petersen et al., 2015). To ensure adequate statistical power for data analysis, a retrospective power analysis for the primary and secondary outcome measures was conducted. The statistical power of the study for all outcome measures were more than 80%. These reported values exceeded the minimum proposed value of .80 by Cohen (J Cohen, 1988). Therefore, the study had sufficient power to detect change in the outcome if they were truly present.

5.4 Demographic characteristics of the sample

Prior to recruitment of the preschools, matching of preschools was conducted between the SIMSP and POHP to minimise differences in demographic background between the groups. This was important to ensure the differences in the findings between the groups were primarily due to the intervention and not the confounders. Factors that were matched were the location, type of preschool, and number of students in each preschool.

At baseline, significant differences were observed in children's gender and father's education level between groups. More fathers with no formal education and primary education level were included in the SIMSP, whereas the proportion of fathers with education level up to STPM/College was significantly higher in the POHP compared to the SIMSP ($p < 0.005$). It was identified that the difference could be due to one of the preschools in the POHP had more fathers with a diploma compared to its matching pair the SIMSP. It could be said that this factor was not within the control of the researcher as the matching was done based on location which mirrored the socioeconomic position. Also, the difference could be that the rural and urban categories of the preschools was decided by the Ministry of Education and not specifically based on income or education levels of the parents as these factors are difficult to determine in the community. Based on this finding, in theory, the SIMSP would have been in a more disadvantaged position at baseline due to differences in father's education level. However, the findings of the primary outcome of the study indicated otherwise which provided a strong evidence in favour of the SIMSP.

Despite a significant difference in father's education level between the SIMSP and POHP, data from the caries levels and dental plaque of the children between groups at baseline indicated that the groups were effectively similar in terms of their oral health status and oral disease level. As health in general is associated with sociodemographic

factors, it could be argued that the non-significant difference in the oral health status between both groups at baseline indicated that overall both groups were not significantly different in terms of their SES at baseline (Rai & Tiwari, 2018).

Children in the SIMSP and POHP had similar caries level and dental plaque scores at baseline. Although caries was not an outcome measure of the study, its assessment was necessary to assess if differences in caries levels existed between the groups at baseline. With the majority (95.6%) of the preschool children had cavitated lesions ($ICDAS_{3-6}$), this indicated that the study area had high disease burden in term of caries prevalence of deciduous teeth. Similarly, caries assessment at tooth level showed no significant difference between the SIMSP and the POHP at baseline indicating both groups were similar in terms of oral health status at the start of the study. Majority of the teeth were charted as non cavitated caries lesion ($ICDAS_{1-2}$).

5.5 Immediate impact of the SIMSP based on study objectives

5.5.1 To assess the effect of the SIMSP over and above the existing POHP in improving oral hygiene level among 5-6-year-old children in the Kampar District over 6 months (Primary objective).

At baseline, there was no between-group difference in the proportion of children with visible dental plaque, and there was no between-group difference in mean dental plaque scores were observed. However, after 6 months, significantly less proportion of children in the SIMSP had visible plaque than the proportion of children in the POHP, and their mean plaque score decrement after 6 months was significantly higher in the SIMSP than that in the POHP. Similar findings were found at tooth level where significantly more children in the SISMP had clean labial surfaces of 53 – 63 than those in the POHP, and 2 teeth, i.e. 52 and 62 had a significantly higher mean plaque score decrement than those in the POHP after 6 months. At the same time, significantly more children in the SIMSP had

improvement in their plaque score change from score 2 to score 0 than those in the POHP. All these improvements were consistent in favour of the SIMSP. The significant improvement in dental plaque indicates that children in the SIMSP had a lower risk of developing caries after 6 months than children in the POHP with regards to the presence of dental plaque bacteria. This is because the quantity of cariogenic bacteria responsible for dental caries initiation and progression was significantly lower in the SIMSP than children in the POHP group (Axelsson, Nyström, & Lindhe, 2004). This positive finding in the primary objective in favour of the SIMSP over and above the POHP indicated that the SIMSP was significantly better than the existing POHP in improving oral hygiene level of the preschool children. This may contribute towards better oral health status of the preschool children in the future.

The much improvement in oral hygiene level of the SIMSP children could be attributed to the teacher-supervised daily toothbrushing at school in the SIMSP over 6 months. The daily toothbrushing at school also helped to inculcate a positive toothbrushing habit among children at a young age which would impact positively on future caries reduction in the permanent teeth (P. E. Petersen et al., 2015). Daily toothbrushing at school also ensured that the children were exposed to fluoride that helped to control caries initiation and progression (Walsh et al., 2010). The daily toothbrushing at school was reinforced by home supervised toothbrushing at night by parents. This is especially relevant in the Kampar district because the preschool children have high caries levels (Perak Oral Health Division, 2019).

The findings in this study were similar with findings from study in the UK and a study in Thailand where a school-based oral health promotion programme was combined with a teacher-supervised toothbrushing programme (Petersen et al., 2015; Wind, Kremers, Thijs, & Brug, 2005). In both studies, the children brushed their teeth frequently

which resulted in reductions of dental plaque scores, caries risk, and better delivery of fluoride from the toothpaste.

Effect size was defined by Cohen (1962) as a measure of the degree of difference or association deemed large enough to be of 'practical significance'(Cohen, 1962). For the readers to appreciate the magnitude or importance of a study's findings, it is almost always necessary to include some measure of effect size in the results section (American Psychological Association, 2010). Effect size differs from significance tests because it focuses on the meaning of the results and enables comparison between or among studies which further enables researchers to judge the practical significance of quantitative research results (Kotrlik, Williams, & Jabor, 2011). Fan (2001) suggested that good research report should present both statistical significance testing results and effect sizes to indicate practical significance (Fan, 2001).

In this study, the SIMSP produced a moderate effect (0.64) on dental plaque reduction over and above the POHP. This is important because on average investigators in clinical studies would anticipate effect sizes between 0.2 to 0.4 that indicates good practice and corresponds to clinically meaningful difference (Rothwell, Julious, & Cooper, 2018). As effect size is the magnitude of the impact observed from an intervention or an experiment, this shows that the implementation of the SIMSP produced an effect of moderate magnitude over and above the POHP in improving preschool children's oral hygiene levels. It also indicates that the SIMSP is far more superior and arguably more effective than the POHP. The moderate effect size from the SIMSP may be the result of a combination of several interventions including OHE to the parents and children, as well as daily toothbrushing training and monitoring by teachers.

Oral hygiene level of children can provide valuable information as proxy for their toothbrushing activity and the likely exposure to fluoride toothpaste (Public Health

England, 2015). Supervised toothbrushing activities in schools can potentially establish a regular oral hygiene practice among children and it can easily be conducted by teachers on a daily basis (Petersen & Kwan, 2004). Besides in-school supervised toothbrushing, the SIMSP also targeted parents on the need for monitoring regular toothbrushing of their children at home, the importance and appropriate use of fluoride toothpaste at home, and control of sugars intake. This information was given to parents through meeting with the DTs at school and through the OHE infographics sent to parents over a period of 6 months. This may have contributed to the overall improvement of plaque score as well. The findings also showed the importance of targeting significant others in relation to preschool children as they depended a lot on others for their daily life activities. Similar results were seen in a study in India where mothers of preschool children received daily OHE SMS. The results of the study showed a significant reduction in their children's visible plaque index (Sharma et al., 2011).

The results showed that the children with high caries risk levels in SIMSP were the ones that benefited the most from this study as the plaque score reduction was consistently higher among these children. In the current oral health services setting where the resources are limited, the use of CRA can help to prioritise treatment planning for preschool children.

The oral cleanliness index used in this study recorded the presence of plaque on labial surfaces of 53 to 63. Similar method of recording oral hygiene levels was done in the oral health survey of five-year-old children in 2016–2017 in England and in the NOHPS Malaysia in 2015 (Oral Health Division, 2017; Public Health England, 2015). This index was used for this study so that the results can be compared with outcomes from other earlier surveys or studies using the same index. A disadvantage of using the index is that plaque in posterior surfaces of the teeth were not recorded. This may result

in a drawback, since preschool children may have poor dexterity in toothbrushing especially on the posterior teeth (Mescher, Brine, & Biller, 1980). However, it is expected for preschool children to get assistance during toothbrushing from their parents / carers at home because toothbrushing skills are low in children younger than 10 years of age. It is strongly recommended that toothbrushing be performed or assisted by parents in this age group. Hence, parental supervision is considered necessary and recommended until children reach 10 years of age (Pujar & Subbareddy, 2013). Based on the results from the present study, majority of parents from both groups reported that they monitored their children's toothbrushing activity. Furthermore, children's skills in brushing their own teeth can improve with daily practice and motivation from their parents and teachers (Unkel, Fenton, Hobbs, & Frere, 1995).

5.5.2 To assess the impact of the SIMSP over and above the existing POHP in 6 months in terms of children's oral health and related behaviours (Secondary objective 1a)

There were improvements in terms of toothbrushing habit, use of fluoridated toothpaste, bottle feeding patterns, and carbonated drinks intake in the SIMSP group. Emphasis on the importance of toothbrushing using fluoridated toothpaste twice a day through OHE and distribution of toothbrush and fluoridated toothpaste for home use might have contributed to the increase in these oral health habits.

At baseline, there was significant difference between the groups in terms of bottle-feeding frequency with higher percentage of children in the SIMSP used bottle feeding daily. At follow-up, both groups showed significant reductions in bottle feeding frequency and between-group difference was no longer significant. Therefore, it could be argued that the impact was a lot more among children in the SIMSP than children in the POHP. This may be attributed to the information given to parents about the negative

effects of prolonged use of bottle feeding during the meeting and in the infographics sent to parents. During the meeting, many parents were aware of the recommendation to stop bottle feeding early however lack the knowledge and motivation to do so. Since the meeting was also attended by the children, the agreement to stop bottle feeding was achieved in unison between the parents and their children.

Numerous studies have documented the cariogenic effects of prolonged or nocturnal bottle feeding in children (Seow, 2012; Koranyi, Rasnake, & Tarnowski, 1991). According to American Academy of Paediatrics, toddlers are advised to stop bottle feeding usage by the age of one (American Academy of Pediatrics AAP, 2002). The findings from the study indicates that a high number of preschool children in the age of 5-6 years are still using bottle feeding. This practice could have contributed to the high prevalence of caries among the children in the sample. In the SIMSP, information on bottle feeding use was retrieved from parents as part of the CRA process. Once the information was obtained, OHE against bottle feeding was given accordingly to parents whose children were still on bottle feeding. This could explain why children in the SIMSP showed more changes in their bottle feeding frequency than those in the POHP.

As for the consumption of carbonated drinks, a significantly higher proportion of children in the intervention (99.6% vs 97.3%) consumed carbonated drinks 1-3x/week or less than those in the control group ($p = 0.033$). A study by Ismail (2009) indicated that carbonated drinks were significant predictors of higher caries increment in primary teeth (Ismail, Sohn, Lim, & Willem, 2009). Therefore, this finding was a good sign for improvement in behaviours among the preschool children especially those in the SIMSP in reducing risk of caries development. The reduction in carbonated drink consumption in the SIMSP could be attributed to the meeting with parents where the DTs delivered dietary sugars advice to the parents along with the presence of their child.

Apart from a significant improvement in carbonated drinks intake, the researchers cannot conclude if the SIMSP had significant impact on the overall improvement of OHBs between children in both groups as children in the POHP also reported improvements in many of the OHB items. Between-group comparisons showed that children in the SIMSP showed no significance changes in OHB items than children in the POHP except for carbonated drink intake frequency.

The non-significant differences in OHB items between the groups could be due to several factors. First, behaviour change can be a long and time-consuming process. Establishing positive OHB in children is a process which involves changes in lifestyle, priorities, schedules and other normal routines (Löe, 2000). Since this study was conducted in a span of 6 months, initial positive changes in OHB items were expected. Second, preschool children's behaviours are much determined and influenced by their parents' attitude, knowledge, and practices towards oral health. To develop personal skills in relation to oral hygiene practices, participation of the individual is crucial, or in this study the parents' and their children's participation. As for the preschool children, a wide range of factors may influence them in modifying or determining their OHB, i.e. to establish good oral routines early in life. Continuous positive influences from the parents and teachers can result in favourable OH behaviours.

Based on the follow-up results, there was no significant difference in toothbrushing frequency between the two groups. However, as mentioned earlier, plaque levels in the SIMSP was significantly lower than that in the POHP after 6 months. The improvement in plaque levels could be attributed to the improvement in the toothbrushing techniques among children in the SIMSP than children in the POHP which led to a more effective plaque removal. The supervised daily toothbrushing exercise in the SIMSP over a period of 6 months provided an opportunity for the children to develop a toothbrushing

habit using the correct toothbrushing technique that have gradually improved the children's ability to brush effectively on their own. This is very important because poor toothbrushing habits with poor technique was significantly related to that caries prevalence among preschool children (Boustedt et al., 2020).

In terms of toothbrushing frequency 2 or more times daily, there was a 3.7% difference between the SIMSP and POHP. This result could be seen as small, however, at population level a difference of 3.7% for preschool children who brushed 2 times or more daily could be interpreted as producing a huge clinical significance as a large number of children would be implicated. They would have a higher chance of oral health improvement in the long term.

For the frequency of using toothpaste when brushing, 3.5% more children in the SIMSP used toothpaste when brushing their teeth than children in POHP. Similarly, a 3.5% difference at population level would mean a huge number of children would benefit from regular use of toothpaste while brushing their teeth. If the toothpaste used was a fluoridated toothpaste, it could be translated to a huge preventive strategy against future caries.

Findings suggested that the SIMSP had contributed significantly towards improving the children's toothbrushing skills. This can be supported by a review that concluded children showed significant improvement in toothbrushing skills when demonstration and supervision were provided continuously (Habbu & Krishnappa, 2015). In addition, constant removal of dental plaque and optimal exposure to fluoride will reduce the risk of future caries development. Improvement is toothbrushing behaviour is more achievable in most families with preschool children and clearly a less demanding behaviour change than sugar reduction (Boustedt et al., 2020). Therefore, this outcome is a good indicator of the positive change in toothbrushing behaviour. In our study, the

plaque scores were recorded by blinded examiners in the morning before morning break and before daily toothbrushing session took place. So, it is safe for us to conclude that the improvement in plaque control was genuine and without bias.

5.5.3 To assess the impact of the SIMSP over and above the existing POHP in 6 months in terms of parents' OHL (Secondary objective 1b)

Parents' OHL is an important factor contributing to the overall health of the children (Vann Jr et al., 2010). Poor health literacy is associated with poorer perceptions of health, decreased utilisation of services, and poorer understanding of verbal and written instructions for self-care (Dudovitz, Teutsch, Holt, & Herman, 2020).

OHL is defined as the degree to which individuals have the capacity to obtain, understand and utilise basic oral health information (Sabbahi et al., 2009). By referring to this definition, we attempted to improve parents' OHL through face to face OHE and the delivery of OHE infographics 2-weekly over the duration of 6 months. To further improve parents' understanding of the OHE, we provided a two-way communication platform via WhatsApp application for them to communicate with dental service providers, and for the SIMSP it was the DTs. However, this was not available for parents who received printed infographics. Even though health literacy is commonly defined as an individual trait, there is an increasing recognition that health literacy does not depend on the skills of individuals alone but the health system itself needs to align health care demands better with the public's skills and abilities (French, 2014). Therefore, during the planning of the SIMSP, we took careful consideration of various factors such as the topics, use of words, infographics designs, and many other factors to ensure that the SIMSP package was suitable for the recipients, in this case the parents. We refrained from using medical or dental jargons to avoid misunderstanding. DTs were also trained to use simple words to convey OHE to parents. Remarkably, at follow-up, the results showed

that the overall OHL of parents in the SIMSP increased a lot more than parents in the POHP with large effect size. Our results corroborate with the outcomes from a study conducted in Johor state, Malaysia which tested a family dental wellness intervention programme on mothers of preschool aged children (Azhani Ismail, 2016). The study was conducted in a clinical setting where mothers needed to attend a few OHE sessions for a period of 3 years at 6 months intervals. At follow-up,the results showed a significant increase in mothers' OHL levels. Even though the SIMSP was conducted in a different setting with shorter intervention period, it was proven effective to increase parents' overall OHL levels similar with a programme that had longer implementation period.

For the knowledge domain, there was a significant mean score increment in knowledge score in the SIMSP than that in the POHP with large effect size. This finding was expected and could be attributed to the OHE infographics sent to parents in the SIMSP via WhatsApp messaging as the content of the infographics were directly related to the items in the knowledge domain of the OHL questionnaire. The infographics covered 10 topics that would help parents to improve their OHK and use the information to achieve an optimum oral health for their children and themselves. The use of WhatsApp for the delivery of the infographics had significantly improved the process of knowledge sharing. In a FGD conducted by Ismail (2016), the mothers of preschool aged children perceived that social media interaction such as WhatsApp group could improve the communication between the dental providers and the participants in terms of information sharing and updating the family dental wellness programme (Ismail, 2016).

According to the Oxford dictionary, comprehension is defined as the ability to understand something (Oxford, 2011). In the study questionnaire, the comprehension domain tested the parents' ability to understand healthcare instructions using their reading comprehension skills. Respondents needed to answer five questions based on their

understanding of a short scenario given regarding fluoride varnish application. Both baseline and follow-up findings showed that majority of the parents had poor level of comprehension with no significant difference between the groups. In fact, both groups showed decrement in comprehension domain mean scores at follow-up.

From the results, it showed that majority of the respondents had poor reading comprehension to correctly answer the questions. These results were contradicting with the outcomes from a study conducted by Ismail et.al. in (2016) where the results from this study showed 74.7% of mothers in the intervention group were categorized as "good" in the comprehension domain compared to the control group with just 46.5% (Ismail, 2016). However, the results from this current study correlates with the findings from a study on paediatric oral health literacy, which reported that many parents are unable to comprehend health information (Richman et. al., 2011). Reading comprehension is a complicated process because it involves different factors like vocabulary, fluency, culture, and familiarity with the topic (Abdelaal & Sase, 2014). The possible reason for the poor outcome from this study was due to the respondents' unfamiliarity to the subject given which was fluoride varnish application. In the SISMP, information about fluoride varnish was not covered well during parent-DT meeting but was included in the OHE infographics. The results indicated that providing information alone may not be adequate for parents to comprehend. As for the POHP, no prior information with regards to FVA was given to the parents. The importance from this result called for improvement of information delivery especially with regards to topics that were unfamiliar to the parents but important for them to know and understand.

In general, children's prevention of dental disease depended on their parents' confidence or self-efficacy to convert OHK into the necessary parenting skills to promote oral health of their children (Freeman et. al., 2010). Therefore, it is paramount importance

for parents to have good level of skills and motivation to care for their children's oral health. From this study, the mean score increment of the skills and motivation domain in the SIMSP was higher than that in POHP with large effect size. The large effect size was probably attributed by the SIMSP's focus on oral hygiene self-care through developing skills that enable parents to identify their own oral health problems, dental plaque control, healthy diet, effective toothbrushing technique and other oral health related behaviours. This result was in line with the results from a previous study that saw a large improvement in mothers' skills and motivation from an intervention programme that used anticipatory guidance to improve parents' OHL (Ismail et. al., 2018).

The face to face consultation in the SIMSP may have triggered parents' awareness in regards of their children's oral health. Mothers of young children are particularly receptive to dental advice such as brushing teeth twice a day with fluoride toothpaste, reducing the frequency of sugar consumption, and regular dental visits (Ramos-Gomez, Jue, & Bonta, 2002). It was later strengthened with the oral health infographics which included motivation and guidance to acquire dental treatment. In contrast to POHP, the oral health education information to parents (if any) was given through letters via the class teachers. This practice is perceived by the DTs to be less effective to gain parents' awareness of their children's oral health, which in turn was reflected by their lower skills and motivation.

The total OHL scores of parents in the SIMSP had increased more than those in the POHP with large effect size (0.97). This indicates that the SIMSP produced a large magnitude of effect on parents' OHL compared to the POHP which corresponds to good practice. We highly recommend for implementation of the SISMP in preschools as the large effect size of the SIMSP on parents' OHL indicates that the SIMSP is a far more superior programme than the POHP to improve parents' OHL.

5.5.4 The implementation fidelity of the SIMSP protocol in terms of parents' compliance in attending the parent-DT meeting at school (Secondary Objective 2a).

Caries in young children can be prevented to a great extent if parents are sufficiently educated and motivated. Parents' knowledge and oral hygiene behaviours are the key factors that determine their children's oral health care (Miller et al., 2010). The child imitates parental behaviours, including oral hygiene habits. Thus, toothbrushing at an early age depends on parents' knowledge and behaviours (Begzati, Bytyci, Meqa, Latifi-Xhemajli, & Berisha, 2014).

In the SIMSP, DTs tried to empower parents to care for their children's oral health. Parent-DT meeting was scheduled in school approximately 2 weeks after baseline dental check up and parents were invited to attend through an invitation letter which was distributed by preschool teachers. Overall, 286 of 344 parents (83.1%) who were involved in the SIMSP attended the meeting. This high attendance rate of parents could be attributed to the advance planning by the DTs. Since the parents were informed early about the meeting, they were able to make prior arrangements, i.e. taking leave from work in order to attend the meeting. Compared to the previous years under the existing POHP, the DTs were only able to engage with a few number of parents only. (Perak Oral Health Division, 2019). The high attendance rate of parents was also attributed to the teachers' support. Most of the teachers took effort to remind the parents about the meeting via the preschool WhatsApp group or phone calls a few days before the meeting. One preschool even prepared light refreshments for the parents who attended the meeting. This was evident that teachers could play a big role as a mediator between the oral health service, the children, and their parents as proposed by Antunes in 2008 (Antunes et al., 2008). The good cooperation between the preschool teachers and the dental service personnel had

resulted in satisfactory attendance of parents for the meeting. This good compliance from parents in attending the meeting had allowed the DTs to deliver customise OHE to a high number of parents.

Cultural differences were also taken into consideration during the meeting when the DTs had to learn a few Orang Asli (Aborigine people) words to be used during the meeting. A study conducted in New South Wales, Australia was co-designed for Aboriginal children. The results from the intervention showed that there were significant reductions in tooth decay, plaque scores, and gingivitis after 2 years. The authors concluded that the co-design elements in the study were critical to the programme's success (Dimitropoulos et al., 2020) Even though the SIMSP was not co-designed to fit a particular community, the DTs were well aware of the parents' culture before meeting them. From the observation done by the researcher (NH), the Orang Asli parents from the Orang Asli community were very receptive and communicated well with the DTs.

5.5.5 The implementation fidelity of the SIMSP protocol in terms of teachers' compliance in delivering in-class OHE, dental worksheets, and supervising daily toothbrushing with the preschool children (Secondary objective 2b).

In the SIMSP protocol, teachers were required to deliver in-class OHE on a fortnightly basis followed by a worksheet for the children to complete at the end of each lesson. The oral health lessons were delivered over a period of 6 months. In addition to that, teachers were required to supervise the children on daily toothbrushing at school. From the self-reported records by teachers, the compliance rate of teachers in delivering the in-class OH lessons and dental worksheets were both at 96.8%. Two preschool teachers did not manage to complete the in-class oral health lessons because they were on maternity leave. The teachers' compliance rate in supervising daily toothbrushing at school was 93.7%.

Two preschools in the SIMSP did not participate in the supervised toothbrushing exercise due to limited space.

The high compliance rate of teachers with regards to the SIMSP protocol was attributed to their overwhelming support for the programme and the ease of delivering the OHE using the teacher's booklet as the teaching aid. In the current POHP, even though teachers were encouraged to deliver OHE in class, they were not supplied with teaching aids despite the evidence from the literature of teachers' role and commitment in the success of school-based oral health programmes (Antunes et al., 2008; Petersen & Kwan, 2004). A study by Chandrashekar et. al. (2014) evaluated the OH outcomes form OHP programmes among rural schoolchildren who received OHE from qualified dentists and school teachers. He concluded that frequent OHE by trained teachers were feasible and more effective than the infrequent OHE by qualified dentists in improving children's oral cleanliness levels (Chandrashekar et al., 2014).

On a daily basis, the teachers in the SIMSP were required to supervise toothbrushing activity of the children after morning snack. All children were supplied with a toothbrush and fluoridated toothpaste for this activity. At the 6-month examination, there were significant differences in plaque scores between the groups with less plaque seen in the SIMSP group. Supervised toothbrushing at school has the potential to establish a regular oral hygiene practice as it can easily be conducted by teachers (Cooper et al., 2013; Pine, 2007). This is especially relevant in areas with high disease burden and shortage of health personnel especially DTs. Two preschools recorded poor fidelity to this activity. The reason was due to the lack of toothbrushing facility as the two preschools were located in a small and confined area. As the result, they had not participated in the daily toothbrushing activities. In the existing POHP, teachers were encouraged to

conduct toothbrushing drills among the children according to the POHP guidelines. However, no data is available on its implementation.

The high compliance rate of toothbrushing supervision by the teachers in the SIMSP could be attributed to the free supplies of toothbrush and toothpaste provided for school use. This factor may pose as a challenge for the sustainability of the SIMSP in the future because oral hygiene materials will incur some financial cost to the oral health service and/or preschools. As a result, sponsors for oral hygiene aids are required. This could be obtained from private companies as a means of corporate social responsibility and the contribution should be tax deductible.

5.5.6 The implementation fidelity of the SIMSP protocol in terms of DT's compliance in sending oral health infographics to parents via WhatsApp application (or paper infographics) (Secondary objective 2c)

For the SIMSP, ten oral health infographics were delivered to parents in a span of six months' period. The compliance rate of DTs to deliver oral health infographics to parents during the period was 100%. The sending of the oral health infographics to parents had never been implemented in the POHP. The rationale for this intervention was to enable DTs to deliver continuous OHE to parents on topics relevant to their family's oral health over a period of time. The high fidelity rate was attributed to the ease of delivering the oral health infographics via WhatsApp and the parents' readiness to participate in the programme that benefitted their children. Since the infographics were already reviewed and vetted prior to use, the DTs were confident to share the information. Parents from two preschools in the Orang Asli community were given printed versions of the infographics through class teachers because of low hand phone usage and poor internet coverage in the Orang Asli area. This intervention was also working because the usage of WhatsApp application among Malaysian citizens is very high (Malaysian

Communications and Multimedia Commision, 2018). Therefore, it was the social media application of choice for this study. What is appealing about using the WhatsApp or any electronic messaging application was it provided a 2-way communication platform between the oral health personnel and the parents by providing cues to action, prompts, reminders, reinforcement, and feedback with regards to oral health, all of which are important promoting factors of behavior change (Norman, Kolodziejczyk, Adams, Patrick, & Marshall, 2013). Electronic messages have the advantage of reaching large segments of previously unreachable populations with evidenced–based information, in real time and real–life settings (Hashemian et al., 2015). However, this advantage is not attainable by using printed OHE infographics. WhatsApp usage has been adopted by many other disciplines in dentistry for different reasons such as oral medicine consultation (Petruzzi & De Benedittis, 2016), oral cancer knowledge (Nayak, Nayak, Sathiyabalan, Aditya, & Das, 2018), and even in interdisciplinary communication (Ramdurg, Naveen, Mendigeri, Sande, & Sali, 2016). However, issues pertaining to confidentiality, data security and storage, record keeping and reporting had cause for concern among clinicians, patients and law makers (Mars & Scott, 2016). For the SIMSP, additional consent was retrieved from parents prior to sending the oral health infographics via WhatsApp and parents were allowed to leave the WhatsApp group anytime they want. None of the parents left the group until the end of the study.

5.6 Process evaluation of the SIMSP through qualitative study with the dental team

Process evaluation through FGD was conducted to gain valuable insights into the implementation process of the SIMSP and indirectly support the quantitative findings of the present study. The qualitative evaluation can generate important qualitative data of

the SIMSP, which cannot be obtained using quantifiable measurements (Elo et al., 2014). The aim of the FGD was to allow a dynamic discussion by the participants to take place on the assigned topics related to the SIMSP.

During the FGD, the participants' expressions were observed in terms of their voice tone, confidence level, and their answers. An uninterrupted discussion was allowed to take place until the discussion on a certain topic has reached saturation (Krueger, 2014). In terms of data analysis, the framework method analysis was used to analyse the qualitative data (Galel et al., 2013). In this method, the emerging codes were developed based on answers from the set of open-ended questions prepared prior to the FGD. The open-ended questions were prepared to guide the FGD and to ensure the same questions were asked in the two different sessions of FGD. Therefore, the cumulative opinions gathered from the two different sessions of FGD can be concluded. The FGD was conducted with the dental team that was involved in the SIMSP, which comprised of DTs and HAs. The FGD was conducted in two sessions, one session for different work positions. This was done to allow homogeneity of participants within the group and prevent differences in job positions to affect the discussion. Overall, the FGD topic guide consisted of 5 domains, i.e. appropriateness of the SIMSP, the effectiveness of the SIMSP, the facilitators and barriers to implement the SIMSP, and recommendations for improvement of the SIMSP.

The FGD participants consisted of 5 DTs and 4 HAs. There was only one male participant who worked as a HA while the other 8 participants were female DTs and HAs.

5.6.1 The perspectives of the dental team on the appropriateness of the SIMSP in the preschool settings (Secondary objective 3a)

In general, all DTs and HAs agreed that the SIMSP is a suitable and appropriate programme for the preschool children because the programme included parents' participation. All participants agreed that a child's oral health is highly influenced by their parents' actions and programmes that include the participation of parents are always welcomed. Even though the dental team was aware of the importance to include parents in the existing POHP, they had little idea and support how to realise it.

The DTs reported that they were very satisfied with the parent-DT meetings because they had the opportunity to directly address the child's oral health problems with the parents and offer the right advice. For the POHP, they only communicated with parents through a letter passed on by the class teacher. A qualitative study by Aljafari et al, (2015) reported that currently efforts to prevent caries at the primary care level especially for high risk children are falling short (Aljafari, Gallagher, & Hosey, 2015). The advice given to families seemed to be generic rather than tailored for each child. The main focus seemed to revolve around avoiding sugary foods and improving the frequency of toothbrushing. The generic advice was ineffective and may not solve the problems of high caries rate among the children that resulted in high rate of referral for tooth extraction under general anaesthesia (Aljafari et. al., 2015). In the SIMSP, the DTs identified the risk factors associated with a particular child and gave the right OHE accordingly to the parents.

All participants agreed that an intervention programme like the SIMSP is best implemented during preschool years to correspond with the eruption of PFM. Using the principles of anticipatory guidance, parents were informed about the incoming eruption of permanent first molars (Sharma, Jayaprakash, Rajasekharan, & Sharma, 2014). This

information was repeated again in the infographics sent to parents. For children with clinically visible PFM in the mouth, the DT will show the PFM to the parents as many parents were unaware of the PFM's appearance in the mouth. Suitable advice on oral hygiene care and the avoidance of sugary diet was delivered to parents. It is important for DTs to impart information about the PFM eruption time because parental lack of knowledge on the PFM eruption time was shown as one of the predisposing factors for dental caries in these teeth (Songur et al., 2019).

Although improving the knowledge and awareness is not directly linked to behaviour change, improved knowledge and awareness of parents and caregivers on the child's oral health is a key element of dental prevention in preschool children (R. S. Naidu & Nunn, 2020). In the participants' opinions, the SIMSP was more comprehensive compared to the existing POHP because it take into account of all parties that were involved in preschool children's oral health. With this, the responsibility to promote oral health among preschool children will not fall solely on the dental mobile team. This is in line with the recommendation by Public Health of England for collaborative effort in partnership with dentists, schools and parents to address inequalities in children's oral health (Henderson & Rubin, 2014).

5.6.2 The perspectives of the dental team on the effectiveness of the SIMSP in the preschool settings (Secondary objective 3b)

Through the parent-DT meeting, parents were expected to have better awareness and knowledge about their children's oral health, the risk factors and preventive strategies for plaque control and dental caries. Poor dental awareness will lead to oral hygiene neglect, and this was evident from the high caries experience among the children. The dental teams perceived that the SIMSP was effective to improve parents' dental awareness compared with the existing POHP.

The parent-DT meeting applied the principles of motivational interviewing which is a patient-centered interviewing method that focuses on building intrinsic motivation for change by exploring and resolving uncertainties about oral health among the parents (Borrelli, Tooley, & Scott-Sheldon, 2015). During the meeting, the parents' uncertainties of their children's oral health status were lightened by informing them of their children's caries levels, with visual assistance from the pictures in the CRA from. This helped parents to become more aware of their children's OH problems and became motivated because they knew exactly what to do to improve their child's OH problems. For both the SIMSP and POHP, DTs can only perform ART on preschool children. Those who require more complex treatment are referred to dental clinic. With increased awareness among parents from the SIMSP, the DTs perceived that parents will be more sensitive to their children's oral health needs and become less dependent on the school oral health service by voluntarily taking their children for dental visits for preventive purposes as well as curative.

The dental team also perceived that the SIMSP was effective to improve parents' OHL. Through face to face consultation during parent-DT meeting, DTs were able to observe parents' reaction during the meeting. It is important to be able to identify parents' reactions because people with low OHL do not often ask as many questions as those with high OHL. They are less likely to ask a health care provider to repeat a concept they do not understand. Dental health care providers must be aware of this and take measures to make themselves clear to the patient (Katz, Jacobson, Veledar, & Kripalani, 2007). Through the meeting with the parents, the DTs were able to provide answers to parents' queries, address their concerns, teach oral hygiene skills, i.e. effective toothbrushing techniques for their child, and give suitable dietary sugars advice.

The participants perceived that the SIMSP was effective to improve preschool children's oral health and related behaviours especially the toothbrushing habit. A review has shown that children showed a significant improvement in toothbrushing skills when demonstrations and supervisions were provided (Habbu & Krishnappa, 2015). From the participants' observations, most preschool children in the SIMSP voluntarily brushed their teeth after morning break without waiting for their teacher's instructions. This progress was observed after a few months of implementing the daily supervised toothbrushing drill at school. The DTs felt that in-class oral health lessons given by teachers contributed to this behaviour change as well. Many studies on teachers' role to deliver OHE to preschool children resulted in good oral health outcome measures and showed positive improvement in children's oral health and OHK (Chachra et al., 2011; Dimitropoulos et al., 2020; Jaime et al., 2015; Karuveettil et al., 2020; Petersen et al., 2015).

Based on the Communication-Behaviour Change framework for school-based interventions by Pine (2007), active and personalised interactions, skills training and daily reinforcement provide a higher chance of achieving behaviour change in children (Pine, 2007). As for preschool children, reinforcement of OHE at this age can benefit the children because their lifelong beliefs, attitudes and skills are still developing. To further increase children's attention to OHE, use of different approaches in OHE activities was recommended based on children's age. In the SIMSP, active interactions were achieved during OHE sessions and daily TBD. Supplemental dental worksheets were distributed to children after OHE sessions in class to further improve their understanding on the subject. It is notable that OHE by teachers to young children is a key strategy to encourage the children to enjoy and practice toothbrushing in an efficient way as the academic schedules are more flexible and OHE is based on learning by do, show and tell technique (Fernando et al., 2013).

5.6.3 The perspectives of the dental team on the facilitators to implement the SIMSP in the preschool settings (Secondary objective 3c)

The oral health programme administrators at the district and state levels were aware that in order to improve OHB of the public, it would require considerable efforts on the part of health educationists (Mani et al., 2012). According to the FGD participants, the SIMSP was well accepted by the district and state oral health administration teams that enabled the SIMSP to be implemented as part of the oral health programme of the Ministry of Health. Currently, the state oral health programme is planning to introduce a dedicated dental team concept for preschool children and it was still in the preparation stage. Therefore, the SIMSP that included a dedicated dental team had the potential to provide evidence to the administrators on how to formulate guidelines for the dedicated dental team. As a show of support, the district's senior dental officer gave permission for a number of DTs and HAs to be part of the SIMSP in this study. This facilitated the DTs to implement the SIMSP fully according to its protocol.

In order to generate a less formal setup during the parent-DT meeting, the DTs and HAs were given permission by the state oral health division to wear a non-uniform attire to provide a non-threating atmosphere during the parent-DT meeting. The DTs felt that this decision had made the parents to be at ease and helped to encourage maximum attendance and participation by the parents. This was done because based on their observations in the existing POHP, parents tended to get anxious when they saw the dental team in their work uniform. As reported by many, dental anxiety or dental fear can be a major barrier to seeking professional dental care, and the implications on dental disease are significant, and the condition can also lead to a range of other psychosocial problems (De Jongh, Adair, & Meijerink-Anderson, 2005; Hmud & Walsh, 2009). The decision for

wearing an informal attire during the parent-DT meeting had facilitated the SIMSP by encouraging parent's participation in children's OH care.

The SIMSP also received tremendous support from the managers of other participating departments. During one of the parent-DT meeting at a *KEMAS* preschool, the district *KEMAS* manager attended the session to observe the conduct of the study. The DT team was informed by the teacher that the Community Development Department welcomed the oral health programme conducted by dental team at their facilities because this effort can improve the oral health of the children and the community in general.

During the implementation of the SIMSP, DTs adapted to the community's environment by using simple words when communicating with parents. Furthermore, it is essential for oral health personnel to recognise the social, cultural, and environmental context in which certain behaviours occur. Language barriers can be a contributor to a patient's low health literacy level. When a person is under stress, comprehension and communication are inherently easier if it was undertaken in the patient's native language. If using simple language is not the language of the health provider, communication with patients will be hindered. Spoken language skills and reading skills can be drastically different within the general population, and these differences can be greatly magnified in persons who are communicating in a language that is not native to them.(Schiavo, 2011). The ability of DTs to use plain language that was simple, easily understood and jargon–free was important in ensuring that the parents understood the OHE messages.

The SIMSP was formulated based on the recommendations in the NOHPS 2015 survey (Oral Health Division, 2017). Among the recommendations were to strengthen the healthcare provider's role in providing oral health advice to parents/guardians, promote OHL among parents and consolidate the use of social media to promote OH to young children. During FGD, the DTs admitted that the SIMSP tool i.e. CRA form and

materials i.e. OH infographics facilitated them to provide OHE advice to parents. On the individual level, multiple factors including clinical, environmental, and behavioral factors were considered when assessing the caries risk in young children, including factors associated with the primary caregivers. Whereas at the community level, the use of CRA procedure can guide the design of public interventions, time allocation, and resources to those with the greatest need. For the individual child, CRA is an essential key element for the decision-making and management of ECC. The different risk categories should ideally be linked to personalized preventive measures and follow-up intervals (Tinanoff et al., 2019)

This study was highly dependent on the teacher's involvement. As stated by the DTs, they were very grateful and satisfied with the teachers' participations in gathering the parents for the parent-DT meeting. Based on their past experience in the POHP, teachers tended to be less cooperative especially when the teachers were asked by the DTs to invite parents to the preschool during a dental visit. According to Leurs et al (2000), barriers to health promotion in primary schools are "a lack of knowledge" and a "lack of consensus" in schools with regard to the importance of health promotion (Leurs, Bessems, Schaalma, & De Vries, 2007). The dental team perceived the improved cooperation by the teachers was due to the teachers' belief in the benefits of the SIMSP and increased awareness for good OH after being exposed to the SIMSP. Besides their role as a mediator between the OH personnel, the children, and the parents, the teachers were very dedicated to deliver the in-class OHE. As the OHE booklet has not yet been formally incorporated into the preschool curriculum, the execution of the in-class OH lessons and daily toothbrushing at school depended highly on the teachers' time and commitment. As reported in the fidelity report, most teachers managed to complete the module within the study duration.

5.6.4 The perspectives of the dental team on the barriers to the implementation of the SIMSP in the preschool settings (Objective 3d)

According to the FGD participants, although majority of parents attended the meeting with DTs, a minority could not attend the meeting. According to the teachers, parents' full engagement in the SIMSP continued to be the main challenge in implementing the SIMSP. Even though parents were informed early of the meeting, work commitments hindered them from attending the meeting. Inevitably, previous studies have suggested that the severity and susceptibility to dental caries were not viewed as seriously as other life-threatening chronic diseases such as cancer (Begzati et al., 2015). What is more concerning, ECC is not limited to children in low SES (Çolak et al., 2013; Mejàre et al., 2014). However, in another review of the literature, it showed that the most crucial factor involved in the ECC development was the SES of the family, where ECC was strongly associated with SES and the role played by parents/caregivers as the main source of attitudes toward oral care and values (Congiu et al., 2014) A local study by Mani et al (2012) concluded that parents showed relatively good knowledge, but poor attitude and practice towards the OH of their children. It is possible that parents were not informed about the details of oral disease and the causes. The authors suggested that an in-depth education about caries aetiology was more likely to bring about behaviour change in parents (Mani et al., 2012). Another study by Begzati et al, (2014) found that there was a high level of negligence in the oral hygiene care of young children. Based on the study, 38% of the mothers stated that their children did not brush their teeth at all and only 11% of the interviewed mothers demonstrated proper techniques of toothbrushing (Begzati et al., 2014). Additionally, another study found that there was a poor judgment of mothers regarding primary teeth that they will be replaced, thus neglecting the care for children's primary teeth (Amin & Harrison, 2009). Based on the evidence, it was paramount to establish a partnership with the family, and to ensure parents' involvement in their

children's OH in order to decrease the risk factors for caries development. However, it was acknowledged that not all parents could attend the meeting due to work commitment. One way to overcome this problem is by conducting the meeting with parents during weekends, and a mechanism needs to be established in the ministry to allow DTs to work during weekends once or twice a year to meet up with the parents.

DT's high workload was perceived as the main internal barrier to the implementation of the SIMSP. The DT's current job scope is very broad and demanding. Their job scope required them to be involved in many other dental programmes such as primary and secondary school oral health programme, toddlers' programme, oral health promotion and many others. In their opinion, they can deliver the SIMSP well if they focus solely on the preschool programme. Human resource management and job description in Malaysian government organisation is under the provision of the Public Service Department (Public Service Department, 2020). However, local management has the authority to reorganise the job scope as long as it is within the personnel's job description. Therefore, it will be up to the local organisation to redistribute the human resource manpower to meet with the service demands. This should occur through the existing resources without putting extra financial burden over the limited health resources.

Although this is not a direct barrier faced by the DTs in implementing the SIMSP, majority of the participants were concerned about the continuity of the SIMSP due to the limited resources faced by the state OH division. The resources included human workforce, oral hygiene materials, and transportation cost. They hoped that the state oral health division would be able to resolve these potential problems in the future by collaborating with relevant industries to adopt the SIMSP at preschools. At the same time, the results from the study have provided evidence of the effectiveness of the SIMSP over

and above the POHP in improving the oral hygiene level of the preschool children, improving the teachers' role in preschool children's OH, and most importantly the improvement of the parents' OHL and their participation in the SIMSP. This evidence should be strong enough to convince the Ministry of Health to redirect some financial assistance to pay for evidence-based interventions such as the SIMSP. The DTs believed the SIMSP would be the ideal programme to replace the existing POHP.

5.6.5 The perspectives of the dental team on suggestions for improvement of the SIMSP in the preschool settings (Objective 3e)

All the participants agreed that the SIMSP should include a dental officer as part of the dedicated preschool team that visit the preschools. This is because during the parent-DT meeting, some DTs were asked questions beyond their ability to answer satisfactorily such as in-depth questions about fluorides, complex dental treatment, i.e. root canal treatment, oral surgeries, and aesthetic dentistry for children especially if their children are suffering from ECC. In the presence of a dental officer, these enquiries can easily be explained by him/her. The dental officer can also supervise the session and issue time slips to parents as proof of their attendance at the meeting to be given to their employers when requested. Furthermore, the participants perceived that parents would be more interested to attend the meeting if a dental officer was present.

The participants also suggested for the WhatsApp infographics to be managed by a dental officer rather than DTs. As the purpose of the WhatsApp to provide a two-way communication platform with parents, the participants opined that it was best handled by a dental officer who could answer queries from parents. Evidently, the use of WhatsApp and other social apps provided collaboration opportunities for busy health professionals to provide peer-to-peer support and health education for the general public (Kamel Boulos, Giustini, & Wheeler, 2016). In addition, it is best if the state oral health division

could provide a sim card for the purpose of the SIMSP. The participants felt using a personal phone number could be unsafe and less professional.

In terms of training, majority of DTs perceived their training in delivering the SIMSP could be improved further in particular the training in delivering OHE to parents. This was also one of the reasons why they requested for dental officers to be included in the SIMSP. Apart from training to improve and update their OH knowledge, DTs felt they required further training in communication skills because they need to communicate with parents in a clear, accurate and effective manner. As suggested by Berger and Batista (1993), DTs or other oral health providers should always explain the reasons why a treatment has been recommended and emphasise the benefits of complying with the treatment plan. This is also relevant when delivering OHE to parents. It is important to be clear and concise when explaining how a patient should comply with oral health advice. Patients can easily become confused with dental terms if their use is not sufficiently explained using simple words. Pictures drawing, using visual aids, or active demonstrations will aid in the comprehension of instructions. DTs should also speak slowly and allow ample time for the parents to voice any questions. Communication is more likely to be effective if DTs rethink the words and manner used to convey the message and put themselves in the parents' position (Berger & Battista, 1993). They unanimously felt that they needed further training in this.

All participants agreed that the SIMSP is better than the current POHP as they perceived that preschool children, teachers, and parents benefitted tremendously from this programme. All the participants suggested for the SIMSP to replace the current POHP. However, they do have concerns about other stakeholders' opinions, especially parents. The participants perceived that opinions and suggestion from parents can further improve this programme because the parents' participation is the key factor for the success of the

SIMSP. The participants were curios whether the intervention in SIMSP had an impact to improve parents' belief to care for their children's OH. Parental beliefs had been shown to be a very important element in the success of many behavioural intervention studies (Hollister & Anema, 2004; Pine et al., 2000; Trubey, Moore, & Chestnutt, 2014). Feedback from the parents on the SIMSP should be obtained.

In the SIMSP, the preschool children were supplied with two sets of toothbrush and fluoridated toothpaste for school and home use. The reason they were supplied with these materials was to ensure that the preschool children were well equipped to brush their teeth twice daily with supervision from their teachers and parents. The FGD participants were concerned about future adherence and sustainability of the SIMSP in terms of supplying the preschool children with two sets of toothbrush and toothpaste. Therefore, there was a suggestion to obtain funding or sponsorship from the relevant industry to supply toothbrushes and toothpastes for the SIMSP under the industry's corporate social responsibility programme. A prospective cohort study conducted by Boustedt et al., (2020) evaluated toothbrushing habits and prevalence of ECC in young children aged 5 years. He found that the habit of toothbrushing less than twice daily and the difficulties to perform the procedure during the first preschool years were significant determinants of caries prevalence at the age of 5 years. Therefore, health professionals should give special attention and assist parents to improve and optimise their children's toothbrushing behaviour during the preschool years (Boustedt et al., 2020).

5.7 Implications of the SIMSP

The internal validity of the study was considered high as the study utilised a robust study design with low attrition rate, high implementation fidelity and used appropriate data analysis methods. In terms of external validity, the results can be generalised to individual children provided the preschool size is small, i.e. 20 children. For larger cluster size, the

effect may be attenuated if clustering effect exists. In Malaysia, an average preschool can accommodate between 10 to 25 children, therefore the results may be generalised to most preschool settings (Mustafa & Azman, 2013). Furthermore, the use of pragmatic study design and the inclusion of all types of preschool in all locations indicated the results may be applicable to preschools in the country (Zwarenstein et al., 2008).

Several outcomes from this study gave statistically significant results between SIMSP and POHP with most of the results favouring SIMSP. This allowed the researchers to believe that the improvement achieved in the SIMSP did not happen by chance and there was significant difference between the two programmes.

Effect size is one way to measure the effectiveness of a particular intervention and to provide evidence of the intervention's clinical significance. Some results from this study has yielded moderate to large effect size which provided clinical significance of the SIMSP over POHP. Since SIMSP is an intervention that was designed for community levels, it can give a large positive impact on preschool children's oral health if implemented.

The benefits obtained from this study was that the SIMSP included several interventions combined together in one programme including OHE to parents and preschool children, dental visits by DTs and daily toothbrushing at schools supervised by teachers. Based on the current study, these are the possible implications of the SIMSP if the programme is absorbed into the preschool oral healthcare programme.

First, this study demonstrated a new and feasible method to engage parents of preschool children. In the SIMSP, parents were given individual face-to-face OHE and dietary advice based on their child's oral health status and caries risk levels. Studies have shown that OHE targeting parents, especially mothers in the prevention of ECC and

dental plaque were shown to be beneficial (Harrison, Veronneau, & Leroux, 2012; Saengtipbovorn, 2017). In the POHP, OHE was given via a general approach, normally through dental health talk at preschools without parents' involvement. The parent-centred and individualised OHE strategy approach in the SIMSP was able to gain parents' attention and improved their awareness on their child's OHB. The SIMSP introduced the use of brief counselling technique by applying the principles of motivational interviewing (Borelli, 2015). This method can aid the delivery of oral health advice and facilitate behaviour change (Naidu & Nunn, 2020). Even though the DTs faced time limitation to deliver a rigorous OHE to parents during the meeting, continuous OHE was achieved in the SIMSP through the use of Whatsapp application or delivery of printed OHE. DT's role in providing oral health advice were strengthen with the use of CRA and oral health infographics. Furthermore, in the current situation of COVID-19 global pandemic, electronic platform is the best tool for providing OHE to the public either through electronic messaging system i.e. WhatsApp, Telegram and SMS or the social media, i.e. Facebook, YouTube, Instagram, and others. Based on these benefits, the inclusion of the SIMSP into the statewide preschool oral healthcare programme is recommended.

Second, the formulation of the children's treatment plan through the use of CRA provides a better approach to address dental caries and dental plaque problems in children. The SIMSP provides a platform for DTs to assess children's CRA and formulate treatment plan that includes promotive, preventive, and curative aspects of caries and their risk factors with active participations of parents and teachers. This is missing in the existing POHP. The findings in the SIMSP were similar to the findings in an intervention study named MICRA in Thailand where motivational interviewing and CRA were used (Saengtipbovorn, 2017). However, in that study, it was unclear whether the positive results were due to the use of motivational interviewing, CRA or the combination of both.

Third, the findings of the study on SIMSP provided local evidence and justification to review the existing POHP guideline. Since the guideline was published in 2003, there had been many new interventions for oral health promotion activities. The improvement of POHP must consider the use of affordable, accessible, sustainable, and evidence-based strategies. The SIMSP is the ideal template to follow. The SIMSP emphasised on supervised toothbrushing at school as this practice has the potential to establish a regular oral hygiene habit among the children and it can easily be conducted by teachers (P. E. Petersen et al., 2015; Skeie & Klock, 2018). This is especially relevant in areas with high disease burden and shortage of health personnel especially DTs. Some of the strongest clinical trials in dentistry have supported the efficacy of daily or twice daily brushing with fluoride toothpaste for the prevention of dental caries (dos Santos et al., 2013; Twetman, 2009).

Fourth, the adoption of SIMSP into the current preschool oral healthcare programme would have managerial implications in human resource management especially involving DTs and dental officers in the government service. If the SIMSP is to be adopted, DTs will have to focus their services with preschool children. This is to allow for proper planning and execution of the programme and probably to extend the programme to private preschools as well. We would suggest for reorientation of the incremental school programme, either for primary or secondary schools, to be managed by dental officers. In the current situation where there is a high influx of dental officers into the government service but limited dental facilities, it is highly recommended that dental officers to be actively involved in school dental programme.

Globally, schools are proven to be an ideal platform for health promotion activities and community engagement (Petersen & Kwan, 2010). Acknowledging the teacher's influence on their students' health and their skills to teach, the fifth implication is that it

may be best for OHE to be delivered by teachers in the classroom setting on a regular basis provided they are well equipped with the right tools and materials to do it. For example, the SIMSP OHE booklet can serve as a teaching aid with a variety of topics suitable for preschool aged children. The partnership between teachers and the dental service providers should be a permanent strategy for OHP, and teacher's involvement in delivering structured OHE to the children routinely should be integrated into the preschool educational system and reflected in the teacher's training and educational materials provided to all preschools. This strategy can improve the delivery and effectiveness of OHE to the preschool children. If the in-class OHE package of the SIMSP is successfully included in the preschool curriculum by the Ministry of Education, the children would leave the preschool years and enter the primary school system with improved OHK, attitudes and behaviours, as well as good oral hygiene level. These positive outcomes will be further strengthened by the Dr Muda programme in the primary school setting that seek to improve children's health (and oral health) using a child-to-child health education concept. In Malaysia, evaluation of the Dr Muda programme in primary schools had been conducted and the programme had been shown to be effective to improve oral health behaviours, oral health status, and oral health related quality of life of 11-12-year-old schoolchildren (Yusof & Jaafar, 2013).

Lobbying the Oral Health Programme for the adoption of the SIMSP into the POHP would require solid evidence that proves the effectiveness of the SIMSP. As mentioned earlier, interventions of this programme were formulated based on recommendations in the NOHPS 2015 that were:

i) To strengthen the healthcare provider's role in including parents/guardians in their child's oral health care

ii) Promote oral health literacy among parents

iii) Consolidate the use of social media to promote oral health to young children. (Oral Health Division, 2017)

The study showed that SIMSP had fulfilled all the recommendations mentioned above based on the following findings:

i) High fidelity for DT-parent meetings where parents were advised and motivated by DT to care for their children's oral health through individual and customised information given to parent.

ii) Results showed improvement in parents' OHL with large effect size.

iii) High fidelity for use of Whatsapp as a social and digital platform to convey OH messages to promote oral health

Based on the findings from this study which included the reduction of plaque level among the preschool children, increased brushing frequency and use of toothpaste and improvement in parents' OHL had proven that SIMSP intervention package can provide a holistic approach to tackle the issues in improving preschool children's oral health. The children with high risk for caries were found to be the ones that benefitted the most from this programme.

Since the program utilises readily available human resources, adopting the intervention into the current POHP is possible.

5.8 Limitations of study

All participants entered into the study followed fixed inclusion and exclusion criteria. Only preschool children from government funded preschools were included. Hence, the interpretations, conclusion and recommendations from the study are mostly applicable to

government funded preschools only. Private preschools were not included because they do not receive dental visits from DTs unless they request the service on annual basis.

As the children only spend 2 years at preschools, only short-term evaluations of the SIMSP were conducted. The effect of SIMSP on caries prevention was not evaluated. However, the significant changes in plaque scores in the SIMSP children could be used as a proxy outcome for future oral health improvement in the long term especially when oral hygiene habits developed during childhood tend to last until adulthood (Alm, Wendt, Koch, Birkhed, & Nilsson, 2012).

In this study, the examiners had difficulties to allocate time for the research (data collection) as their schedules were quite full. This was especially true when they had to go back to the preschools a few times to examine the children including those who were absent on the first examination day. This may have contributed to the 9.4% attrition rate of the follow-up participants and resulted in 80.1% response rate at follow-up. However, response rates of 50–80% at follow-up have been suggested as acceptable in intervention studies (Fewtrell et al., 2008). As a corrective measure, the ITT analysis was performed to avoid the effects of dropouts. This method allowed the researcher to make accurate conclusions regarding the effectiveness of the intervention because ITT analysis preserves the prognostic balance between the study groups (McCoy, 2017).

Two preschools in the SIMSP intervention lacked toothbrushing facility as both preschools were confined to a small space. As the result, they had not participated in the daily toothbrushing exercise. This had limited the chance for the preschool children to benefit fully from the SIMSP. Positive results from this study can be used as evidence to convince the preschool management to provide a toothbrushing space at the preschool in the future.

The way teachers delivered the in-class OHE and different delivery sequences of class lessons can affect the outcome because it can contribute to different levels of knowledge and understanding among the children. Furthermore, lessons that were conducted earlier in the study will provide more time for the children to improve their behaviours. To standardise this, teachers were trained prior to the commencement of the intervention and were advised to follow the teaching sequence in the booklet over the duration of the study.

Due to time limitation, no process evaluation was conducted to explore the opinions from parents and teachers involved in the SIMSP. Acknowledging the importance of stakeholder's analysis, their views and opinions would have contributed to meaningful qualitative data to evaluate their perceptions of the SIMSP and how the intervention can be improved further.

This study may be exposed to some degree of response bias due to the use of self-reported questionnaire as a method of data collection (Furnham, 1986). Parents might have given their answers that were favourable to the researcher but might not reflect the true phenomena, in this case the change in behaviours. This was minimised by informing the respondents about the confidentiality of their responses and were encouraged to be honest in all their responses.

In this study, there was a possibility that the questionnaire was answered by different parents at baseline and follow-up. However, the questionnaire asked about the behaviours of the child which were usually well known by both parents because they live in the same house. It is safe to predict that the parents' knowledge of the child's behaviours is not significantly different. As for the parents' oral health literacy part, we could assume there was sharing of knowledge between the parents that received the oral

health information through the DT-parent meeting and oral health infographics. This could explain improvement of OHL scores in the SIMSP.

The reliance on self-reported data only for recording the implementation fidelity may also contribute to reporting bias as the participants may over or under report the activities. In order to ensure proper implementation of the study, multiple visits to the SIMSP preschools was done by the researcher. The monitoring process was followed by open discussions between the researcher and the preschool teachers to further improve the in-class OHE delivery and TBD.

Given the fact that oral health information is readily and easily accessible by anyone especially during this electronic era, it is inevitable that some parents may be exposed to contamination bias (Torgerson, 2001). Parents in the POHP may be exposed to the oral health infographics sent to the parents in the SIMSP as the infographics can be shared through Whatsapp. However, based on the large magnitude of OHL improvement among the parents in the SIMSP than parents in the POHP, it was safe to conclude that contamination bias was very minimal or unlikely to happen among the parents in the POHP.

Teachers in the SIMSP and POHP may have existing knowledge on oral health from their previous training. Hence, this existing knowledge may contribute to contamination bias as teachers in the POHP may also convey some oral health information in class to the children. Nevertheless, teachers in the SIMSP were provided with the OHE booklet that contains more comprehensive information on oral health and nutrition to help them to conduct the in-class OHE.

Randomised control trials are considered the gold standard by which the effectiveness of various treatments or interventions are determined. This is because this

design minimises the risk of confounding factors from influencing the results (Akobeng, 2005). Even so, for this study, both parents and teachers can be confounders to the oral hygiene levels and OHB outcomes in this study. To reduce this effect of confounding factors, matching was done during research planning to ensure both groups were demographically equal. However, some differences between the group may be unavoidable but it may not be significant as the disease level of children was similar at baseline.

CHAPTER 6: CONCLUSION AND RECOMMENDATION

6.1 Conclusion

The conclusions that can be drawn from the present study are presented according to the study objectives below:

6.1.1 To assess the effect of the SIMSP over and above the existing POHP in improving oral hygiene level among 5-6-year-old children in the Kampar District over 6 months.

i. After 6 months, significantly more preschool children in the SIMSP had "teeth appear clean" than preschool children in the POHP.

ii. Preschool children in the SIMSP showed significant improvement in oral hygiene levels than those in POHP. At follow-up, the preschool children in the SIMSP had higher mean plaque score decrement than preschool children in the POHP with moderate effect size.

iii. A significantly higher proportion of children in the SIMSP had an overall plaque score decrement from score 2 to score 0 than children in the POHP.

iv. A significantly higher proportion of preschool children in the SIMSP with high CRA level had a decrement in plaque score after 6 months than children in the moderate or low CRA levels.

6.1.2 To assess the impact of the SIMSP over and above the existing POHP in 6 months in terms of children's oral health and related behaviours (Secondary objective 1a)

In terms of carbonated drinks intake frequency at follow-up, there was a significant difference between groups where a significantly higher proportion of children in the POHP took carbonated drinks daily compared to those in the SIMSP.

6.1.3 To assess the impact of the SIMSP over and above the existing POHP in 6 months in terms of Parents' OHL (Secondary objective 1b)

i. Parents in the SIMSP had a significantly higher mean score increment in the oral health knowledge domain than parents in the POHP after 6 months with large effect size.

ii. For the comprehension domain, no significant difference in the mean scores was observed between groups at baseline and follow-up.

iii. For the skills and motivation domain, parents in the SIMSP showed higher improvement in the scores than parents in the POHP after 6 months with large effect size.

iv. Overall, parents in the SIMSP showed higher improvement in the overall OHL scores than parents in the POHP after 6 months with large effect size.

6.1.4 To assess the implementation fidelity of the SIMSP protocol in terms of:

i. Parents' compliance in attending the parent-DT meeting at school (Secondary objective 2a)

Majority of parents attended the parent-DT meeting at the preschools.

ii. Teachers' compliance in delivering in-class OHE, dental worksheets, and supervising daily toothbrushing with the preschool children (Secondary objective 2b)

The compliance rate of teachers to deliver in-class oral health lessons and dental worksheets and supervising daily toothbrushing at school was high.

iii. DT's compliance in sending oral health infographics to parents via Whatsapp application (or paper infographics) (Secondary objective 2c)

The compliance rate of DTs in delivering oral health infographics to parents over the period of 6 months was 100%.

6.1.5 To undertake a process evaluation of the SIMSP by exploring the perspectives of DT on the following factors

i. Appropriateness of the SIMSP for preschool setting (Secondary objective 3a)

a) Based on the FGD involving the DTs and HAs, it was concluded that the SIMSP was perceived as an appropriate programme for preschool children because it had improved parental involvement in preschool children's oral health.

b) The SIMSP addressed preschool children's individual dental problems with their parents. Therefore, customised oral health information was given to parents based on their children's oral health problems.

ii. Effectiveness of the SIMSP in the preschool setting (Secondary objective 3b)

a) The FGD participants perceived the SIMSP increased parents' awareness of their preschool children's oral health through the parent-DT meetings.

b) According to the participants' observations, the SIMSP had improved the preschool children's toothbrushing habits.

c) The FGD participants perceived the SIMSP improved parents' OHK through the parent-DT meetings and oral health infographics.

d) From the FGD, the participants agreed that SIMSP has the potential to improve preschool children's oral health. This opinion was supported from the DT's observation where they found preschool children from SIMSP had cleaner teeth at follow-up visits.

iii. Facilitators to implement the SIMSP in the preschool setting (Secondary objective 3c)

The participants perceived multiple factors facilitated the implementation of the SIMSP as listed below.

a) Support from the oral health programme administrators because the administrators were aware of the need to improve the current POHP.
b) The SIMSP received good support from parents and this was evident from high attendance of parents at the parent-DT meetings.
c) Participants perceived that parents and their preschool children were more responsive during the parent-DT meeting due to the less formal set up at preschools.
d) The SIMSP provided simple but important oral health messages that were easy for DTs to deliver and easy for parents to understand.
e) The CRA form which was used as a consultation tool was helpful to provide individual OHE and the provision of toothbrush and toothpaste to preschool children allowed the children to practice toothbrushing regularly in school and at home.
f) All participants agreed that preschool teachers support was paramount to the success of the SIMSP.

iv. Barriers to implement the SIMSP in the preschool setting (Secondary objective 3d)

a) DTs perceived their high workload on other programmes acted as a barrier for them to fully focus on the SIMSP for preschool children.
b) Full parental involvement in the SIMSP will continue to be a challenge for the dental team.
c) Limited resources of manpower and oral health materials were perceived as barriers that could hinder the implementation of the SIMSP.

v. Suggestions for improving the SIMSP in the preschool setting (Secondary objective 3e)

a) A dental officer should be included as part of the SIMSP team.

b) Need to acquire the opinions from other stakeholders regarding the SIMSP i.e. parents of preschool children and preschool teachers.

c) Provision of continuous training to DTs was needed in order to improve their OHK and communication skills.

d) Collaborations with relevant stakeholders for the sustainability of the SIMSP.

Overall, the findings from this study provided empirical evidence for the effectiveness of the SIMSP in improving children's plaque scores, selected oral health behaviours, and parental OHL over and above that of the existing POHP over 6 months in Kampar district, Perak, Malaysia.

As the SIMSP is mostly based on readily available resources including teachers and parents, it would be feasible to replicate this in other government preschool settings which share the same characteristics.

6.2 Recommendations

Based on the study findings, the following recommendations are made:

1. Due to the positive findings from the study, it was evident that the SIMSP can improve preschool children's oral hygiene levels, selected OHB of the children, and parents' OHL. This evidence can be used to absorb the SIMSP into the current preschool oral healthcare programme in Kampar district and subsequently at the state and national level.
2. With regards to implementing the SIMSP on the current preschool oral healthcare programme in Kampar district, these recommendations are made:

i) Revision to the DTs job scope. Currently, DT's job scope is very wide and diverse. The revision should justify the number of DTs in the service and their job descriptions which only allow them to provide simple and non-invasive dental treatment to patients under the age of 18 years.

ii) Resource redistribution through reorientation of the incremental school dental programme, where it is recommended that dental officers to be actively involved in the school dental programme.

iii) Allocation of funding is allocated to run the programme effectively throughout the year including purchasing of materials such as toothbrush and toothpaste.

iv) Endorsement from preschool authority to provide better environment to support the SIMSP activities for example a toothbrushing area.

v) In terms of training, the DTs should be exposed to adequate training to improve their communication skills to interact with parents and increase and update their OHK.

vi) Constant two-way communications between the stakeholders, i.e. district oral health service department and education departments is recommended to ensure the availability of appropriate support, guidance, and expert advice to overcome any difficulties and limitations to implement the SIMSP.

vii) In terms of oral health delivery to preschool children, it is recommended to include the teacher's OHE booklet as part of the preschool curriculum for teachers to deliver oral health lessons in the class.

viii) Due to its positive impacts of the SIMSP on government funded preschools, it is recommended to test the effect of the SIMSP on private preschools.

6.3 Recommendation for future studies

Based on the findings and limitations faced in this study, the following recommendations are made for future studies on the SIMSP:

i) To undertake longer-term evaluations of the SIMSP. The current study only involved evaluations after 6 months. This shorter-term evaluation would only be beneficial to see the SIMSP's immediate impacts. The longer-term evaluation would be useful to assess the SIMSP's effectiveness on the children's caries status and oral health related quality of life. Therefore, it is recommended to follow-up the preschool children annually for the next 5 years.

ii) Another set of evaluation should be done to analyse the data based on per-protocol because retrospective analysis of power indicated that the sample size at follow up was sufficient for the assessment of outcomes using per protocol analysis.

iii) To extend the FGD to include preschool teachers and parents who were involved in the SIMSP in order to explore their perspectives on the process implementation of the SIMSP in terms of its appropriateness, effectiveness, facilitators, barriers, and suggestions for improvement.

iv) A study to assess the sustainability of the SIMSP over a longer duration of time.

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LIST OF PUBLICATIONS AND PAPERS PRESENTED

Publications

1. Effects of the SIMS programme on oral hygiene levels of 5-6-year-old children in Kampar district, Malaysia: A cluster randomised control trial. Makara Journal of Health Research (Published) WoS
2. Effects of the SIMS programme versus Preschool Oral Healthcare Programme on oral hygiene levels of 5-6-year-old children. Study protocol for a cluster randomised control trial. Submitted to Trials (under correction by authors) ISI/WoS

Presentation

1. International Invention and Innovation in Dentistry Exhibition (IIIDenTex) 2019

   Date : 24 June 2019, Venue : Hatten Hotel, Malacca

   Presentation Title : Development of an Oral Health Education Booklet to Improve Oral Health Behaviours in Preschool Children

   Achievement : Silver Medal
2. 3rd International Conference in Oral Microbiology and Oral Immunology In-conjunction with 13th Postgraduate Conference 2020

   Date: 9 September 2020

   Presentation Title: The effects and feasibility of the SIMS programme to improve preschool children's oral hygiene level: A cluster randomized control trial