

MS BATHSHEBA TURTON (Orcid ID : 0000-0001-5464-9305)

Article type : Original Manuscript

Evaluation of a Community-Based Early Childhood Caries (ECC) Intervention in Cambodia

Bathsheba Turton¹, Callum Durward², Felicity Crombie³, Karen Sokal-Gutierrez⁴,
Sopharith Soeun⁵, David J. Manton⁶.

¹Bathsheba Turton

Faculty of Dentistry, University of Puthisastra, Phnom Penh

²Callum Durward

Faculty of Dentistry, University of Puthisastra, Phnom Penh, Cambodia

³Felicity Crombie

Melbourne Dental School, University of Melbourne, Australia

⁴Karen Sokal-Gutierrez

School of Public Health, University of California, Berkeley

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1111/cdoe.12599](https://doi.org/10.1111/cdoe.12599)

This article is protected by copyright. All rights reserved

⁵Sopharith Soeun

Faculty of Dentistry, University of Puthisastra, Phnom Penh

⁶David J. Manton

Centrum voor Tandheelkunde en Mondzorgkunde, UMCG, University of Groningen, the Netherlands.

*Corresponding author:

Bathsheba Turton

PO Box 1403, University of Puthisastra

Phnom Penh

Cambodia

E:bethy.turton@gmail.com

Statement of Contribution

BT, CD, DM, KS contributed to study design. BT, SS, FC contributed to data collection. BT, DM, FC contributed to data analysis. All authors contributed to interpretation of results and drafting of the manuscript.

Acknowledgements

The study was funded by One-2-One Cambodia (a Non-Governmental Organization) and fluoride varnish was donated by Ivoclar Vivadent (Luxembourg). The following people contributed to field based data collection during the non-randomised controlled

trial: Sieng Tida, Cham Roeun, Heng Chanlay, Sok Phirak, Loy Sreylan, and Horn Vitou. Mr Sompheak Sam and Mr Counleang Seng facilitated the stakeholder focus groups.

Objective: To critically evaluate an Early Childhood Caries (ECC) intervention performed by non-dental primary health care providers.

Methods: This mixed-methods investigation includes data from three sources: (1) a pilot non-randomised controlled trial to examine clinical outcomes at four health centres; (2) stakeholder focus group interviews; and (3) a survey of parents whose children were exposed to the intervention. The pilot study involved four Community Health Centres in rural Cambodia whereby mother-child (6-24 months-of-age) dyads received oral health education (OHE), toothbrushes, fluoride toothpaste and fluoride varnish on up to six occasions as part of the routine vaccination schedule. Outcomes were: presence of ECC; impacts on Oral-Health-Related Quality-of-Life (OHRQoL); stakeholder perceptions of intervention delivery; and parental perceptions of fluoride varnish.

Results: Participants in the intervention group had six times lower odds of developing ECC than those in the comparison group after controlling for socioeconomic status (OR 0.13). Those in the intervention group also had a large reduction OHRQoL scale scores. Key knowledge and practice gaps were identified among stakeholders. Surveyed parents had favourable views of the fluoride varnish placement by medical professionals and four out of five stated that they would recommend fluoride varnish for other children. Primary health care providers, commune council representatives and community health promoters supported oral health interventions being provided in CHCs.

Conclusions: OHE and fluoride varnish interventions provided by non-dental primary health workers were feasible and acceptable for stakeholders in a Cambodian setting. The intervention group had lower ECC experience and better OHRQoL at two years-of-age.

Introduction

The oral health of Cambodian children is amongst the poorest in the world¹. By age 3, 84.9% of children have early childhood caries (ECC) and 16% have one or more pulpally-involved teeth, severely affecting their Oral-Health-Related Quality-of-Life (OHRQoL)². The manifestation of dental caries is a sign of complex social and structural systems that generate inequality, and addressing the problem requires multi-sectoral support. Accordingly, any intervention to reduce the caries burden should generate evidence for both its therapeutic benefit and appropriateness for the existing health care system. This requires mixed-methods study designs that account for all agents within the system.

The health professionals who have most contact with Cambodian children during the early years-of-life are midwives and primary care providers based in Community Health Centres (CHC). Nine out of ten women receive post-natal care, and three out of four children receive their full complement of basic vaccinations, beginning in infancy³. The 2011 Cambodian National Oral Health Survey report recommended that action should be taken to reduce caries experience among the youngest age groups⁴. Interventions to prevent ECC in Cambodian preschoolers should be evidence-based and consider risk factors specific to the Cambodian context.

At the time of the conception of the study (2015), fluoride varnish application was not widely practised in Cambodia and there were no inter-disciplinary initiatives to deliver oral health interventions to preschool children in the public health care system. In addition, only limited resources were available for large-scale studies through government or global health granting bodies. Consequently, the Oral Health Bureau (OHB), Department of Preventive Medicine, Ministry of Health, Cambodia worked with a group of three Non-Governmental Organisations (One-2-One Cambodia, Reproductive and Child Health Alliance (RACHA), and the Buddhist Library Cambodia Project) to launch a series of pilot studies collectively known as “Cambodia Smile”. Relevant provincial health departments approved the provision of oral health interventions for mother-child dyads within four CHC. The aim of this study was to critically review the feasibility of the Cambodia Smile intervention by considering clinical outcomes, acceptability, and stakeholder perceptions.

Methods

A mixed-methods approach was used to examine critically the feasibility, acceptability and outcomes of the Cambodia Smile intervention. Evaluation included: (1) a non-randomised controlled trial to examine clinical outcomes in four CHC; (2) stakeholder focus groups; and (3) a survey of parents of children receiving the Cambodia Smile intervention. Ethical approval was obtained from by the National Ethics Committee for Health Research, Ministry of Health, Cambodia.

Non-randomised controlled trial and pilot study

The aim was to clinically evaluate the potential for the caries preventive effect of the intervention. The key outcomes were caries prevalence defined at two thresholds (one or more white spot lesions and one or more cavitated lesions) and OHRQoL. A two year interventional study was based in four CHCs. Mothers were invited to participate with their new-born babies and informed consent was gained both verbally (explained by primary health care provider) and in writing. Participants were matched with a comparison group recruited after two years. The study was conducted in accordance with the ethical principles described in the Declaration of Helsinki and ethical approval was provided by the National Ethics Committee for Health Research in Cambodia and by the University of Melbourne Human Research Ethics Committee.

Health Centre and Population Selection

Inclusion criteria for the intervention group were based on a child's birth at one of four selected CHCs in Kampong Speu Province from February 2015. The sample size calculation was designed to detect a difference of one less tooth with a carious lesion in the intervention group (than the comparison group). G*Power version 3.1.9.7 was used to determine that a sample size of 392 (196 in the comparison group and 196 in the intervention group) would be required in order to achieve 95% power. Mother-child dyads were recruited until the desired sample size was reached (July 2015). Inclusion criteria for the comparison group were based on the child being born 22-26 months prior to data collection at one of four randomly selected

CHCs within the same operational district, but from different villages to children in the intervention group. Children with underlying chronic medical conditions were excluded. None of the children in the study had access to reticulated or naturally fluoridated water.

Clinical Intervention

The clinical interventions comprised: (1) Oral Health Education (OHE) using a pictorial flip chart – including the delivery of dietary advice (especially dietary sugars reduction) and oral hygiene instruction; (2) provision of toothbrushes and fluoridated toothpaste (50 g, 1000 ppm fluoride as per Cambodian Ministry of Health recommendations) for both mother and baby at baseline, and for baby at subsequent visits; and (3) the application of fluoride varnish (Fluor Protection N; 7000 ppm F; Ivoclar Vivadent; Schaan, Liechtenstein) once teeth had erupted. The interventions were delivered during routine CHC vaccination, vitamin A supplementation and de-worming medication visits. This created six intervention opportunities at three to six month intervals across the first two years-of-life according to the routine schedule for vaccinations and supplementation in Cambodia. Interventions were delivered by primary health care providers (nurses and midwives) who received an initial eight hour package of training and three hour refresher training every six months throughout the project.

The questionnaire

Trained interviewers administered questionnaires to each caregiver at the 2 year follow-up for the intervention group and at recruitment for the comparison group. Data regarding maternal education, household income, diet and the Family Impact Scale (FIS) were collected. The FIS is an OHRQoL instrument, previously validated for use in a Cambodian population¹. The instrument includes eight questions across three domains: family activities, family emotions, and family conflict. The response options for each item were “Never” (score 0), “Once or twice”, “Sometimes”, “Often”, or “Every day or almost every day” (scores 1, 2, 3, 4 respectively). A participant had an ‘impact’ for a particular item if they responded with a score 3 or above, consistent with the conventions established in the cross-cultural adaptation of the instrument⁵. Diet was assessed using a 24hour diet diary to determine the frequency of

consumption of foods and drinks. Socio-economic status was determined based on household monthly income and maternal education level.

Clinical measures

Wet teeth were examined uncleaned in accordance with the four stage ECC classification⁶. Three examiners were calibrated against the principal investigator during a four hour training session and generated an intra-class correlation coefficient of >0.9. Data from the four stage ECC classification system are recorded as ECC-1 for carious lesions where there is a white-spot appearance on the enamel, ECC-2 for carious lesions with early enamel breakdown and ECC-3 for carious lesions where there is a visible cavity extending into dentine. The term 'mean ECC' refers to the sum of all lesions across the three categories, while 'mean ECC-3' refers to just the lesions in the ECC-3 category. The Green's Simplified Plaque Index was used to assess the amount of plaque accumulation observed on the primary right maxillary central incisor⁷. Children were examined in the supine position by an examiner and assistant with a mouth mirror and hand-held torch illumination with appropriate infection control measures in place.

Data management and analysis

Data were collected on paper forms and participants were identified by a unique identification (ID) number. Midwives were given a list of children to follow-up and one phone call per month was made by the research coordinator to the CHCs to encourage follow-up. Data were entered into SPSS Version 23 (IBM Corp., NY, USA) and both descriptive and bivariate analyses were performed. Data were regrouped to identify children in different caries categories. The term 'any caries' was defined as any child with one or more lesions which scored ECC-1 or above. The term 'any cavity' referred to any child with one or more lesions in the ECC-3 category. Chi squared tests were used to examine differences in proportions between groups. The Kruskal Wallis test was used to examine differences in the rank score of the number of carious lesions in individuals by group membership. The alpha value was set at $P < 0.05$. Proportional differences in OHRQoL were assessed by calculating effect size, based on dividing the change in prevalence by the

baseline prevalence. A binary logistic regression model was used to examine odds ratios for any caries, any cavity, or any impact in FIS after controlling for monthly household income.

Survey of parents of children receiving the Cambodia Smile interventions

The aim of the parental survey was to seek feedback from those who had been exposed to the Cambodia Smile package to assess the level of acceptability to the community. The Cambodia Smile package was integrated into the Cambodia Longitudinal Health and Nutrition study in 2017 during its fifth follow-up phase. During the sixth follow-up (in 2019), parent(s) of participants who had fluoride varnish placed previously were asked a series of questions about their perceptions of the intervention. One of eight trained interviewers who were independent of the Cambodia Smile intervention administered questionnaires and data were entered directly into tablets using Kobo-toolbox software, and summarised using simple descriptive statistics.

Stakeholder focus groups

The aim of the stakeholder focus groups was to gain perspective from the implementers and commune level decision makers about the acceptability and feasibility of the proposed Cambodia Smile package. The focus groups included participants from three communes in Kratie province, where the intervention is planned to start in 2021 but where they had not been exposed to the intervention previously. At each commune, three different focus groups were conducted for the three key stakeholders: (1) CHC staff, including the chief of the CHC, midwives, nurses and those responsible for vaccination; (2) members of the village health support group who raise awareness of health issues and prevention under the direction of the CHCs and Commune Council; and (3) Commune Council representatives such as the chief of the commune and council members. Focus group discussions were held separately at participant workplaces. The same discussion guides were used for each group. The topics included: oral health service demand; perceptions of toothpaste use; perceptions of fluoride varnish; workflow for provision of vaccinations and how oral health interventions might be integrated; and perceptions of oral health promotion materials. Interviews were conducted systematically by the monitoring and evaluation team of the RACHA NGO, who were experienced in conducting qualitative research. Interviewers first visited the Cambodia Smile

project sites in Kampong Speu province and then undertook three hours training by the lead investigator (BT) on the discussion guide topics ahead of conducting focus groups. Each focus group was run by a facilitator and scribe (who noted concepts raised in real time). Focus groups were conducted in the Khmer language and recorded using mobile phones. Key concepts were extracted from the real-time notes and from listening to the recorded interviews later. Once key quotes had been identified, they were translated into English, and descriptions of the key themes were reported in English.

Results

Non-randomised controlled trial and pilot study

More than 85% (n = 316) of participants came from households that earned less than USD150 per month. There were significant differences between the comparison and intervention groups in terms of maternal education and household income, whereby the latter group had a broader spread of participants across education and household income levels (Table 1).

Within the intervention group, 186 of 262 mother-child dyads were followed up at age two years (29.0% lost to follow-up). Of the children, 53.8% were female (n = 199) and there was no difference in mean age (months) between the comparison and intervention groups (Table 2). Children lost to follow-up were not significantly different from others in the intervention group with respect to baseline socio-demographic indicators, such as gender, mother's education or household income. Intervention group participants received an average of 2.1 intervention encounters (range one to six) across the course of the study; 63/186 (33.9%) participants followed-up at two years had not presented for any interventions once teeth had erupted (that is, had not received any fluoride varnish applications).

In the intervention group, there were no significant differences in caries experience by socio-demographic characteristics at two-year follow-up. Severe caries experience was present among children in all sociodemographic subgroups of the intervention cohort; the mean number of lesions (mean ECC) was 5.8 (SD 5.0); the mean number of cavitated lesions

involving dentine (ECC-3) was 1.3 (SD 2.0). Overall, the prevalence of any carious lesions was 62.1% (n= 116) and the prevalence of any cavitated lesions was 37.9% (n= 71).

The mean number of ECC lesions among children in the intervention group (2.9) was one-third that of the comparison group (8.7). The prevalence of any white spots was also significantly lower in the intervention group (n = 127; 68%) than the comparison group (n = 173; 94%) (Table 3). Children who received OHE (and the provision of toothbrush and toothpaste) had half the mean number of carious lesions scoring ECC-1 or higher than the comparison group.

There were statistically significant differences between the intervention and comparison groups in the prevalence of impacts and mean scores on the overall FIS and its subscales (Table A1). There was between 69.1% and 75.0% relative difference in prevalence of impacts on the FIS scale and subscales whereby those in the comparison group had a higher proportion of participants with one or more impacts. There was a moderate-to-large effect size for the difference in mean scores and those in the comparison group had higher mean values on the FIS scale and the three subscales.

The mean plaque scores for the comparison and intervention groups were 2.1 (SD 1.0) and 0.9 (SD 0.4), respectively. There was no significant difference in frequency of 'non-nutritious food' (packaged snacks, candies, and sugar-sweetened beverages [SSB]) consumption by group membership. Children in the comparison and intervention groups consumed a mean of 0.4 (SD 0.7) and 0.4 (SD 0.7) SSB, and 0.7 (SD 1.1) and 0.6 (SD 1.1) packaged snacks per day, respectively.

There were notable differences in outcomes between the intervention and comparison groups after controlling for socio-economic status (Table 4). Intervention group children were approximately one-sixth as likely to develop any carious lesions or any impacts across the FIS, and half as likely to develop any cavitated lesions. The odds of developing cavitated lesions were 15% lower if the child was exposed to fluoride varnish in addition to OHE.

Survey of parental perceptions

The list of questions in the discussion guide is presented in Table A2, and data on participant socio-demographic characteristics are presented in Table A3 of the supplementary material.

Although many respondents were not present for the fluoride varnish application the year before, or could not recall it, there was an overall positive response to the intervention, and five out of six would recommend the use of fluoride varnish for other children. Although 65.5% of respondents reported purchasing toothpaste for their children, only 20.9% reported that they used toothpaste with their child the previous day. A majority (86.6%) of respondents were happy to have had an oral health intervention provided by non-dental professionals (Table 5).

Stakeholder focus groups

Overall, 14 members of the Volunteer Health Support Group (VHSG), 15 members of commune councils and 25 CHC staff were interviewed. Three key themes emerged. The first theme was that most stakeholders were aware of the severity of oral health problems in Cambodian children.

For example - VHSG participant, a 26year-old female

“I saw my nephew who had a gum swelling with my own eyes and there was a discharge of pus around the dental cavity. He cried out and he could not eat or drink. I took him for an oral health check-up many times.”

The second theme was that there appeared to be an incorrect understanding about optimal oral hygiene practices for preschool-age children.

For example - Commune Council Member, a 63year-old female

“The infant should start to brush their teeth at the age of 3 years, three times-per-day: early morning after they wake up, after lunch and at night-time before going to bed.”

Most stakeholders agreed that oral health interventions should be available in a CHC.

For example - Chief of a CHC, a 43year-old female

“First, the service must be available at the CHC; then human resource would need to be developed. They should train the staff related to the skills and then do outreach activities to spread information about fluoride varnish placement and that it can be accessed at the health centre.”

Commune Council Member, a 37year-old female

“I want to have oral health care services available at the CHC as there is no such service here while other services are already in place.”

A descriptive summary of key stakeholder focus groups is presented in Appendix 3.

Discussion

The Cambodia Smile intervention took place in a challenging environment. The results of this study demonstrate that the Cambodia Smile interventions:(1) lead to clinically significant reductions in caries experience; (2)lead to a reduction in adverse QoL impacts among 2year-olds;and (3) were acceptable to stakeholders and parents. Studies performed in challenging environments often require design compromises and therefore it is important to publish the results in the context of robust critical interpretation⁸. The main limitations of the study were the inability to conduct a conventional randomised controlled trial, perform focus group interviews to full theme saturation, and have a representative sample of intervention group parents to respond to surveys. The strength of this study was the combination of a clinical trial together with studies to gauge community and patient perceptions. The information obtained will be useful when planning larger scale studies and for the development of public health policies to address the problem of ECC in Cambodia.

This article is protected by copyright. All rights reserved

While the caries preventive and OHRQoL benefits of the intervention may be subject to some over-estimation bias, even if the benefits were half of those determined, this intervention would produce substantial health gains. The most recent Cochrane review estimated that delivery of fluoride varnish to preschool children could render a relative risk of caries progression as -0.30 (95% CI -0.69, 0.09)⁹. Contextualizing the findings within the global literature affirming the effectiveness and acceptability of fluoride varnish provides further confidence of the effectiveness and acceptability of this intervention⁵.

The findings of the present study are more favourable than other recent fluoride varnish studies¹⁰; some of which were underpowered¹¹⁻¹², and others conducted in populations with an ECC prevalence in 2 year-olds below 40%¹²⁻¹⁸. In some studies, only participants who had already reached 2 to 3 years-of-age with no clinical signs of dental caries were recruited¹⁷⁻¹⁹. Recent studies on fluoride varnish for prevention of ECC are centred on populations which do not match the characteristics of the Cambodian environment. The explanation for the effectiveness of fluoride varnish therapy in the present study may include that it was placed: (1) at a time when the caries process was underway but the lesions were initial and non-cavitated; and/or (2) in the context of a population with universally high caries risk and low exposure to fluoride from other sources. Although there is a scarcity of English language literature on fluoride varnish for preschool children from Low and Middle Income countries, studies in higher income settings such as Australia^{20,21}, Ireland²¹, and Scotland²³, have found that fluoride varnish interventions targeted at marginalised communities report similarly favourable results.

In addition to the benefits of the intervention in terms of reducing caries experience, it appears that the interventions also had benefits for the family unit. This study was unique in that it included an OHRQoL measure for a preventive intervention. Although any OHRQoL measure that attempts to assess outcomes for participants who are not yet able to articulate their own opinions has limitations²⁴, the differences in both mean scores and the prevalence of impacts across the FIS scale and subscales suggest that the intervention was beneficial. The differences observed were similar to the medium-to-large effect sizes reported in another

nine studies that used the FIS to assess changes in OHRQoL after dental treatment under general anaesthesia²⁵.

An important feature of the intervention was that it was conducted by non-dental professionals: this approach allows incorporation of dental care with relatively little investment and has demonstrated some success in previous studies²⁶. A benefit of a cross-disciplinary approach is that it can facilitate consistency in health messaging across disciplines, presenting an opportunity to address dental knowledge gaps exposed during the health professional focus groups. Unfortunately, this type of task shifting is not without challenges and previous studies or commentaries have cited issues around lack of training, unfavourable remuneration structures, time pressure, and lack of referral pathways for managing oral conditions that might be identified²⁶⁻²⁹. Despite the challenges, the use of non-dental professionals, particularly in maternal-child interventions, appears to be a promising for early intervention and for addressing some of the social determinants of disease^{30,31}.

As well as demonstrating the clinical effectiveness of an intervention, stakeholder perceptions are also central to the justification of upscale/service delivery and this aspect is lacking from many studies from low and middle income countries³². Data from the present investigation suggest that the intervention is acceptable to primary health care providers and parents. The outcomes of the key stakeholder focus groups and parental surveys demonstrated: (1) that performing oral health interventions in a primary health care environment would be welcomed; and (2) there are specific and modifiable gaps in knowledge and practice related to oral health practices for young children in Cambodia to be addressed.

Key opportunities for enhancement of the intervention at scale were identified. The first is to understand the drivers for accessing and providing the intervention. It was evident that although six intervention opportunities were available, only two opportunities (on average) were realised, highlighting the need for multiple chances to access the intervention. This should be factored into future monitoring and evaluation activities. The second intervention opportunity is to address the knowledge and practice gaps that were evident among both health professionals and parents. Health professionals appeared to be unaware that in a high-

risk population brushing with fluoride toothpaste should be initiated at eruption of the first tooth^{33,34}. Despite parents having toothpaste in the home, only one in five used it for their preschool child on the day prior to the survey.

At this stage, the intervention is focused on targeting the most easily modifiable risk factors, such as lack of oral hygiene and exposure to fluoride, and it is a tangible first step at reducing the ECC burden in Cambodia. There are very few studies addressing ECC management in low and low-to-middle income countries and this is partly due to difficulty in attracting funding for large-scale clinical studies, given the lack of central government resources and the low priority assigned to oral health issues by many global health funders. In addition, it should be acknowledged that ECC is a complex problem operating at the intersection of social and structural inequalities that drive differences in areas such as food environments and access to care³⁵.

When examining the benefits of fluoride therapies for moderating caries experience it is important to understand that dental caries is a primarily a socio-behavioural disease and if the causative factors of the process are not controlled, the disease will progress and become a burden at the population level³⁶. Among the intervention group, there was better oral hygiene among children of the intervention group; however, there was no difference in frequency of consumption of non-nutritious (cariogenic) foods between the two groups. This suggests that the intervention did not improve dietary behaviour. Where individually focused interventions might fail, then public policy initiatives such as sugar taxes might be effective in achieving behavioural change^{37, 38}.

Future steps in the further implementation of the Cambodia Smile intervention should include a more rigorous, and larger scale clinical study to verify the clinical benefits. Further research is also needed to better understand the most effective approaches for reducing sugar consumption among young children in a Cambodian environment. The intervention is consistent with the WHO recommendations for reducing ECC^{26,28} which makes it well-placed to inform policy recommendations and investigations on economic modelling which would be required to attract local and central government funding.

Conclusions

Oral health education and fluoride varnish interventions provided by non-dental primary health workers are feasible in a Cambodian setting and led to significantly lower ECC experience and more favourable OHRQoL at 2years-of-age. Future investigations should employ a stronger effort to reduce sugars consumption, and a rigorous clinical study to validate these findings and offer strong evidence for policy recommendations.

References

1. El Tantawi M, Folayan MO, Mehaina M, Vukovic A, Castillo JL, Gaffar BO, Arheiam A, Al-Batayneh OB, Kemoli AM, Schroth RJ, Lee GH. Prevalence and data availability of early childhood caries in 193 United Nations Countries, 2007–2017. *Am J Public Health*. 2018;108:1066-72.
2. Turton B, Chher T, Sabbah W, Durward C, Hak S, Lailou A. Epidemiological survey of early childhood caries in Cambodia. *BMC Oral Health*. 2019;19:107.
3. National Institute of Statistics, Cambodia. The 2014 Cambodia Demographic and Health Survey. 2014.
4. Chher T, Turton B, Hak S, Beltran E, Courtel F, Durward C, Hobdell M. Dental caries experience in Cambodia: findings from the 2011 Cambodia national oral health survey. *J Int Oral Health*. 2016;8(1):1-16.
5. Khoun T, Malden PE, Turton BJ. Oral health-related quality of life in young Cambodian children: a validation study with a focus on children with cleft lip and/or palate. *Int J Paediatr Dent*. 2018;28:326-334.
6. Evans RW, Feldens CA, Phantunvanit P. A protocol for early childhood caries diagnosis and risk assessment. *Community Dent Oral Epidemiol*. 2018;46:518–25.
7. Greene JC, Vermillion JR. Oralhygiene index: a method of classifying oral hygiene status. *J Am Dent Assoc*.1960;61:172–179.

8. Petersen PE, Ogawa H. Prevention of dental caries through the use of fluoride—the WHO approach. *Community Dent Health*. 2017;33:66-8.
9. de Sousa FS, Dos Santos AP, Nadanovsky P, Hujoel P, Cunha-Cruz J, de Oliveira BH. Fluoride varnish and dental caries in preschoolers: a systematic review and meta-analysis. *Caries Res*. 2019;53:502-13.
10. Mishra P, Fareed N, Battur H, Khanagar S, Bhat M, Palaniswamy J. Role of fluoride varnish in preventing early childhood caries: A systematic review. *Dent Res J*. 2017;14:179.
11. Memarpour M, Fakhraei E, Dadaein S, Vossoughi M. Efficacy of Fluoride Varnish and Casein Phosphopeptide-Amorphous Calcium Phosphate for Remineralization of Primary Teeth: A Randomized Clinical Trial. *Med Princ Pract*. 2015;24:231–7.
12. Oliveira BH, Salazar M, Carvalho DM, Falcão A, Campos K, Nadanovsky P. Biannual Fluoride Varnish Applications and Caries Incidence in Preschoolers: A 24-month Follow-Up Randomized Placebo-Controlled Clinical Trial. *Caries Res*. 2014;48:228–36.
13. Agouropoulos A, Twetman S, Pandis N, Kavvadia K, Papagiannoulis L. Caries-preventive effectiveness of fluoride varnish as adjunct to oral health promotion and supervised tooth brushing in preschool children: A double-blind randomized controlled trial. *J Dent*. 2014;42:1277–83.
14. Anderson M, Dahllöf G, Twetman S, Jansson L, Bergenlid A-C, Grindefjord M. Effectiveness of Early Preventive Intervention with Semiannual Fluoride Varnish Application in Toddlers Living in High-Risk Areas: A Stratified Cluster-Randomized Controlled Trial. *Caries Res*. 2017;50:17–23.
15. Divaris K, Preisser JS, Slade GD. Surface-Specific Efficacy of Fluoride Varnish in Caries Prevention in the Primary Dentition: Results of a Community Randomized Clinical Trial. *Caries Res*. 2013;47:78–87.
16. Jiang EM, Lo ECM, Chu CH, Wong MCM. Prevention of early childhood caries (ECC) through parental toothbrushing training and fluoride varnish application: A 24-month randomized controlled trial. *J Dent*. 2014;42:1543–50.
17. Muñoz-Millán P, Zaror C, Espinoza-Espinoza G, Vergara-Gonzalez C, Muñoz S, Atala-Acevedo C, et al. Effectiveness of fluoride varnish in preventing early childhood caries

- in rural areas without access to fluoridated drinking water: A randomized control trial. *Community Dent Oral Epidemiol.* 2018;46:63–9.
18. McMahon AD, Wright W, Anopa Y, McIntosh E, Turner S, Conway DI, Macpherson LM. Fluoride Varnish in Nursery Schools: A Randomised Controlled Trial—Protecting Teeth@ 3. *Caries Res.* 2020;22:1-9.
 19. Tickle M, O'Neill C, Donaldson M, Birch S, Noble S, Killough S, et al. A randomized controlled trial of caries prevention in dental practice. *J Dent Res.* 2017;96:741-6.
 20. Lawrence HP, Binguis D, Douglas J, McKeown L, Switzer B, Figueiredo R, Laporte A. A 2-year community-randomized controlled trial of fluoride varnish to prevent early childhood caries in Aboriginal children. *Community Dent Oral Epidemiol.* 2008;36:503-16.
 21. Jamieson L, Smithers L, Hedges J, Mills H, Kapellas K, Ha D, Do L, Ju X. Follow-up of Intervention to Prevent Dental Caries Among Indigenous Children in Australia: A Secondary Analysis of a Randomized Clinical Trial. *JAMA network open.* 2019;2:e1915611-.
 22. Tickle M, O'Neill C, Donaldson M, Birch S, Noble S, Killough S, Murphy L, Greer M, Brodison J, Verghis R, Worthington HV. A randomised controlled trial to measure the effects and costs of a dental caries prevention regime for young children attending primary care dental services: the Northern Ireland Caries Prevention In Practice (NIC-PIP) trial. *Health Technol Assess.* 2016;20):1-96.
 23. Macpherson LM, Rodgers J, Conway DI. Child smile after 10 years part 2: programme development, implementation and evaluation. *Dental Update.* 2019;46:238-46.
 24. McGrath C, Broder H, Wilson-Genderson M. Assessing the impact of oral health on the life quality of children: implications for research and practice. *Community Dent Oral Epidemiol.* 2004;32:81–5.
 25. Park JS, Anthonappa RP, King NM, McGrath CP. The family impact of dental general anaesthesia in children: A meta-analysis. *Int J Paediatr Dent.* 2019;29:149-61.
 26. George A, Sousa MS, Kong AC, Blinkhorn A, Norrie TP, Foster J, Dahlen HG, Ajwani S, Johnson M. Effectiveness of preventive dental programs offered to mothers by non-

- dental professionals to control early childhood dental caries: a review. *BMC oral health*. 2019;19:172-183.
27. Quinonez RB, Kranz AM, Lewis CW, Barone L, Boulter S, O'Connor KG, Keels MA. Oral health opinions and practices of pediatricians: updated results from a national survey. *Acad pediatr*. 2014;14:616-23.
 28. Benzian H, Hobdell M, Holmgren C, Yee R, Monse B, Barnard JT, van Palenstein Helderma W. Political priority of global oral health: an analysis of reasons for international neglect. *Int Dent J*. 2011;61:124-30.
 29. Steffensen JE. Literature and concept review: issues in maternal and child oral health. *J Public Health Dent*. 1990;50:358-369.
 30. Medeiros PB, Otero SA, Frencken JE, Bronkhorst EM, Leal SC. Effectiveness of an oral health program for mothers and their infants. *Int J Paediatr Dent*. 2015;25:29-34.
 31. Sheiham A, Alexander D, Cohen L, Marinho V, Moysés S, Petersen PE, Spencer J, Watt RG, Weyant R. Global oral health inequalities: task group—implementation and delivery of oral health strategies. *Adv Dent Res*. 2011;23:259-67.
 32. Cook N, Siddiqi N, Twiddy M, Kenyon R. Patient and public involvement in health research in low and middle-income countries: a systematic review. *BMJ open*. 2019; 1: e026514.
 33. Phantumvanit P, Makino Y, Ogawa H, Rugg-Gunn A, Moynihan P, Petersen PE, et al. WHO global consultation on public health intervention against early childhood caries. *Community Dent Oral Epidemiol*. 2018;46:280-7
 34. World Health Organization, 2019. Ending childhood dental caries: WHO implementation manual. Smith L, Blinkhorn F, Moir R, Brown N, Blinkhorn A Baker 2019.
 35. Baker SR. No simple solutions, no single ingredient: systems orientated approaches for addressing wicked problems in population oral health. *Commun Dent Health*. 2019;36:3.
 36. Sheiham A, James WPT. Diet and Dental Caries The Pivotal Role of Free Sugars Reemphasized. *J Dent Res*. 2015;94:1341-7
 37. Moynihan P, Miller C. Beyond the Chair: Public Health and Governmental Measures to Tackle Sugar. *J Dent Res*. 2020:0022034520919333.

38. Peres MA, Macpherson LM, Weyant RJ, Daly B, Venturelli R, Mathur MR, Listl S, Celeste RK, Guarnizo-Herreño CC, Kearns C, Benzian H. Oral diseases: a global public health challenge. *The Lancet*. 2019;394:249-60.

List of Tables and Figures

Table 1. Sociodemographic characteristics at follow-up, by group

Table 2. Attrition analysis at 2 y for the intervention group

Table 3. Clinical characteristics by exposure to the intervention

Table 4. Multivariate models for exposure to the intervention by the odds of any caries, any cavity or any impacts across the FIS

Table 5. Description of fluoride varnish perceptions by caregivers

Table A1. Family Impact Scale and subscale results by group membership

Table A2. Questions included in the survey of parental perceptions

Table A3. Sociodemographic characteristics of participants with both questionnaire and dental examination

Table 1 – Sociodemographic characteristics at follow-up, by group

	Intervention n(row %)	Comparison n(row %)	Total n(column %)	P-value ^a
Sex^b				
Male	83 (44.6)	87 (47.3)	170 (45.9)	0.359
Female	102 (54.8)	97 (52.7)	199 (53.8)	
Maternal Education				
Illiterate	17 (9.1)	0 (0.0)	17 (4.6)	<0.001
Primary	108 (58.1)	184 (100.0)	292 (78.9)	
Secondary or High-school	58 (31.2)	0 (0.0)	58 (15.7)	
Tertiary	3 (1.6)	0 (0.0)	3 (0.8)	
Household income^c				
<50	16 (8.6)	0 (0.0)	16 (4.3)	<0.001
51-150	116 (62.4)	184 (100.0)	300 (81.1)	
151-250	49 (26.3)	0 (0.0)	49 (13.2)	
>250	5 (2.6)	0 (0.0)	5 (1.4)	
Total^c	186 (50.3)	184 (49.7)	370 (100.0)	

^a P-value expressed for differences among groups within the same column.

^b gender data missing from one participant.

^c Reported household income at follow-up

Table 2 – Attrition analysis at 2 y for the intervention group

	Baseline n (Column %)	Lost n (row %)	Followed-up n (row %)	P-value ^b
Sex^a				
Male	123 (47.1)	40 (32.5)	83 (67.5)	0.157

Female	138 (52.9)	36 (26.1)	102 (73.9)	
Baseline household monthly income				
<50	22 (8.4)	6 (27.3)	16 (72.7)	0.689
51-150	160 (61.1)	44 (27.5)	116 (72.5)	
151-250	74 (28.2)	25 (33.8)	49 (66.2)	
>250	6 (2.3)	1 (16.7)	5 (83.3)	
Total	262 (100.0)	76 (29.0)	186 (71.0)	

^a sex data missing from 1 participant

^b differences in proportions were tested using the chi squared test

Table 3 – Clinical characteristics by exposure to the intervention^a.

	ECC μ (SD)	ECC-3 μ (SD)	Any white spot n (%)	Any cavity n (%)
Comparison	8.7 (4.9) ^a	1.6 (2.2) ^a	173 (94.0) ^a	88 (47.8) ^a
Intervention	2.9 (3.0)	1.0 (1.8)	127 (68.3)	53 (28.5)
OHE Only	3.3 (3.3) ^b	1.2 (2.1) ^b	78 (69.6) ^b	35 (31.3) ^b
FV & OHE	2.3 (2.5)	0.6 (1.2)	49 (66.2)	18 (24.3)

^a P-value<0.001 for comparison of means or proportions between the control and intervention groups; χ^2 statistic or Kruskal-Wallis as appropriate.

^b P-value<0.001 for comparison of means or proportions between the OHE and FV&OHE group; χ^2 statistic or Kruskal-Wallis as appropriate.

Table4 – Multivariate models for exposure to the intervention by the odds of any caries, any cavity or any impacts across the FIS

	Any White Spot		Any Cavity		Any Impacts	
	Odds Ratio (SE)	P-value	Odds Ratio (SE)	P-value	Odds Ratio (SE)	P-value
Constant	25.10 (0.58)	<0.001	0.72 (0.40)	0.427	1.71 (0.54)	0.219
Comparison group ^a	-	<0.001	-	0.002	-	<0.001
OHE	0.13 (0.40)	<0.001	0.54 (0.28)	0.034	0.16 (0.34)	<0.001
OHE & FV	0.14 (0.39)	<0.001	0.39 (0.28)	0.001	0.17 (0.32)	<0.001
Household income	0.86 (0.15)	0.314	1.06 (0.12)	0.614	0.86 (0.14)	0.267

^aReference category

Table 5 – Description of Fluoride Varnish (FV) perceptions by caregivers

	Total n (%)	Kratié n (%)	Ratinakiri n (%)	P-value ^a
Total Number of respondents	3514	1937	1577	-
Recalls having FV placed	684 (19.5)	639 (33.0)	45 (2.9)	<0.001
Knows the reason for FV placement ^b	513 (75.0)	491 (76.8)	22 (48.9)	<0.001
States reason for FV as: ^b				
Prevent white spots	82 (12.0)	81 (12.7)	1 (2.2)	<0.001
Prevent cavities	290 (44.8)	289 (44.8)	4 (8.9)	<0.001
Stop cavities getting larger	23 (3.4)	19 (3.0)	4 (8.9)	<0.001
Reduce tooth sensitivity	24 (3.5)	22 (3.4)	2 (4.4)	<0.001
Antibacterial	259 (37.9)	246 (38.5)	13 (28.9)	<0.001
Other reason	10 (1.5)	10 (1.6)	0 (0.0)	<0.001
Unlikely to recommend FV for others ^b	116 (16.9)	106 (16.6)	10 (8.8)	0.037

Last vaccination given in health post setting	2915 (83.0)	1659 (85.7)	1256 (79.6)	<0.001
Purchased toothpaste for their child	2302 (65.5)	1401 (72.3)	901 (57.1)	<0.001
Happy to have FV placed by non-dental provider	3044 (86.6)	1758 (90.8)	1286 (81.5)	<0.001

^aP-value calculated using χ^2 test for differences among groups within the same row

^bproportions calculated as part of the sub group of participants who stated they recalled the fluoride varnish placement (N= 684)

Author Manuscript