

# Effectiveness of school-based strategies to prevent tooth decay in Filipino children: A cluster-randomized trial

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## Abstract

**Objectives:** Evidence for affordable and pragmatic programmes to address the burden of untreated tooth decay in children in low- and middle-income settings is limited. This study aimed to (1) assess the effect of a government-run, school-based daily group toothbrushing programme compared to standard school-based oral health education on the incidence of dental caries and odontogenic infections in Filipino children over a period of 3 years; and (2) assess the additional preventive effect of on-demand oral urgent treatment (OUT) and weekly fluoride gel application.

**Methods:** A cluster-randomized trial was conducted in Camiguin, Philippines. Schools in three regions were randomly assigned to one of three intervention groups: The Essential Health Care Programme (EHCP), which includes daily toothbrushing with fluoride toothpaste; EHCP plus twice-yearly access to on-demand urgent oral treatment (EHCP + OUT) and EHCP plus weekly application of high-concentrated fluoride gel (EHCP + Fluoride). Schools in a nearby province with a similar child population were selected as external concurrent control group. Clinical oral examinations were performed by calibrated dentists from a random sample of 682 seven-year-old students who were examined at baseline and over the following 3 years. Outcome variables were the number of decayed primary teeth, the number of decayed, missing and filled permanent teeth (DMFT) and surfaces (DMFS), and the number of permanent teeth with pulpal involvement, ulcerations, fistula or abscess (PUFA). Data were analysed using multilevel mixed-effects negative binomial regression.

**Results:** Three years after implementation, increments in dental caries and odontogenic infections in permanent teeth did not significantly differ between the EHCP and control group, yet the incidence of DMFT was lower by 22% in children receiving EHCP. Compared to controls, children receiving EHCP + Fluoride had a significantly lower increment of DMFT, DMFS and PUFA by 40%, 40% and 47%, respectively. Children receiving EHCP + OUT had lower incidence rates of DMFT and DMFS than control children by 23% and 28%, respectively. A lower incidence rate was also found for PUFA, but the effect was not statistically significant.

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**Conclusions:** Findings suggest that the weekly application of fluoride gel and urgent oral treatment, in addition to daily school-based toothbrushing with fluoride toothpaste, are realistic and effective strategies to lower the burden of dental caries in Filipino children. Implementation challenges may explain why no substantial caries-preventive benefits were demonstrated for school-based toothbrushing only. Intervention compliance should be considered in future programme implementation and evaluation research.

**KEYWORDS**

dental caries, fluoride, oral treatment, prevention, school health, toothbrushing

## 1 | INTRODUCTION

Filipino school children suffer from an alarmingly high burden of tooth decay that has been labelled as a “silent public health crisis.”<sup>1,2</sup> A national oral health survey revealed that 97% of 6-year-old children had dental caries with a mean of 8.4 affected teeth, and 85% had odontogenic infection.<sup>1</sup> High prevalence and severity of untreated tooth decay are common observations around the globe, particularly for children in low- and middle-income countries and deprived populations.<sup>3</sup> Unfortunately, the significant negative consequences of tooth decay on health, growth and quality of life of children often go unnoticed and simple preventive interventions are not prioritized.<sup>4–8</sup>

Even though schools have long served as a platform for public health interventions, there is no generally agreed model for oral health promotion and limited evidence is available for realistic approaches in low- and middle-income settings.<sup>9</sup> Due to the limited resource availability, the shortage of the oral health workforce and the overwhelming burden of disease, it is important to strengthen evidence for preventative interventions that are cost-effective and that can be applied within the existing education sector structures. Interventions requiring special training, costly supplies and equipment, or referral to a dental clinic are not realistic and will have limited population-wide impact over time since they can only reach a limited number of children. Instead, the World Health Organization (WHO) and FDI World Dental Federation recommend that oral health promotion efforts focus on increasing the availability and use of fluorides and providing oral care that matches community needs and available resources.<sup>10–13</sup> The caries-preventive benefits of fluorides have been well-established in the literature<sup>14</sup> and can be delivered through various forms, including fluoridation of water, salt or milk, the use of fluoride toothpaste or through application of gels or varnishes. In addition to prevention, access to basic emergency oral care and pain relief is required to address acute consequences of oral disease in populations.

The Philippine Department of Education (DepEd), with technical support from the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ), created the Essential Health Care Programme (EHCP) to address priority diseases of primary school students in the

Philippines, including tooth decay. Building on the Fit for School approach, EHCP integrates water, sanitation and hygiene interventions in primary schools, including the construction of handwashing facilities, the practice of daily group handwashing and toothbrushing and biannual deworming.<sup>15,16</sup>

The Fit for School Health Outcome Study (FITHOS) was undertaken by the Regional Office of the Department of Education, Health and Nutrition Unit, in Cagayan de Oro, Misamis Oriental, with technical and financial support by GIZ and international academic institutions. FITHOS is a longitudinal cohort study designed to strengthen evidence of the health impact of EHCP. The study protocol included an assessment of different approaches to addressing the burden of tooth decay in children, including daily group toothbrushing with fluoride toothpaste and additional access to on-demand oral urgent treatment (OUT) or weekly application of high-concentrated fluoride gel. Results of the FITHOS presented here were not part of the previous publication of the full methodology and 1-year results.<sup>17</sup>

The oral health-related objectives of the study were thus:

1. To assess the effect of school-based daily group toothbrushing with fluoride toothpaste compared to standard school-based oral health education on the development of dental caries and odontogenic infections in Filipino children over a period of 3 years.
2. To assess the additional preventive effect of on-demand oral urgent treatment and weekly fluoride gel application, in addition to daily group toothbrushing with fluoride toothpaste.

The hypotheses were that children receiving daily group toothbrushing with fluoride toothpaste as part of EHCP, and those receiving additional OUT or weekly application of fluoride gel, would have lower incidence of dental caries and odontogenic infections compared to children receiving standard oral health education. Compared to children receiving daily group toothbrushing with fluoride toothpaste only, it was hypothesized that children receiving additional OUT and those receiving additional weekly application of fluoride gel, would have lower incidence of odontogenic infections and a lower incidence of dental caries and odontogenic infections, respectively.

## 2 | METHODS

### 2.1 | Study design and sample

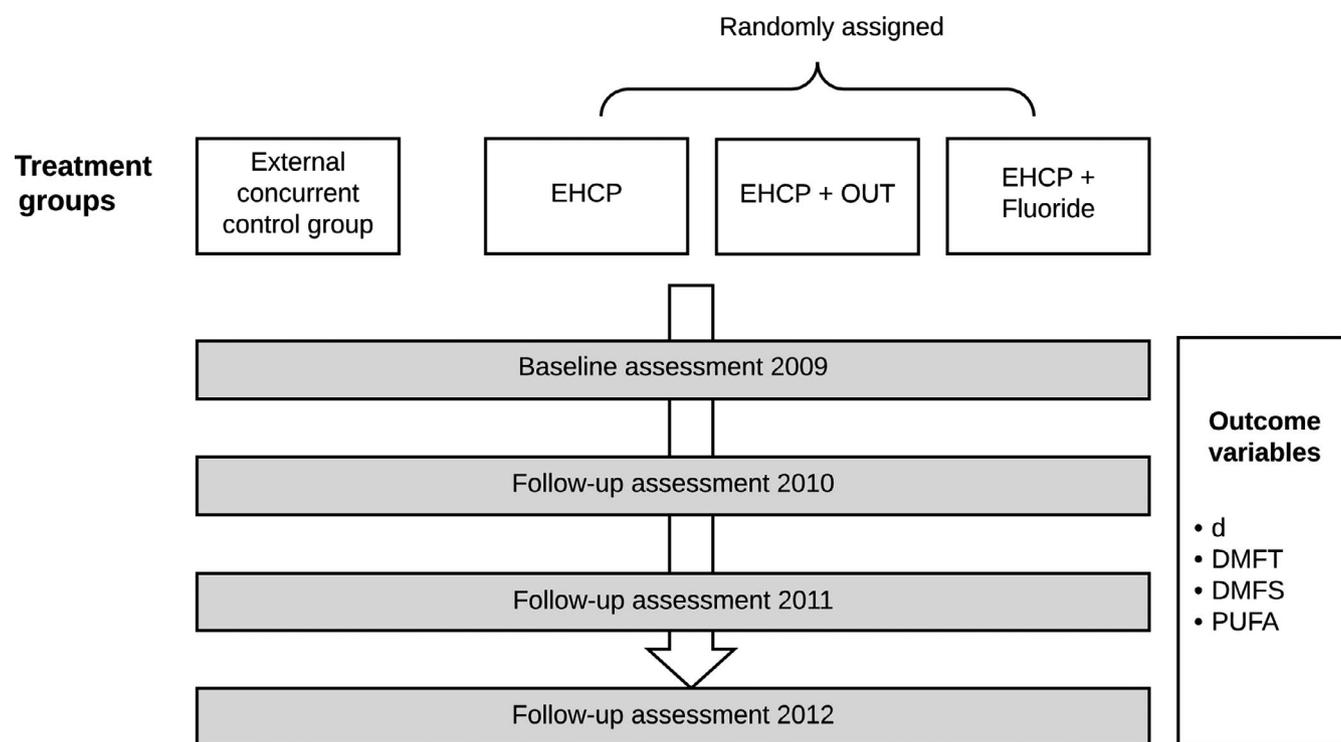
The Fit for School Health Outcome Study was a cluster-randomized trial conducted in the Philippines from 2009 to 2012 (Figure 1). The study was reviewed and approved by the Institutional Review Board of the Kinaadman Research Center (Xavier University, Cagayan de Oro, Philippines) and is registered with the German Clinical Trial Register DRKS (DRKS00003431) and the WHO (WHO Universal Trial Number U1111-1126-0718). Written consent was obtained from parents or caregivers for all children participating in the study. This study is reported in compliance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The general methodology, sampling procedure, sample size calculation and other study details are described in a previous publication.<sup>17</sup>

The study was conducted on the island province of Camiguin because of its comparably low migration rate and stable socio-economic indicators. Drinking water in the Philippines, including Camiguin, is not fluoridated; data from the National Oral Health Survey revealed that 99.2% of water samples present concentrations between 0.04 and 0.6 ppm, which is below the optimal fluoride concentration of 0.7 ppm in a subtropical climate.<sup>1</sup> The study consisted of three experimental groups and an external concurrent control group. Three regions in Camiguin (with a total of 56 schools on the Island) were randomly assigned to the three experimental

groups with simple randomization using three shuffled folded notes. No allocation of concealment method was used. From each region, a random selection of schools was drawn until at least 200 first-grade students could be included. Due to the local government's decision to implement EHCP in the entire province of Camiguin, a concurrent external control group without the EHCP programme was selected from Gingoog City (Northern Mindanao) on the nearby mainland, which had a similar child population in terms of socioeconomic characteristics. Inclusion criteria for the selection of public elementary schools for both experimental and control groups were as follows: school's location either along a highway or no more than one kilometre from a highway; no problems related to law and order in the surrounding community. In each school, baseline data were collected from a random sample of first-grade students aged 6–7 years in 2009, and data were collected in August–September of each following year until 2012.

The four study groups had the following characteristics:

1. Intervention group one (four schools,  $n = 160$  children) received the EHCP programme, consisting of daily supervised group handwashing with soap, daily supervised group toothbrushing with fluoride toothpaste (0.3 ml per usage, containing 1450 ppm fluoride), as well as biannual deworming with a single dose of albendazole.
2. Intervention group two (eight schools,  $n = 169$  children) consisted of EHCP with additional access to OUT (EHCP + OUT) as defined by the WHO, in which emergency oral care was offered twice



**FIGURE 1** Study design of the Fit for School Health Outcome Study. EHCP, Essential Health Care Programme; EHCP + Fluoride, Essential Health Care Programme + weekly application of fluoride gel; EHCP + OUT, Essential Health Care Programme + Oral Urgent Treatment

a year at each participating school for children suffering from toothaches due to advanced dental caries. These on-demand services included extractions, draining of abscesses and drug administration where required.

- Intervention group three (six schools,  $n = 192$  children) received EHCP with the addition of a high-concentrated fluoride gel once a week instead of the usual toothpaste regimen (EHCP + Fluoride). Fluoride gel (Elmex GelW, Gaba GmbH Lörrach, Germany; 0.3 ml per usage containing 12 500 ppm fluoride) was applied on the toothbrush, and children were instructed to brush for 2 min, after their normal group toothbrushing routine.
- The external control group (three schools,  $n = 161$  children) received a standard health education programme as defined by the Philippine DepEd, including a single commercial toothpaste sachet, a toothbrush and an instructional oral health message at the beginning of the school year. The standard health education programme is implemented on a national level in all public elementary schools in the Philippines, including the schools from the three experimental groups.

## 2.2 | Data and procedures

Oral examinations were performed by three calibrated dentists in a schoolyard or inside a classroom following the WHO Basic Methods for Oral Health Surveys 4th edition<sup>18</sup> and methods by Monse et al.<sup>19</sup> Demographic data collected for each participant included age, sex, participant grade, the number of siblings, and whether the child has a television at home. Additional information on examiner training and calibration and oral examination processes are available in a separate publication.<sup>17</sup>

Outcome variables were derived for the number of decayed primary teeth (d), the number of decayed, missing, and filled permanent teeth (DMFT) and the number of decayed, missing and filled tooth surfaces (DMFS),<sup>17</sup> as well as the total number of permanent teeth with pulpal involvement, ulcerations, fistula or abscess (PUFA).<sup>19</sup> Only cavitated dentin caries lesions were included in the d, DMFT and DMFS. Analysis of the primary dentition (d) was calculated using the total observed caries experience (TOCE): primary teeth with caries were maintained (analytically) through the duration of the study to avoid any bias due to exfoliation or extraction. For example, if a participant presented at baseline with untreated decay in a primary tooth, then the tooth would maintain its decay status throughout the duration of the study.<sup>20,21</sup> Carryover status was ignored when analysing permanent dentition. Examinations for each child were numbered sequentially. Any participant with missing age or with age that did not increase sequentially by visit was excluded from analysis.

The dentists performing the oral examinations were blind to the different groups. The authors conducting the statistical analyses were not blind. Patients, teachers and care providers could not be blinded.

## 2.3 | Statistical analyses

Incidence density was calculated at the group level for exposed and unexposed groups using the method of Broadbent and Thompson.<sup>22</sup> Incremental change in d, DMFT, DMFS and PUFA scores within subjects was analysed longitudinally using multilevel mixed-effects negative binomial regression. In addition to treatment groups, covariates were included for the per-visit change in the rate of each outcome and subject age at baseline. Models further included any potential confounders identified a priori as any covariates associated with treatment and dentition status and not influenced by either. These included sex, the number of siblings in the family and the presence of a television in the household that latter of which was used as a proxy measure of socioeconomic status. Following model estimation, coefficients were exponentiated to obtain incident rate ratios.

Prevented fractions (PFs) were calculated for DMFT, DMFS and PUFA according to methods by Gaguillo et al.<sup>23</sup> Differences in caries increment between intervention groups and the control group were considered clinically meaningful and clinically decisive if the PFs were between 11% and 20% (moderate effect) or above 20% (substantial effect). No intention-to-treat analyses were performed. The statistical analyses were conducted using Stata v14.0, with statistical significance set at 0.05.

## 3 | RESULTS

The study sample included a total of 682 children who completed all four examinations (follow-up rate from 2009 to 2012: 80.0%). The main reason for loss to follow-up was school drop-out (approximately 5%–7% per year) and families moving from the area to another village for income generation. Summary descriptive statistics are shown in Table 1. There were 328 males (48.1%), and the average age at baseline was 7 years across all experimental groups.

At baseline, the mean number of decayed primary teeth, DMFT, DMFS and PUFA at baseline was  $5.1 \pm 3.3$ ,  $0.7 \pm 1.0$ ,  $0.9 \pm 1.7$  and  $0.1 \pm 0.3$ , respectively. The caries prevalence at baseline was 96.8%, the care index was 0.2%. Figure 2 shows the mean d, DMFT, DMFS and PUFA at the four study points (2009, 2010, 2011 and 2012) per treatment group. Table 2 presents the incidence densities for study outcomes, showing the rate at which new events occur throughout the full study duration. A series of negative binomial regression models comparing treatment groups for each outcome at baseline indicated that there were significant differences in baseline oral health status for all four outcomes. Particularly children in the control group had higher d, DMFT, DMFS and PUFA at baseline than children in the experimental groups.

Longitudinal model results (Table 3) show that children receiving plain EHCP had lower increment of DMFT by 22% (IRR = 0.78, 95% CI = 0.60, 1.01) than the control group, but this was not significant at the 5% level. Increments of d, DMFS and PUFA did not statistically differ between the EHCP group and the control

TABLE 1 Baseline descriptive statistics by treatment group

	Overall	Control	EHCP	EHCP + OUT	EHCP + Fluoride
Total (n (%))	682 (100)	161 (23.6)	160 (23.5)	169 (24.8)	192 (28.2)
Males (n (%))	328 (48.1)	71 (44.1)	79 (49.4)	90 (53.3)	88 (45.8)
Age (mean $\pm$ SD)	7.0 $\pm$ 0.5	6.9 $\pm$ 0.5	7.0 $\pm$ 0.5	7.1 $\pm$ 0.5	7.0 $\pm$ 0.5
TV in household (n (%))	452 (66.3)	112 (69.6)	109 (68.1)	105 (62.1)	126 (65.6)
Number of siblings (mean $\pm$ SD)	3.2 $\pm$ 2.1	3.1 $\pm$ 1.9	3.3 $\pm$ 2.3	3.1 $\pm$ 2.1	3.2 $\pm$ 2.2

Abbreviation: EHCP, Essential Health Care Programme; EHCP + Fluoride, Essential Health Care Programme +weekly application of fluoride gel; EHCP + OUT, Essential Health Care Programme + Oral Urgent Treatment.

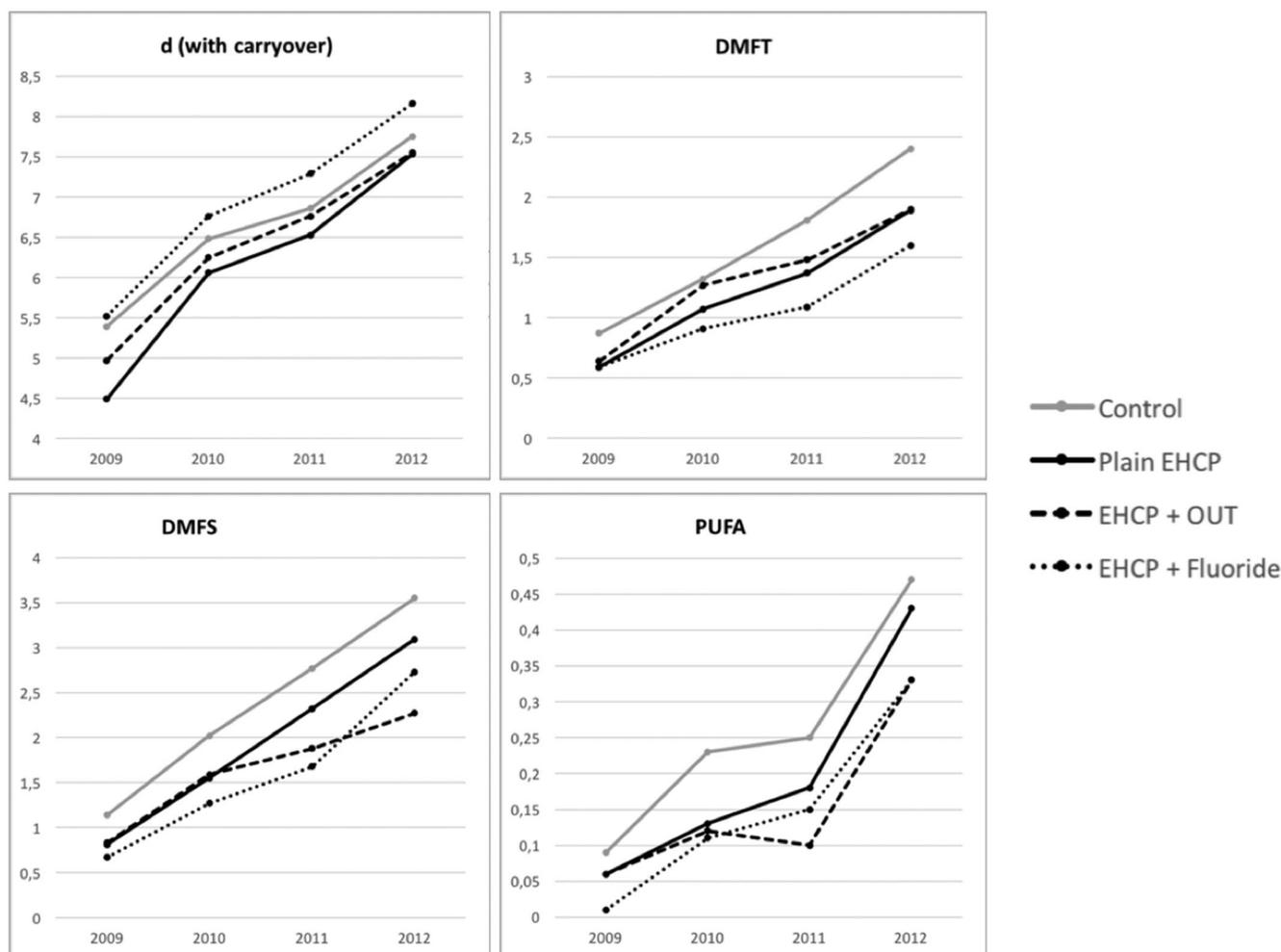


FIGURE 2 Mean d (with carryover), DMFT, DMFS and PUFA in 2009, 2010, 2011 and 2012 by treatment group. EHCP, Essential Health Care Programme; EHCP + Fluoride, Essential Health Care Programme +weekly application of fluoride gel; EHCP + OUT, Essential Health Care Programme + Oral Urgent Treatment

group. Compared to controls, children receiving EHCP + Fluoride had significantly lower increments of DMFT, DMFS and PUFA by 40% (IRR = 0.60, 95% CI = 0.47, 0.77), 40% (IRR = 0.60, 95% CI = 0.44, 0.83) and 47% (IRR = 0.53, 95% CI = 0.29, 0.90), respectively, after adjusting for confounders. Children receiving OUT in addition to EHCP also had lower incidence rates of incremental DMFT and DMFS by 23% (IRR = 0.77, 95% CI = 0.59, 0.99) and

28% (IRR = 0.72, 95% CI = 0.52, 0.99), respectively, than controls. Lower incidence rates were also found for PUFA by 46% (IRR = 0.54, 95% CI = 0.29, 1.03), but effects were not statistically significant. No significant differences in d were found for plain EHCP, EHCP + Fluoride, EHCP + OUT compared to standard care. As expected, the incidence rates of d, DMFT, DMFS and PUFA all increased with age. The participants' sex, the number of siblings

	d density	DMFT density	DMFS density	PUFA density
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
Control	1.63 ± 0.8	0.39 ± 0.4	0.57 ± 0.6	0.5 ± 0.9
EHCP	1.46 ± 0.8	0.41 ± 0.3	0.70 ± 0.7	0.4 ± 0.8
EHCP + OUT	1.63 ± 0.8	0.39 ± 0.4	0.57 ± 0.6	0.3 ± 0.8
EHCP + Fluoride	1.46 ± 0.8	0.31 ± 0.3	0.59 ± 0.7	0.3 ± 0.7

TABLE 2 Incidence densities for d, DMFT, DMFS and PUFA by treatment group

Abbreviation: EHCP, Essential Health Care Programme; EHCP + Fluoride, Essential Health Care Programme +weekly application of fluoride gel; EHCP + OUT, Essential Health Care Programme + Oral Urgent Treatment.

TABLE 3 Models for the increment in d (with carryover), DMFT, DMFS and PUFA with treatment × time interaction

Variables	(1)	(2)	(3)	(4)
	d	DMFT	DMFS	PUFA
Plain EHCP versus Control <sup>a</sup>	0.96 (0.84–1.09)	0.78*** (0.60–1.01)	0.82 (0.59–1.14)	0.85 (0.46–1.56)
EHCP + OUT versus Control <sup>a</sup>	0.98 (0.86–1.12)	0.77*** (0.59–0.99)	0.72*** (0.52–0.99)	0.54*** (0.29–1.03)
EHCP + Fluoride versus Control <sup>a</sup>	1.09 (0.96–1.23)	0.60*** (0.47–0.77)	0.60*** (0.44–0.83)	0.53*** (0.29–0.99)
Constant	14.29*** (7.34–27.82)	0.01*** (0.00–0.06)	0.01*** (0.00–0.04)	0.00*** (0.00–0.00)
Observations	2610	2610	2610	2610
Number of id	682	682	682	682

Note: Negative binomial regression. Coefficients are Incidence Risk Ratios (IRR). 95% CI in parentheses.

Abbreviation: EHCP, Essential Health Care Programme; EHCP + Fluoride, Essential Health Care Programme +weekly application of fluoride gel; EHCP + OUT, Essential Health Care Programme + Oral Urgent Treatment.

<sup>a</sup>Adjusted for visit, age at baseline, sex, number of siblings, household television.

\*\*\* $p < .01$ ; \*\* $p < .05$ ; \* $p < .1$ .

TABLE 4 Prevented fractions<sup>a</sup> for DMFT, DMFS and PUFA by treatment group

Treatment group	DMFT	DMFS	PUFA
	%	%	%
EHCP	9.3	8.0	-3.31
EHCP + OUT	9.1	6.7	35.3
EHCP + Fluoride	28.6	19.7	25.9

Abbreviation: EHCP, Essential Health Care Programme; EHCP + Fluoride, Essential Health Care Programme +weekly application of fluoride gel; EHCP + OUT, Essential Health Care Programme + Oral Urgent Treatment.

<sup>a</sup>Formula: (3-year increment in DMFT, DMFS or PUFA in the control group - 3-year increment in DMFT, DMFS or PUFA in the experimental group)/3-year increment in DMFT, DMFS or PUFA in the control group × 100%.

and whether they lived in a household with a television were not significantly associated with d, DMFT, DMFS or PUFA.

Mainly positive preventive fractions PFs were found in all three experimental groups, indicating that the crude 3-year increment in

DMFT, DMFS and PUFA was lower in the experimental groups than the control group (Table 4). For the EHCP + Fluoride intervention compared to care as usual, the preventive effect was substantial for DMFT and PUFA and moderate for DMFS. For the EHCP + OUT intervention, a substantial preventive effect was found for PUFA.

## 4 | DISCUSSION

This study investigated school-based strategies to prevent dental caries in a high-risk child population in the Philippines. The interventions studied, namely toothbrushing with fluoride toothpaste, weekly application of fluoride gel and on-demand oral urgent care, are all supported by strong evidence from controlled clinical studies.<sup>14,24,25</sup> Still, public health research is crucial to evaluate the effectiveness of such interventions when implemented at population or community levels under real-life circumstances, particularly in low- and middle-income settings where the disease burden is high, resources are scarce and workforce capacity is limited. In the current study, interventions were implemented in an unsupported

government-run school programme, which provided such a real-life setting. The findings of this research help to understand which interventions can be applied and translated into realistic oral health promotion strategies in high-risk populations and contributes to the evidence base for informed policy decisions.

This study showed clear caries-inhibiting benefits of a weekly use of a high-concentrated fluoride gel in addition to daily school-based toothbrushing, significantly reducing the incidence of decayed permanent teeth, decayed permanent surfaces and pulpally involved permanent teeth after 3 years by 40%, 40% and 47%, respectively. A Cochrane review confirmed the clinical effectiveness of fluoride gels, including the absence of adverse health effects from accidentally swallowing the gel.<sup>25</sup> High-concentrated fluoride gel does not require professional intervention, but can safely be applied by children from 6 years onwards under supervision of a school teacher at low costs. These findings highlight that the use of fluoride gels in schools offers a realistic and potentially cost-effective approach to promote child oral health, which can be implemented at meaningful scale.

Findings also suggest that the additional provision of on-demand emergency oral treatment for children suffering from toothache due to advanced dental caries may contribute to a reduction in the number of permanent teeth with dental caries or odontogenic infections. In the Philippines, around 80% of children suffer from dental infection.<sup>1</sup> The toothache that follows on is often severe, resulting in lost time from school, poor school performance and decreased quality of life.<sup>26-28</sup> Since children often have limited access to oral health care, priority should be given to ensuring basic, essential services for the most urgent oral health needs of schoolchildren. Such services, involving mainly dental extractions, can be delivered by a trained dental nurse,<sup>29</sup> thereby providing a realistic solution for low-resource settings.

Children receiving school-based toothbrushing only had a 22% lower rate of DMFT in children receiving EHCP compared to standard care, which was significant at the 10% level, but not at the 5% level. No impact was found on DMFS and PUFA. Other studies across various countries reported positive impacts of school-based daily toothbrushing with fluoride toothpaste on children's caries experience.<sup>30-33</sup> A cohort study similar to the FITHOS was conducted to evaluate the health impacts of the EHCP programme (implemented as the "Fit for School" programme) in elementary schools in Cambodia, Indonesia and Lao PDR.<sup>16</sup> Findings showed a 24% reduction in the number of decayed permanent teeth (PF ranging from 18% to 38% among the three participating countries), which confirms the findings of a Cochrane meta-analysis of the caries-preventive benefits of fluoride toothpaste.<sup>34</sup> Conversely, evidence for the effectiveness of educational approaches to produce sustained oral health improvements is very weak, particularly when solely focused on knowledge provision and toothbrushing instructions.<sup>35</sup>

There are several factors that may explain why this study found only small reductions in dental caries in the permanent teeth by school-based toothbrushing alone. First, the quality of programme implementation may have played an important role; notably,

implementation was supervised by school teachers, not by dedicated project team members. Poor compliance to the protocol limits the ability of potentially effective interventions to reach their full potential. Although data on implementation quality were not available in this study, challenges with intervention compliance are common barriers to effective school-based hygiene interventions.<sup>36</sup> First-year findings of the FITHOS were promising, showing lower caries incidence in the EHCP group compared to the control group, although this finding was not statistically significant.<sup>17</sup> It is probable that engagement after the first year and intervention compliance deteriorated, as no monitoring system was in place to control for adherence to the protocol. Hence, institutional compliance with intervention protocols may be a crucial confounding factor that should be considered in future programme implementation, long-term management and evaluation research.

Second, it is plausible that this study may not have been able to demonstrate substantial impact due to some methodological limitations. Although the experimental arms were randomly assigned, randomization of the control group was not possible based on the local government decision to implement EHCP in the entire province of Camiguin. Despite efforts to select an external concurrent control group from another province based on similar socioeconomic and health characteristics, there were significant baseline differences in caries status between children in the control arm versus the experimental arms. These baseline differences did not allow true comparison of the interventions' effect relative to the control group. Furthermore, these differences suggest that there may have been important confounding factors, such as socioeconomic status, hygiene and dietary factors, that were unequally distributed among the experimental and control groups. Attempts were made to minimize these effects by analysing caries outcomes as the increment between baseline and study completion and by adjusting for potential confounders, such as television ownership, age and sex. Bias from potentially selective drop-out was probably minimal, since the 3-year follow-up rate was high. However, no intention-to-treat analyses were performed, and therefore, selection bias cannot be completely discarded.

School-based toothbrushing remains one of the few realistic public health strategies in low- and middle-income settings known to deliver positive oral health benefits. The results of this study, demonstrating reductions in dental caries but not significant, reinforce calls for regular monitoring of implementation quality, commitment and capacity of school staff and governance under the education sector's leadership for school-based toothbrushing to be effectively implemented. Notably, the Philippine Department of Education has recently required including supervision of daily hygiene activities at school (e.g., handwashing and toothbrushing) in teacher's job descriptions; complemented by developing a water, sanitation and hygiene (WASH) policy; implementing guidelines for teacher training; and ensuring budget allocations are made for hygiene supplies (e.g., soap and fluoride toothpaste). A monitoring system was also put in place to institutionalize responsibility of hygiene activities within public schools nationwide.

In conclusion, this study showed clear caries-inhibiting effects of the weekly application of high-concentrated fluoride gel, in addition to daily school-based toothbrushing with fluoride toothpaste, providing evidence that this is a potentially viable strategy to reduce the incidence of tooth decay and odontogenic infection in permanent teeth of Filipino children. Furthermore, the provision of on-demand urgent oral treatment shows to be a realistic and essential service in schools to lower the burden of dental caries in children. This study did not demonstrate significant caries-preventive benefits of school-based toothbrushing only versus standard health education, which may be due to implementation challenges. Findings of this study have been instrumental to advocate with decision makers to re-direct the limited resources for oral health care towards locally determined effective interventions that are focused on increasing the use of fluorides and providing urgent oral care for the most frequent needs of children, using the school as a health-promoting setting. This is an essential approach to address the "silent public health crisis" of dental caries in low- and middle-income settings.

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#### CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

#### AUTHOR CONTRIBUTIONS

BM, EN and HB conceptualized the study. BM and EN were the principal investigators. BM, EN, GSI and SM supported the data collection in the field. RRR and DD performed the statistical data analysis and contributed to writing the paper. RRR, BM, DD, GSI, SM, EN and HB contributed to the critical interpretation of the data. DD drafted the first version of the paper and was involved in conceptualizing the study and data interpretation. All authors gave their final approval and agree to be accountable for all aspects of the work.

#### DATA AVAILABILITY STATEMENT

The data sets analysed during the current study are available from the corresponding author on reasonable request.

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#### REFERENCES

1. Monse B, Benzian H, Araojo J, et al. A silent public health crisis: untreated caries and dental infections among 6- and 12-year-old children in the Philippine National Oral Health Survey 2006. *Asia Pac J Public Health*. 2015;27(2):2316-2325.
2. Benjamin RM. Oral health: the silent epidemic. *Public Health Rep*. 2010;125(2):158-159.
3. Global Burden of Disease 2017 Oral Disorders Collaborators, Bernabe E, Marcenes W, et al. Global, regional, and national levels and trends in burden of oral conditions from 1990 to 2017: A systematic analysis for the Global Burden of Disease 2017 study. *J Dent Res*. 2020;99(4):362-373.
4. Sheiham A. Dental caries affects body weight, growth and quality of life in pre-school children. *Br Dent J*. 2006;201(10):625-626.
5. Krisdapong S, Prasertsom P, Rattananangsim K, Sheiham A. School absence due to toothache associated with sociodemographic factors, dental caries status, and oral health-related quality of life in 12- and 15-year-old Thai children. *J Public Health Dent*. 2013;73(4):321-328.
6. Mota-Veloso I, Soares ME, Alencar BM, Marques LS, Ramos-Jorge ML, Ramos-Jorge J. Impact of untreated dental caries and its clinical consequences on the oral health-related quality of life of schoolchildren aged 8–10 years. *Qual Life Res*. 2016;25(1):193-199.
7. Praveen BH, Prathibha B, Reddy PP, Monica M, Samba A, Rajesh R. Correlation between PUFA index and oral health related quality of life of a rural population in India: a cross-sectional Study. *J Clin Diagn Res*. 2015;9(1):39-42.
8. Dimaisip-Nabuab J, Duijster D, Benzian H, et al. Nutritional status, dental caries and tooth eruption in children: a longitudinal study in Cambodia, Indonesia and Lao PDR. *BMC Pediatr*. 2018;18(1):300.
9. van Palenstein Helderma W, Holmgren C, Monse B, Benzian H. Caries prevention and control in low- and middle-income countries. In: Fejerskov O, Nyvad B, Kidd E, eds. *Dental Caries: The Disease and its Clinical Management*. Wiley-Blackwell; 2015:405.
10. Petersen PE, Lennon MA. Effective use of fluorides for the prevention of dental caries in the 21st century: the WHO approach. *Community Dent Oral Epidemiol*. 2004;32:319-321.
11. van Palenstein Helderma W, Benzian H. Implementation of a Basic Package of Oral Care: towards a reorientation of dental NGOs and their volunteers. *Int Dent J*. 2006;56(1):44-48.
12. Petersen PE. World Health Organization global policy for improvement of oral health – World Health Assembly 2007. *Int Dent J*. 2008;58:115-121.
13. FDI World Dental Federation. Promoting oral health through fluoride: Adopted by the FDI General Assembly: August 2017, Madrid, Spain. *Int Dent J*. 2018;68(1):16-17.
14. Walsh T, Worthington HV, Glenny AM, Marinho VC, Jeroncio A. Fluoride toothpastes of different concentrations for preventing dental caries. *Cochrane Database Syst Rev*. 2019;3:CD007868.
15. Monse B, Naliponguit E, Belizario V, Benzian H, van Helderma WP. Essential health care package for children—the 'Fit for School' program in the Philippines. *Int Dent J*. 2010;60(2):85-93.
16. Duijster D, Monse B, Dimaisip-Nabuab J, et al. 'Fit for school'—a school-based water, sanitation and hygiene programme to improve child health: results from a longitudinal study in Cambodia, Indonesia and Lao PDR. *BMC Public Health*. 2017;17(1):302.
17. Monse B, Benzian H, Naliponguit E, Belizario V, Schratz A, van Palenstein Helderma W. The Fit for School Health Outcome Study - a longitudinal survey to assess health impacts of an integrated school health programme in the Philippines. *BMC Public Health*. 2013;21(13):256.
18. World Health Organization. *Oral Health Surveys Basic Methods*. 4th ed. WHO; 1997.

19. Monse B, Heinrich-Weltzien R, Benzian H, Holmgren C, van Palenstein Helderman W. PUFA – an index of clinical consequences of untreated dental caries. *Community Dent Oral Epidemiol.* 2010;38:77-82.
20. Ruff RR. Total observed caries experience: assessing the effectiveness of community-based caries prevention. *J Public Health Dent.* 2018;78(4):287-290.
21. Hummel R, Akveld NAE, Bruers JJM, van der Sanden WJM, Su N, van der Heijden GJMG. Caries progression rates revisited: a systematic review. *J Dent Res.* 2019;98:746-754.
22. Broadbent JM, Thomson WM. For debate: problems with the DMF index pertinent to dental caries data analysis. *Community Dent Oral Epidemiol.* 2005;33:400-409.
23. Gargiullo PM, Rothenberg RB, Wilson HG. Confidence intervals, hypothesis tests, and sample sizes for the prevented fraction in cross-sectional studies. *Stat Med.* 1995;14:51-72.
24. Frencken JE, Holmgren C, van Palenstein Helderman W. Basic Package of Oral Care. 2002. Accessed August 22, 2019. <http://www.chdentalinstitute.org/images/bpoc.pdf>
25. Marinho VC, Worthington HV, Walsh T, Chong LY. Fluoride gels for preventing dental caries in children and adolescents. *Cochrane Database Syst Rev.* 2015;6:CD002280.
26. Jackson SL, Vann WF, Kotch JB, Pahel BT, Lee JY. Impact of poor oral health on children's school attendance and performance. *Am J Public Health.* 2011;101(10):1900-1906.
27. Piovesan C, Antunes JLF, Mendes FM, Guedes RS, Ardenghi TM. Influence of children's oral health-related quality of life on school performance and school absenteeism. *J Public Health Dent.* 2012;72(2):156-163.
28. Seirawan H, Faust S, Mulligan R. The impact of oral health on the academic performance of disadvantaged children. *Am J Public Health.* 2012;102(9):1729-1734.
29. Watt RG, Daly B, Allison P, et al. Ending the neglect of global oral health: time for radical action. *Lancet.* 2019;394:261-272.
30. Rong WS, Bian JY, Wang WJ, Wang JD. Effectiveness of an oral health education and caries prevention program in kindergartens in China. *Community Dent Oral Epidemiol.* 2003;31(6):412-416.
31. Al-Jundi SH, Hammad M, Alwaeli H. The efficacy of a school-based caries preventive program: a 4-year study. *Int J Dent Hygiene.* 2006;4(1):30-34.
32. Macpherson LM, Anopa Y, Conway DI, McMahon AD. National supervised toothbrushing program and dental decay in Scotland. *J Dent Res.* 2013;92(2):109-113.
33. Da Silva AM, Hedge S, Akudo Nwagbara B, et al. Community-based population-level interventions for promoting child oral health. *Cochrane Database Syst Rev.* 2016;9:CD009837.
34. Marinho V, Higgins J, Logan S, Sheiham A. Topical fluoride (tooth-pastes, mouthrinses, gels or varnishes) for preventing dental caries in children and adolescents. *Cochrane Database Syst Rev.* 2003;4:CD002782.
35. Stein C, Santos NML, Hilgert JB, Hugo FN. Effectiveness of oral health education on oral hygiene and dental caries in schoolchildren: systematic review and meta-analysis. *Community Dent Oral Epidemiol.* 2017;46(1):30-37.
36. Garn JV, Trinies V, Toubkiss J, Freeman MC. The role of adherence on the impact of a school-based water, sanitation, and hygiene intervention in Mali. *Am J Trop Med Hygiene.* 2017;96(4):984-993.

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