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Cover Page Footnote

The authors would like to thank the Oral Health Programme, Ministry of Health, Malaysia, Perak State Health Department (Oral Health), Perak State Education Department, Perak Department of Community Development, Perak Department of National Unity, and the Kampar district dental clinic for their support in the trial. We would also like to thank the dental therapists, teachers, parents, and children who were involved in the study.

Effect of the SIMS program on oral hygiene levels of 5–6-year-old children in the Kampar District, Malaysia: A cluster-randomized controlled trial

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Abstract

Background: This study evaluated the effect of the “*Senyuman Indah Milik Semua*” program (SIMSP) versus the existing preschool oral healthcare program (POHP) on children’s oral health and parents’ oral health literacy (OHL) in Kampar district, Malaysia. **Methods:** This was a cluster-randomized, matched pair, examiner-blind, controlled trial. Using computer-generated random tables, 14 preschools were allocated to the SIMSP intervention over 6 months and another 14 were allocated to the POHP, which was concealed at the cluster level. Healthy 5–6-year-old children and parents who understood the Malay language were recruited. The SIMSP was comprised of preschool visits by dental therapists (DTs) and oral health education for children and parents. The POHP received visits from DTs only. The primary outcome was the dental plaque score. The secondary outcomes were children’s oral health behaviors and the parents’ OHL. Data were collected during February and October 2019 and analyzed using SPSS software. **Results:** Overall, 653 children were recruited (intervention: 344 vs. control: 309). At 6-months, 83.4% and 76.4% completed the study, respectively. The mean decrease in the plaque score was higher in the SIMSP than the POHP [$p = 0.027$, effect size (ES) = +0.51]. Significantly more SIMSP children consumed carbonated drinks ≤ 1 –3 times/week ($p = 0.033$). Parents in the SIMSP had more knowledge ($p = 0.024$) with higher OHL scores (ES = +0.97) than parents in the POHP. **Conclusion:** The SIMSP was effective for reducing children’s plaque scores, soft drink intake, and improving parents’ OHL than POHP.

Keywords: behavior, child, dental plaque, health literacy, Malaysia, oral hygiene

Introduction

Evidence shows that effective oral health interventions targeting preschool children should incorporate active involvement by parents, teachers, and dental personnel. Interventions that include preschool visits by dental nurses, daily supervised tooth brushing with fluoride toothpaste by teachers, and parental support for home tooth brushing are effective to improve tooth brushing frequency, reduce dental plaque, and control caries in 5-year-old children.^{1–5} In addition, curriculum-based oral health education (OHE) delivered by teachers at preschools is effective for improving oral health behaviors and reducing caries in this age group.⁶ Furthermore, interventions that sought to deliver OHE to parents using pamphlets or social media are also effective for increasing parents’ oral health knowledge (OHK), which benefits their children.^{7,8}

In Malaysia, the national preschool oral healthcare program (POHP) was introduced in 1984 to provide oral

healthcare to preschool children aged 5–6 years when they enter preschool for 2 years.⁹ The POHP is delivered by a team of dental therapists (DTs) who visit preschools twice a year. During the first visit, DTs conducted an oral examination, OHE, a tooth brushing exercise, and a fluoride varnish application (FVA), which contained 22,600 parts-per-million (ppmF) fluoride. The second visit at 6 months involved DTs performing atraumatic restorative treatment using glass ionomer restorations (if required) followed by the second FVA (22,600 ppmF).^{9,10}

Despite the existence of POHP over the past three decades, the prevalence of caries in this age group remains high.¹¹ Data from the national oral health survey in 2005 show that 76.2% of 5-year-olds had caries in primary teeth and this prevalence only decreased to 71.3% in the 2015 survey.^{12,13} In addition, the majority of the children had dental plaque.¹³ The POHP limitations in controlling caries and dental plaque in young children were attributed to limited resources of

the DTs, lack of time, wider job scope, and lack of parental and teacher support for children's oral health.¹³ All of these factors have led to poor self-care behaviors in the children.

Positive changes in children's oral health behaviors during their 2 years in preschool are essential to prevent caries in permanent teeth.¹⁴ As children spend most of their time with either their parents at home or teachers at school, positive changes in oral health behaviors in this age group require support from DTs, parents, and teachers.^{3,15}

Based on findings from the 2015 survey and evidence from the literature, the recommendations put forward to improve the POHP are to strengthen the roles of DTs, empower parents, and include teachers in children's oral health.^{1,3,6,7,16} The use of social media in oral health has also been recommended.¹⁷ As a result, the "*Senyuman Indah Milik Semua*" Program (SIMSP) or "Beautiful Smile for All" Program was introduced in 2019 which improvised on the existing POHP. In the SIMSP, apart from DTs, preschool teachers and parents are included in school and home oral health activities. The aim of the SIMSP is to improve preschool children's oral hygiene and related behaviors during their time in preschool, and to improve parents' oral health literacy (OHL).

The primary objective of this study was to assess the effect of the SIMSP compared to the POHP in improving dental plaque scores among 5–6-year-old children over 6 months. The secondary objectives were to assess the impact of the SIMSP compared to the POHP in improving children's oral health behaviors and parents' OHL over the same 6 months. The null hypothesis to be tested was that no difference would exist in the dental plaque scores, children's oral health behaviors, or the parents' OHL between the SIMSP and POHP over the 6 months.

Methods

Study design. The study design was a pragmatic, cluster-randomized, parallel-group, matched pair, controlled trial with a 1:1 allocation ratio, comparing the SIMSP and POHP in preschools located in Kampar district, Perak state, Malaysia. The clusters were the preschools. The pragmatic study design was preferred to increase external validity so the findings could be generalized to the preschool setting in Malaysia.¹⁸ Ethics approval was granted by the Medical Ethics Committee, Faculty of Dentistry, University of Malaya [Ref: DF C01904/0004(P)]. This study protocol was registered with ClinicalTrials.gov (NCT04339647).

Permission to conduct the study was obtained from the Oral Health Division, Ministry of Health [Ref: KKM.600-55/7/2 Jld.5(43)], Perak State Education

Department [Ref: JPNK.SPS.UPP.600-1 Jld.2(40)], Department of Community Development [Ref: PK100-11/1 JLD.61(44)], and Department of National Unity [Ref: JPNIN.PK.900-2/18 Jld.5(25)]. This study was conducted in compliance with the principles in the Declaration of Helsinki. Written informed consent was obtained from the parents/caregivers before the study began and a verbal agreement was sought from children before the oral examination. To maintain anonymity, all participants were given a unique individual code for all recorded measurements.

Site selection and recruitment. This study was conducted in the Kampar district, Perak, Malaysia because the proportion of preschool children with caries and poor oral hygiene is higher in this district than the national average.¹⁹ The study sample consisted of preschool children and their parents/caregivers. Inclusion criteria for preschools were government-funded preschools that received the POHP. The inclusion criteria for children were 5–6-years of age, healthy, speak and understand the Malay language, and lived with parents/caregivers. The inclusion criteria for parents/caregivers were those who could speak and write the Malay language.

The sample size calculation was based on the effect of the SIMSP on children's plaque scores with a small ES of 0.3 compared to the POHP over 6 months, an α of 0.05 and power of 0.8, 20% non-respondents,²⁰ an intracluster correlation coefficient (ICC) of 0.026 from a pilot study, and an average cluster size of 20. This resulted in a design effect (DE) of 1.49. By multiplying the DE with sample size calculated without the cluster effect using G*Power version 3.1.9.2 software, a sample size of 317 children in each group was required.

Eligible preschools were matched prior to randomization to increase precision and minimize imbalance across the treatment and control groups. Based on the inclusion criteria, 53 eligible preschools were paired according to geographical location, preschool type, and enrollment into 24 pairs (5 preschools were excluded as they could not be paired). This study involved two levels of randomization generated by a statistician employed at the Faculty of Dentistry, University of Malaya. First, 14 match-pairs were randomly selected, which fulfilled the sample size. At the second level, the preschools in each of the matched-pair were randomly allocated to the intervention (SIMSP) or control group (POHP) using computer-generated random numbers. The allocations were concealed at the cluster level and this was kept confidential until the interventions were assigned. The DT team enrolled and assigned the clusters into the intervention and control groups. All children in the 28 preschools and their parents/caregivers who fulfilled the criteria were recruited into the study.

The SIMSP intervention. The SIMSP was designed by experts in the dental public health (DPH) discipline based on scientific evidence, findings from a national survey,¹³ and input from senior dental officers, preschool teachers, and parents. The target groups of the SIMSP were preschool children and their parents and consisted of the following package:

Preschool children: (a) Oral examination, OHE, FVA (22,600 ppmF) twice per year, and simple restorative treatment by DTs (usual care/POHP); (b) In-class oral health lessons by teachers using the teacher's OHE booklet for 6 months; (c) In-school daily supervised tooth brushing with fluoride toothpaste (1,450 ppmF) for 6 months; (d) Supervised home tooth brushing at night by parents/guardians.

Parents/guardians: (a) Attend a parent-DT meeting at school to discuss the child's caries risk assessment (CRA); (b) Received OHE and diet advice from DTs based on child's CRA level; (c) Received free toothbrush and fluoride toothpaste (1,450 ppmF) for child home tooth brushing; (d) Received 10, 2-weekly oral health infographics from DTs sent via an electronic messaging application (WhatsApp) for 5 months (printed versions for parents without a smartphone).

Teacher's OHE booklet. The teacher's OHE booklet was developed by DPH specialists prior to the study. It consisted of 6 domains and 11 topics. The first domain covered basic knowledge on teeth structure, the second domain was on tooth brushing, the third and fourth domains were on dental caries and gum disease, the fifth domain described the effect of sugars on oral health, and the sixth domain was on self-motivation.

The booklet content was validated by a pediatric dentist, a periodontist, and a general dentist. The delivery method, level of language, and the worksheets were assessed by a child psychologist and a group of preschool teachers. The booklet was subsequently tested with a group of preschool children followed by minor corrections before it was finalized. The booklet was subsequently endorsed by the Committee on Preschool Curriculum of the Ministry of Education. Teachers in the SIMSP delivered the in-class oral health lessons using the OHE booklet every 2 weeks for 6 months. Each lesson took 20–30 min followed by a coloring worksheet as part of the learning activities.

Oral health infographics. The oral health infographics for parents/caregivers were developed by DPH specialists and were content validated by a pediatric dentist, a periodontist, and a social media expert prior to the study. It consisted of 5 domains and 10 topics. The first domain provided knowledge on tooth structure and eruption dates, the second domain was on oral health habits and parental roles in children's oral health, the

third domain was on dental caries and gum disease, the fourth domain described proper tooth brushing with fluoride toothpaste, and the fifth domain was on dental treatment and clinical prevention. The infographics were tested with a group of preschool parents before they were finalized. The infographics for the SIMSP were sent to parents/guardians every 2 weeks over 5 months.

CRA form. The CRA form consisted of four parts to assess the children's caries risk considering clinical, environmental, behavioral factors, and parents/caregivers' factors.²¹ Part 1 contained information on the child's caries experience assessed using the International Caries Detection and Assessment System (ICDAS).²² Part 2 contained information on caries risk factors for the child, i.e., presence of plaque, use of fluoride toothpaste, presence of crowding/deep fissures, sugary snacking, night bottle-feeding, and mother/siblings with caries. Part 3 contained information on child's caries risk indicators, i.e., low, medium, or high based on information in Parts 1 and 2. Part 4 contained information on child's caries management.

Control. The control group received the usual care (POHP) delivered by DTs consisting of an oral examination, OHE, FVA (22,600 ppmF) twice a year, and simple restorative treatment by DTs.

Implementation of the intervention. The SIMSP intervention was delivered for 6 months and consisted of three phases:

Phase 1: DTs' first visit to the preschools. DTs visited the preschools in both groups at the beginning of the year to conduct an oral examination on the children to assess caries and dental plaque. A self-administered questionnaire for parents was sent through class teachers.

Phase 2: DTs' second visit to preschools and initiation of the intervention. This visit took place 2 weeks after the first visit. In the SIMSP group, DTs delivered a standardized OHE followed by a FVA (22,600 ppmF) on the children's teeth. During this visit, DTs met with parents to discuss their child's oral health status and to complete the child's CRA form. Parents were given OHE and diet advice based on their child's CRA level (low/medium/high). A free toothbrush and fluoride toothpaste (1,450 ppmF) were distributed to parents for child home tooth brushing along with instructions. Parental agreement to receive 10 oral health infographics sent by DTs via the WhatsApp every 2 weeks for the next 5 months was sought. Teachers were given the teacher's OHE booklet as a teaching aid to deliver in-class oral health lessons during the 6 months, supplies of tooth brushes and fluoride toothpaste (1,450 ppmF) for daily tooth brushing for 6 months, a tooth model, and tooth brushing instructions to help with supervision. In the control group, DTs delivered a

standardized OHE to all children followed by a FVA (22,600 ppmF).

Phase 3: DTs' third visit to preschools. This visit took place 24 weeks after the second visit. In this phase, DTs carried out treatments using glass inomer restorations (if required) followed by a second application of FVA (22,600 ppmF). These procedures were carried out for both groups.

Monitoring implementation fidelity. The researchers observed implementation fidelity of the SIMSP to ensure that it was delivered as per the protocol throughout the 6-month period.²³ Data on implementation fidelity were self-reported by the DTs and teachers. The researchers communicated with the DTs on a weekly basis and went to the preschools every 2 weeks to meet with the teachers. Variations in the implementation process between preschools were minimized through discussion, facilitation, and support.

Outcome variables. The primary outcome was the decrease in the mean plaque score in children after 6 months as assessed by the Oral Cleanliness Index.²⁴ The secondary outcomes were: (1) changes in children's oral health behaviors after 6 months, (2) mean increase in the parents' OHL score after 6 months, and (3) implementation of the SIMSP fidelity outcomes.

Data collection. Data were collected at baseline and after 6 months in the intervention and control groups, which included oral examinations for the children and a self-administered questionnaire for parents at each stage. Baseline data were collected during February–March 2019, the intervention was delivered in April–September 2019, and follow-up data were collected in October–November 2019.

Oral examination. All children who fulfilled the study criteria were examined orally for dental caries and dental plaque at baseline and after 6 months by 3 dental officers who had been trained and calibrated on the examination criteria. A single blinding was applied in which examiners were blinded to the intervention group. They were not involved in sample recruitment or delivery of the intervention. Dental caries were assessed using the ICDAS.²² The inter- and intra-examiner kappa scores for ICDAS ranged from 0.72–0.80 and 0.70–0.84, respectively. The plaque score was assessed using the Oral Cleanliness Index.²⁴ It involved examining the labial surfaces of upper right to upper left primary canines. Each surface was recorded using codes: 0 = teeth appear clean, 1 = presence of plaque around the labial cervical margins and covering less than one-half of the labial tooth surface, 2 = plaque covering more than one-half of the labial tooth surfaces, and 9 = assessment cannot be made.

Parents/caregivers questionnaire. The questionnaire consisted of three sections. Section A consisted of items on socio-demographics of the parents. Section B consisted of items on the child's oral health behaviors (tooth brushing, use of fluoride toothpaste, bottle-feeding, sugary food and drink consumption, dental visits, and FVA). Section C consisted of the Malay version of the Dental Health Literacy Assessment Instrument (DHLAI),²⁵ which consists of three domains; oral Health Knowledge (OHK) with 12 items, comprehension with 5 items, and skills and motivation (SM) with 39 items. Each item on the OHK domain was assessed by one correct answer from 4 options with a total score of 0–12. Each item of the comprehension domain was scored as true/false answer options with a total score of 0–5. Each item of the SM domain was assessed using a 5-point Likert scale from 1 = strongly disagree to 5 = strongly agree with a total score of 0–39. The parental questionnaire was content validated by experts in DPH and tested with a group of parents prior to the study.

Implementation fidelity of the SIMSP. The compliance of DTs, teachers, and parents following the SIMSP protocol was assessed using various methods: in-class lessons by filling in the lesson dates in the OHE booklet by teachers, in-school tooth brushing by completing a tooth brushing diary by teachers, parents' meeting with DTs by completing the attendance list of the DTs, and infographics sent to parents by completing a standardized form by the DTs. Parents received a face towel and home oral hygiene kit while teachers received a bath towel for their participation in the study.

Statistical analysis. The initial assessment of the data showed that the clustering effect of the sample was negligible as the ICC was very low (<0.03) indicating that children within clusters were not correlated with one another and independence of the data was preserved.²⁶ Also, the number of clusters was higher than the average number of children within clusters for the cluster effect to occur or to be accounted for in the analysis,²⁷ i.e., 53.6% of clusters have fewer than 20 subjects each. As a result, the data analysis was conducted using an overall approach at the individual level.

An intention-to-treat analysis (ITT) was carried out for the primary and secondary outcome measures.²⁸ Data were entered and analyzed using SPSS version 21.0 software (SPSS Inc., Chicago, IL, USA). An exploratory data analysis was conducted to assess missing data and data entry errors. Continuous variables are described using descriptive statistics while categorical variables are described as frequencies and percentages.

Between-group differences in the proportions at baseline and after 6 months were assessed using the chi-square test, while within-group differences were assessed using

McNemar's test. Between-group differences in mean scores were assessed using a *t*-test or the Mann-Whitney test for non-normally distributed data. Within-group differences were compared using the paired sample *t*-test. The mean increase was calculated by subtracting the mean value at baseline from the mean value after 6 months. This value indicated the change in mean score over 6 months. ES was calculated using the general linear model to indicate the magnitude of difference between two mean values, i.e., how large the effect of SIMSP was compared to POHP on the outcome. ES was categorized into small (ES = 0.2), moderate (ES = 0.5), and large (ES = 0.8).²⁷ Domain and total scores for the OHL were calculated before between-group comparisons were made. The level of significance was set at $p < 0.05$.

Results

The number of children who fulfilled the inclusion and exclusion criteria and consented to participate in this study was 730. At baseline, 653 children were recruited into the study; 344 in the SIMSP (intervention), with a recruitment rate of 94.0%, and 309 in the POHP (control), with a recruitment rate of 84.9%. A total of 287 (83.4%) and 236 (76.4%) children completed the study, respectively at 6-months. Overall, 130 children did not attend the follow-up oral examination; 19 changed schools and 111 were absent (Figure 1). After the baseline oral examination, the parental questionnaire was distributed to parents through preschool teachers. Of the 653 questionnaires distributed, 517 were returned (response rate = 79.2%). At the 6-month follow-up, 517 questionnaires were distributed to parents and 446 were returned (response rate = 86.3%). Data from 653 children and 517 questionnaires were analyzed based on the ITT. Overall, the post-analysis indicated that the study achieved power of 1.0 for each of the outcomes.

Two factors, such as gender of the child and the father's education level, were significantly different between the groups (Table 1). Significantly more children in the intervention group were male (53.5% vs. 45.0%) than children in the control group. Significantly more children in the control group had fathers with a diploma (25.5% vs. 17.8%) than those in the intervention group. However, no significant difference in caries level was observed between the groups.

No significant difference in the proportion of children with visible plaque was observed between the groups at baseline. At the 6-month follow-up, the proportion of children with visible plaques was significantly lower in the intervention group (56.1% vs. 64.4%) than those in

the control group ($p = 0.031$) (Table 2). In addition, the mean decrease in the plaque score after 6 months was significantly higher in the intervention group (-0.22 , SD = 0.64 vs. -0.14 , SD = 0.48) than that in the control group ($p = 0.027$) with an ES of +0.51 representing a moderate ES. The within-group decrease in the mean plaque score after 6 months was higher in the intervention than the control group, with ESs of +0.12 and +0.07 representing a large and small ES, respectively ($p < 0.001$) (Table 3).

The reported changes in children's home oral health behaviors in both groups after 6 months are shown in Table 4. Significantly more children at follow-up in the intervention group brushed their teeth using toothpaste $\geq 2\times/day$ than at baseline. However, the between-group difference was not significant. A significantly higher proportion of parents in the control group (98.8% vs. 96.1%) monitored their child's home tooth brushing than those in the intervention group ($p = 0.043$). Significant reductions in the proportions of children in both groups who used bottle-feeding, daily bottle-feeding, and bottle-feeding at night were reported after 6 months. However, the between-group differences were not significant. A significantly higher proportion of children in the intervention group (99.6% vs. 97.3%) consumed carbonated drinks 1–3 $\times/week$ or less than those in the control group ($p = 0.033$).

Changes in parental OHL scores by domain are shown in Table 5. The mean increase in the OHK domain score was significantly higher in the intervention group (0.54, SD = 2.75) than that in the control group (0.02, SD = 2.42, $p = 0.024$) after 6 months, with an ES of +0.92, representing a large ES. No between-group difference was observed in the comprehension domain score. The mean increase in the SM domain score was higher in the intervention group than that in the control group, with an ES of +0.97, representing a large ES. The same trend was observed for the total OHL score. The mean increase in the score was higher in the intervention group than that in the control, with an ES of +0.97, representing a large ES.

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

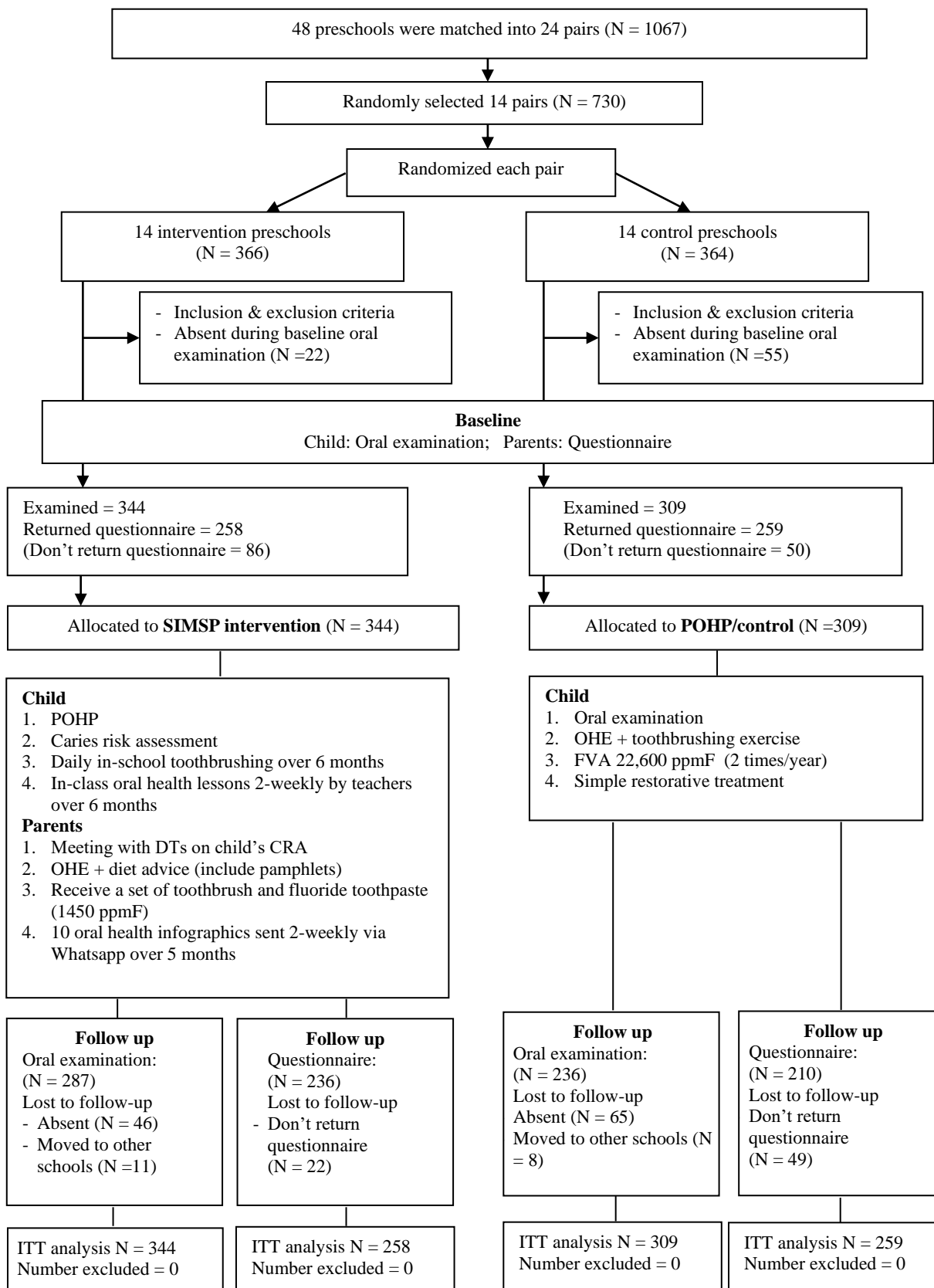


Figure 1. Flowchart of the participants in the intervention and control groups

Table 1. Socio-demographics of the children and parents including children's caries status at baseline between the groups (N = 653)

Variables	Overall N (%)	Intervention N (%)	Control N (%)	<i>p</i> ^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)	0.615
KEMAS	258 (39.5)	135 (39.2)	123 (39.8)	
Perpaduan	109 (16.7)	62 (18.0)	47 (15.2)	
Caries prevalence by person				
Sound/non-cavitated (ICDAS ₀₋₂)	29 (4.4)	13 (3.8)	16 (5.2)	0.386
Cavitated (ICDAS ₃₋₆)	624 (95.6)	331 (96.2)	293 (94.8)	
Caries prevalence by teeth (N = 12940)				
Sound teeth (ICDAS ₀)	2617 (20.1)	1393 (20.4)	1224 (19.9)	0.221
Non cavitated caries (ICDAS ₁₋₂)	6095 (47.0)	3163 (46.2)	2932 (47.8)	
Cavitated caries (ICDAS ₃₋₆)	4266 (32.9)	2283 (33.4)	1983 (32.3)	
Age of parent ¹				
<19	3 (0.5)	0 (0)	3 (1.2)	0.504
20-29	61 (11.8)	30 (11.6)	31 (12.0)	
30-39	305 (59.0)	156 (60.5)	149 (57.2)	
40-49	115 (22.2)	56 (21.7)	59 (22.8)	
>50	13 (2.5)	6 (2.3)	7 (2.7)	
Mother/carer's education ¹				
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 (56.4)	
STPM/diploma	116 (22.5)	58 (22.5)	58 (22.4)	
University	64 (12.4)	28 (10.9)	36 (13.9)	
Father's education ¹				
No formal education	12 (2.3)	11 (4.3) [∞]	1 (0.4)	0.001*
Primary school	40 (7.7)	28 (10.9) [∞]	12 (4.6)	
Secondary school	303 (58.6)	148 (57.4)	155 (59.8)	
STPM/diploma	112 (21.7)	46 (17.8)	66 (25.5) [∞]	
University	40 (7.7)	19 (7.4)	21 (8.1)	
Household income (RM) ¹				
No fixed income	54 (10.4)	29 (11.2)	25 (9.7)	0.161
< 1000	77 (14.9)	48 (18.6)	29 (11.2)	
1001 – 1999	163 (31.5)	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 (10.4)	22 (8.5)	32 (12.4)	
Family status ¹				
Traditional family	482 (93.2)	242 (93.8)	240 (92.7)	0.723
Divorced/single parent	34 (6.6)	16 (6.2)	18 (6.9)	

^aPearson's chi-square; ¹sample did not equal 517 for the parental questionnaire due to missing data; [∞]Z score > 1.96, **p* < 0.05.

Table 2. Presence of dental plaque on the labial surfaces of upper anterior primary teeth at baseline and after 6 months between the groups (N = 653)

	Overall N (%)	Intervention N (%)	Control N (%)	<i>p</i> ^a
Presence of plaque (at baseline)	447 (68.5)	237 (68.9)	210 (68.0)	0.798
Presence of plaque (follow-up)	392 (60.0)	193 (56.1)	199 (64.4)	0.031*

^aPearson's chi-square, **p* < 0.05

Table 3. Mean plaque scores of the children at baseline and after 6 months with effect sizes between the groups (N = 653)

	Overall N (%)	Intervention N (%)	Control N (%)	p^a	ES	ES descriptor
Baseline, mean (SD)	3.58 (3.77)	3.57 (3.69)	3.60 (3.63)	0.930		
Follow-up, mean (SD)	2.52 (3.08)	2.22 (3.05)	2.84 (3.09)	0.054		
Increment, mean (SD)	-1.06 (3.24)	-0.22 (0.64)	-0.14 (0.48)	0.027*	+0.51	Moderate
p^b	<0.001*	<0.001*	<0.001*			
ES		+0.12	+0.07			
ES descriptor		Small	Small			

^aIndependent sample *t*-test, ^bpaired sample *t*-test, SD = standard deviation, ES = effect size, * $p < 0.05$,

Table 4. Children's reported oral health and related behaviors at baseline and after 6 months between the groups (N = 517)

Variables	Overall N (%)	Intervention N (%)	Control N (%)	p^a
Brushed teeth daily				
Baseline	514 (99.4)	256 (99.2)	258 (99.6)	0.560
Follow-up	512 (99.0)	254 (98.4)	258 (99.6)	0.176
Brushed teeth $\geq 2x/day$				
Baseline	361 (69.8)	174 (67.4)	187 (72.2)	0.139
Follow-up	387 (74.9) ^b	189 (73.3)	198 (76.4)	0.231
Brushed using toothpaste $\geq 2x/day$				
Baseline	353 (68.3)	170 (65.9)	183 (70.7)	0.142
Follow-up	384 (74.3) ^b	190 (73.6) ^b	194 (74.9)	0.743
Brushed using fluoridated toothpaste				
Baseline	427 (82.6)	212 (82.2)	215 (83.0)	0.446
Follow-up	451 (87.2) ^b	224 (86.8)	227 (87.6)	0.441
Parents monitored child's brushing				
Baseline	500 (96.7)	246 (95.3)	254 (98.1)	0.067
Follow-up	504 (97.5)	248 (96.1)	256 (98.8)	0.043*
Use of bottle feeding				
Baseline	193 (37.3)	92 (35.7)	101 (39.0)	0.735
Follow-up	148 (28.4) ^b	72 (27.6) ^b	76 (29.3) ^b	0.666
Bottle feeding daily (n = 193)				
Baseline	150 (77.7)	78 (84.8)	72 (71.3)	0.024*
Follow-up (n = 147)	102 (69.4) ^b	54 (76.1) ^b	48 (63.2) ^b	0.177
Bottle feeding at night ¹				
Baseline	173 (33.5)	86 (33.5)	87 (33.6)	0.975
Follow-up	131 (25.3) ^b	64 (24.9) ^b	67 (25.9) ^b	0.801
Bottle feeding every night (n = 173)				
Baseline	135 (78.0)	69 (80.2)	66 (75.9)	0.488
Follow-up	85 (64.9) ^b	45 (70.3)	40 (59.7)	0.203
Sugars intake $\leq 4x/day$				
Baseline	443 (85.7)	222 (86.0)	221 (85.3)	0.816
Follow-up	456 (88.2)	225 (87.2)	231 (89.2)	0.485
Carbonated drinks intake ¹				
Baseline	253 (48.9)	119 (46.3)	134 (51.7)	0.217
Follow-up	267 (51.7)	131 (50.8)	136 (52.7)	0.660
Carbonated drinks intake $\leq 1-3x/week$				
Baseline	512 (99.0)	256 (99.2)	256 (98.8)	0.656
Follow-up	509 (98.5)	257 (99.6)	252 (97.3)	0.033*

^aPearson's chi-square, ^bMcNemar's test with $p < 0.05$, ¹sample did not equal 517 due to missing data, * $p < 0.05$

Table 5. Oral health literacy scores of parents at baseline and after 6 months by the domain and total scores between the groups (N = 517)

Domain	Overall	Intervention (N =258)	Control (N =259)	<i>p</i> ^a	ES	ES descriptor
Knowledge (score = 0-12)						
Baseline, mean (SD)	6.96 (2.52)	6.73 (2.54)	7.19 (2.48)	0.039*		
Follow-up, mean (SD)	7.24 (2.52)	7.27 (2.58)	7.21 (2.48)	0.791		
Increment, mean (SD)	0.28 (2.60) ^b	0.54 (2.75) ^b	0.02 (2.42)	0.024*	+0.92	Large
Comprehension (score = 0-5)						
Baseline, mean (SD)	4.07 (1.09)	4.04 (1.09)	4.09 (1.09)	0.962 ^c		
Follow-up, mean (SD)	4.03 (1.21)	4.00 (1.24)	4.05 (1.18)	0.453 ^c		
Increment, mean (SD)	-0.04 (1.24)	-0.04 (1.25)	-0.04 (1.23)	0.858 ^c	+0.06	Small
Skills and motivation (score = 0-39)						
Baseline, mean (SD)	28.42 (5.99)	28.00 (6.44)	28.83 (5.53)	0.085		
Follow-up, mean (SD)	28.98 (6.08)	28.75 (5.91)	29.20 (6.26)	0.634		
Increment, mean (SD)	0.56 (6.49)	0.75 (6.72)	0.37 (6.27)	0.506	+0.97	Large
Total OHL (score = 0-56)						
Baseline, mean (SD)	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)	40.57 (8.11)	0.699		
Increment, mean (SD)	1.12 (8.67) ^b	1.58 (8.78) ^b	0.68 (8.55)	0.242	+0.97	Large

^aIndependent sample *t*-test, ^bpaired sample *t*-test with *p* < 0.05, ^cMann–Whitney test, SD = standard deviation, ES = effect size, **p* < 0.05

Table 6. Data on the implementation fidelity of the SIMSP including compliance rates of parents, teachers, and dental therapists in delivering the SIMSP protocol

Preschool	Number of children	Parents' attendance at meeting N (%)	In-class oral health lessons ¹ N (%)	Children's worksheets ¹ N (%)	Daily toothbrushing at school ² N (%)	Delivery of 10 infographics to parents n N (%)
Preschool 1	50	40 (80.0)	11 (100)	11 (100)	98 (100)	10 (100)
Preschool 2	59	46 (78.0)	11 (100)	11 (100)	98 (100)	10 (100)
Preschool 3	18	18 (100)	11 (100)	11 (100)	98 (100)	10 (100)
Preschool 4	20	16 (80.0)	9 (81.0)	9 (81.0)	73 (74.5)	10 (100)
Preschool 5	25	25 (100)	11 (100)	11 (100)	98 (100)	10 (100) [∞]
Preschool 6	26	24 (92.3)	11 (100)	11 (100)	98 (100)	10 (100) [∞]
Preschool 7	19	12 (63.2)	11 (100)	11 (100)	98 (100)	10 (100)
Preschool 8	14	13 (92.9)	11 (100)	11 (100)	80 (81.6)	10 (100)
Preschool 9	20	15 (75.0)	10 (90.9)	10 (90.9)	98 (100)	10 (100)
Preschool 10	20	18 (90.0)	11 (100)	11 (100)	98 (100)	10 (100)
Preschool 11	11	7 (63.6)	11 (100)	11 (100)	98 (100)	10 (100)
Preschool 12	13	11 (84.6)	9 (81.0)	9 (81.0)	98 (100)	10 (100)
Preschool 13	25	22 (88.0)	11 (100)	11 (100)	98 (100)	10 (100)
Preschool 14	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)

¹Total number was 11, ²Total number of days was 98, [∞]Printed infographics

Discussion

This study was a pragmatic, cluster-randomized, parallel-group, matched pair, controlled trial that compared the effect of the SIMSP to the POHP on preschool children's oral health parameters over 6 months in the Kampar district, Perak. Overall, the SIMSP intervention has been shown to be effective for reducing children's dental plaque scores, carbonated drink intake, and improving parents' OHK and the

overall OHL compared to the existing POHP with a large ES.

Children's caries levels were assessed to ascertain if differences between the groups existed at baseline prior to the intervention. Despite differences in the children's gender and father's education between the groups at baseline, no significant difference in caries level was observed between the groups at baseline, indicating that both groups had similar disease levels. This was important to ensure that both groups started

the trial with the same disease level. Similarly, no differences in dental plaque scores were observed between the groups at baseline. However, significantly fewer children in the SIMSP had visible plaque at 6-months, and the mean decrease in the plaque score was significantly higher than that in the POHP, with a moderate ES (0.51). In clinical studies, ES values of 0.2–0.4 are considered good practice with clinically meaningful differences in outcomes.²⁹ This finding indicates that the SIMSP is potentially effective for reducing dental plaque. Consequently, children in the SIMSP would have a lower risk of developing caries as the quantity of cariogenic bacteria in plaques was significantly lower than children in the POHP.³⁰ This finding was attributed to the teacher-supervised daily tooth brushing at school and the home supervised tooth brushing by parents in the SIMSP over the 6 months. The findings in this study were similar to findings from studies in the UK, Australia, and Thailand where a school-based oral health promotion program was combined with teacher-supervised tooth brushing activity.^{31–33} Our study was similar to these studies where children brushed their teeth frequently, which resulted in reduced dental plaque scores and caries risk, as well as better delivery of fluoride from the toothpaste. A similar finding was found in a Hong Kong study where a CRA and motivational interviewing were used in addition to OHE.³⁴

In our study, the SIMSP had no significant impact on daily tooth brushing compared to the POHP. The reason for this could be that almost all children in both groups brushed their teeth daily at baseline. Therefore, no meaningful change was found at the follow-up. Also, no significant differences in twice daily tooth brushing or use of fluoride toothpaste were found between the groups. This could be explained by the fact that both programs included tooth brushing. The difference was that in the SIMSP, children had daily supervised tooth brushing at school and this could have contributed to improve their tooth brushing effectiveness which resulted in a significant reduction in dental plaque scores after 6 months. No significant differences in other behavioral items were observed between the groups except for carbonated drink intake per week. The reason could be that changes in behaviors are more difficult to achieve as children are influenced by broader socio-cultural factors, lifestyles, child-rearing practices, and the routines of parents.³⁵ As a result, only initial changes were observed after 6 months.

In the SIMSP, parents were given an individual face-to-face OHE and dietary sugar advice based on their child's oral health status and caries risk level. Studies have shown that OHE targeting parents, particularly mothers, for preventing early childhood caries and dental plaque is beneficial.^{36–38} This parent-centered

and individualized OHE approach in the SIMSP educated parents on positive oral hygiene care and the effect of a sugary diet on children's oral health. At the same time, parents also received OHE infographics for 6 months through WhatsApp messages. As a result, the OHL scores of parents in the SIMSP increased more than those in the POHP with a large ES (0.97). This finding indicates that the SIMSP produced a large magnitude effect on parents' OHL compared to the POHP, which corresponded to good practice and is highly recommended.²⁹ Our findings are similar to findings in India and Trinidad where a mobile-phone text messaging program and motivational interview of parents were effective for improving parents' OHK.^{7,8} The increase in parents' OHL and the in-class OHE by teachers in the SIMSP could have contributed to the significant reduction in the number of children who consumed carbonated drinks ≤ 1 –3 times per week. A similar finding was also reported by a study that targeted parent's knowledge.³⁴

Despite the large ES, the mean OHL scores between groups were not significant. This could be due to the fact that parents in the SIMSP had significantly higher scores only on the OHK domain due to the OHE they received but not in the comprehension and SM domains. The comprehension domain has items on parents' understanding of FVA, and parents tended to have difficulties answering questions on topics unfamiliar to them.³⁹ The SM domain contained items on parents' skills and motivation. Despite that parents in the SIMSP scored higher on this domain, the differences were not significant, as longer time is required for skills to develop. Nevertheless, the large ES of the SIMSP on parents' OHL indicates that the SIMSP is a far more superior program than the POHP²⁷ to improve parents' OHL.

The internal validity of the study was considered high, as we utilized a robust study design with low attrition rate, high implementation fidelity,²³ and appropriate data analysis methods. In terms of external validity, the results can be generalized to individual parents and children provided the preschool size is small, i.e., 20 children per cluster. The effect may be attenuated for a larger cluster size, as a clustering effect may exist. In Malaysia, an average preschool can accommodate between 10 and 25 children; therefore, the results may be generalizable to most preschool settings.⁴⁰ Furthermore, the use of a pragmatic study design and the inclusion of all types of preschools in all locations in the chosen district indicate that the results may be applicable to preschool settings in the country.¹⁸

The effectiveness of the SIMSP on children's plaque scores, carbonated drink intake, and parents' OHL has important implications. First, the SIMSP provides an evidence-based approach to children's oral healthcare

through smart partnerships of DTs, teachers, and parents that is lacking in the POHP. The SIMSP also provides a platform for DTs to assess children's CRA and formulate a treatment plan that includes promotive, preventive, and curative aspects of caries with active participation by parents and teachers. The compliance rates per protocol of the SIMSP were high, and more than 80% of the activities were completed. Therefore, the adoption of the SIMSP into the national preschool oral healthcare program (POHP) is feasible and recommended.

This study had several limitations. First, as children only spend 2 years at preschool, only short-term evaluations of the SIMSP were conducted. However, the significant finding on dental plaque in the SIMSP could be used as a proxy outcome for future caries control, as oral hygiene habits that develop during childhood tend to last until adulthood.⁴¹ Second, despite that the researchers visited the preschools regularly, monitoring of the SIMSP was mainly based on self-reported data. Future studies should include assessments by researchers to avoid over-reliance on self-reported data from participants. Two preschools in the SIMSP did not participate in the daily tooth brushing activities because both were located in a small and confined area. The school authority should provide suitable oral hygiene care facilities in the future.

Future studies should assess the long-term effect of the SIMSP on behavioral changes and caries levels of children. Studies on how to achieve greater participation by parents in the SIMSP are also recommended.

Conclusion

The findings from this study provide empirical evidence of the effectiveness of SIMSP in reducing children's plaque scores, soft drink intake, and parental OHL compared to the POHP over 6 months. The null hypothesis was rejected. This study contributes knowledge of the importance of effective tooth brushing, OHE by teachers, and parents' support for children's oral health. However, further research is needed to assess the sustainability and long-term effect on caries. As the SIMSP is mostly based on readily available resources, it would be feasible to replicate this study in other government preschool settings. It is hoped that the findings from the study will influence policy change and resource distributions to adopt the SIMSP in the current POHP in Malaysia.

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Conflict of Interest Statement

The authors declare no competing interests.

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