

# EFFECTIVENESS OF SCHOOL-BASED FLUORIDE MOUTH RINSING PROGRAM IN SCHOOLCHILDREN FROM KANDY DISTRICT, SRI LANKA

Chandra Herath<sup>1a</sup>, Tharanga Nandasena<sup>2b</sup>, Kaung Myat Thwin<sup>3c</sup>, Anushka Abeysundara<sup>2d</sup>, Sampath Ratnayake<sup>4e</sup>, Hiroshi Ogawa<sup>3f</sup>, Hideo Miyazaki<sup>3,5g</sup>, Takeyasu Maeda<sup>6h</sup>

<sup>1</sup>Department of Community Dentistry, Faculty of Dental Sciences, University of Peradeniya, Peradeniya, Sri Lanka

<sup>2</sup>Department of Basic Science, Faculty of Dental Sciences, University of Peradeniya, Peradeniya, Sri Lanka

<sup>3</sup>Division of Preventive Dentistry, Department of Oral Health Science, Graduate School of Medical and Dental Sciences, Niigata University, Niigata, Japan

<sup>4</sup>Army Hospital, Sri Lanka Army, Sri Lanka

<sup>5</sup>Department of Dental Hygiene and Welfare, Meirin Junior College, Niigata, Japan

<sup>6</sup>Faculty of Dentistry, Graduate School of Medical and Dental Sciences, Niigata University, Niigata, Japan

<sup>a</sup>BDS, MD, Professor; e-mail: chk1719@yahoo.com; ORCIDiD: <https://orcid.org/0000-0002-6570-3343>

<sup>b</sup>BDS, PhD, Professor; e-mail: bgthn@yahoo.com; ORCIDiD: <https://orcid.org/0000-0002-7712-8761>

<sup>c</sup>BDS, PhD, FICD, Assistant Professor; e-mail: kaung@dent.niigata-u.ac.jp; ORCIDiD: <https://orcid.org/0000-0003-0350-7977>

<sup>d</sup>BSc, Senior Technical Officer; e-mail: anushkap12@yahoo.com; ORCIDiD: <https://orcid.org/0000-0002-0267-6106>

<sup>e</sup>BDS, MSc, Doctor; e-mail: sampathratnayake@yahoo.com; ORCIDiD: <https://orcid.org/0000-0001-8396-7302>

<sup>f</sup>DDS, MDS, PhD, Professor; e-mail: ogahpre@dent.niigata-u.ac.jp; ORCIDiD: <https://orcid.org/0000-0003-1070-2172>

<sup>g</sup>DDS, PhD, Professor; e-mail: hideomiy@dent.niigata-u.ac.jp; ORCIDiD: <https://orcid.org/0000-0003-4032-9655>

<sup>h</sup>DDS, PhD, Professor; e-mail: maedat@dent.niigata-u.ac.jp; ORCIDiD: <https://orcid.org/0000-0001-5317-7510>

## ABSTRACT

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**Introduction** Dental caries is still epidemic and a significant public health problem in developing countries. No research on a fluoride mouth rinsing program has been conducted in Sri Lanka yet. Therefore, the purpose of this study was to evaluate the effectiveness of a supervised school-based 0.2% sodium fluoride mouth rinsing program among 6 year-old Sri Lanka school children.

**Material and Methods** This study was conducted on 415 school children from the Yatinuwara educational zone of the Kandy district, Sri Lanka from January 2011 to January 2014. The children were allocated into two groups by adjusting their socio-demographic background and the fluoride level in drinking water at school level; Group 1 received 0.2% sodium fluoride mouth rinses weekly, and Group 2 was the control group. A clinical oral examination and oral health education were performed at baseline and annual follow-ups.

**Results** At the baseline, the mean age of school children in the intervention group and the control group were  $6.17 \pm 0.41$  years and  $6.08 \pm 0.50$  years, respectively. Almost all of the children (>90%) used fluoride toothpaste in both groups. After the fluoride mouth rinsing program, the intervention group (77.8%) showed higher caries free proportion than the control group (63.1%), although no statistically significant difference occurred. The mean DMFT and DMFS indices in the intervention group were significantly lower than those in the control group.

**Conclusion** The school-based fluoride mouth rinsing program indicated a significant tendency of preventing future caries incidence among children with permanent dentition.

## KEYWORDS

Fluoride Mouth Rinsing; Dental Caries; 6 Year-Old; Schoolchildren; Sri Lanka.

## 1. INTRODUCTION

Dental caries is still epidemic and a significant public health problem in many developing countries [1].

Sri Lanka is one of developing countries in South Asia, and the children's oral health is in poor condition [2-4]. According to the 2015-16 National Oral Health Survey, the prevalence of dental caries in

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**\*Corresponding author:** Dr. Kaung Myat Thwin, BDS, PhD, FICD, Assistant Professor, Division of Preventive Dentistry, Department of Oral Health Science, Graduate School of Medical and Dental Sciences, Niigata University; 2-5274, Gakkocho-dori, Chuo-ku, Niigata 951-8514, Japan;

Tel: +81-25-227-2858; Fax: +81-25-227-0807;

e-mail: kaung@dent.niigata-u.ac.jp

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5 year-old children was 63.1%, and the prevalence of untreated active caries was 60.7%. Out of 5-year-olds who had experienced dental caries, 96.2% of them had active caries. Further more, as early as the age of 5-6 years old, some children already had caries on their newly erupted permanent teeth [5]. It is considered as a significant public health problem in Sri Lankan children. It has become a burden not only to the bearers and their families but also to the country [6]. Moreover, it has a great impact on the health policy makers [7]. This increasing burden might be mainly due to the increased rate of sugar consumption and inadequate exposure to fluoride [7-9]. In a region of Sri Lanka, the fluoride levels in water bases showed a great variation from less than 0.05 to 5 ppm [10]. These are very high altitude areas that are exposed to heavy rain throughout the year, and showed very low fluoride levels in drinking water, namely 0.05 to 0.001 ppm. It is the area where our study sample originated. Only 14.7% of the Sri Lankan population get the desired level of fluoride concentration of around 1mg/L through natural drinking water supplies [11]. The evidence-based preventive methods such as topical fluoride applications, fluoride mouth rinsing, diet modifications and good oral hygiene practices are widely used for public caries prevention [2,12]. Daily use of fluoride toothpaste and school-based fluoride mouth rinse programs are recommended to control dental caries in children and adolescents, especially for communities in low fluoridated areas [13]. According to oral health report of the World Health Organization (2013), a reduction in level of caries can be achieved through a joint action of the community, professionals and individuals [14]. The weekly use of fluoride mouth rinse is practiced as a group activity at community levels because it is safe and effective [15]. The effect of fluoride mouth rinses on the incidence of dental caries in children has been extensively investigated, and its effectiveness has been demonstrated for 15%-45% in reducing dental caries over a period of 2-5 years [15-18].

The Ministry of Health, Nutrition and Indigenous Medicine, Sri Lanka has started school dental services since 1953. The school dental therapists of the primary health care team had the main responsibility to provide preventive oriented oral health services for schoolchildren aged 3-13 years old [19]. However, no research on fluoride mouth rinsing program has been conducted in Sri Lanka yet. Therefore, the purpose of this study was to evaluate the effectiveness of the School-based Fluoride Mouth Rinsing (S-FMR) program among 6 year old Sri Lankan schoolchildren.

## 2. MATERIALS AND METHODS

### 2.1. Study population

This study was carried out in the Yatinuwara educational zone of the Kandy district, Sri Lanka

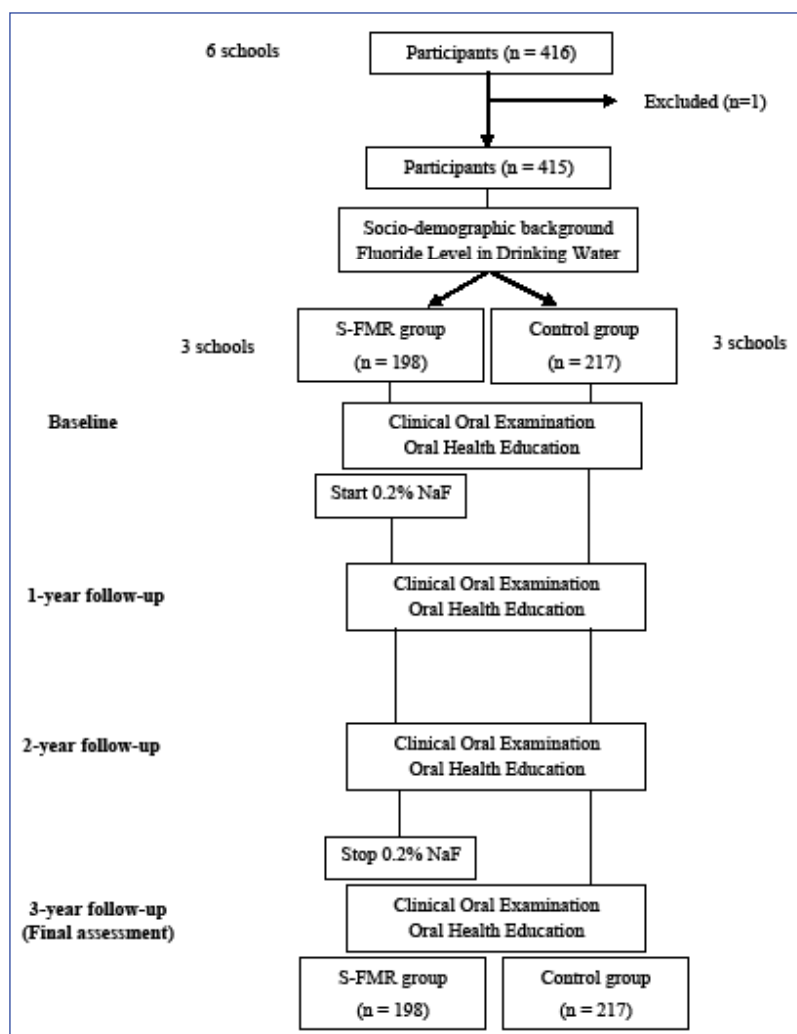
from January 2011 to January 2014. The six schools came from urban, semi-urban and rural areas and were randomly selected based on the probability proportional to size sampling method. Via the school authorities, an elaborative explanation on the background, objectives, methods and significance of the study was presented to children aged 6 years and to their parents or guardians gathered in large forums. Following the explanation, the written consent was obtained from the schools, participating children and their parents or guardians. The S-FMR program started with a total of 415 schoolchildren in the study (Fig. 1). During the 3 years of fluoride mouth rinsing program, there was no drop out since none of the participants moved to any other school, or quit the school during the period. Although there were a number of additional entries to the schools, they were not included in the statistical analysis and so the final number of children who completed the study was 415.

### 2.2. Study setting

Basic socio-demographic information (gender, age, school category, frequency of tooth brushing, usage of tooth paste with fluoride, frequency of intake of sweet food, parents who brush children teeth, income of the family, father's and mother's education levels, and knowledge on factors that influence tooth decay) of schoolchildren were taken at the baseline. Fluoride concentrations were estimated in the sources of drinking water (deep wells, tube wells, streams, and running tap water) of each student participating in the study and the mean fluoride level was 0.078 ppm. There were no significant differences in the fluoride level among the six schools. The participants were instructed and obliged to use fluoridated tooth paste at the baseline and the annual follow-ups. Various types of fluoridated toothpastes are available in local market, which is imported brands as well as locally manufactured brands. The available fluoridated toothpastes in Sri Lanka usually contain 850 - 1000 µg/gF in soluble form. Further more, parents and children were methodically educated on oral health including frequency of tooth brushing, usage of tooth paste with fluoride, frequency of intake of sweet food, parents' involvement during tooth brushing, the knowledge of factors that influence tooth decay, information about nutrition intake and eating habits at the baseline of the study and then annually in order to minimize the different confounding factors and adjust the socio-demographic factors in the sample. The children of the six schools were divided into two groups by adjusting their socio-demographic background and fluoride level in drinking water at school level (which applied a comparison design):: an intervention group (FMR) and a control group.

### 2.3. Clinical oral examination

All the clinical oral examinations were performed by



**Figure 1.** Flow chart of the study design. n: number of participants, NaF: Sodium Fluoride, S-FMR: School-based Fluoride Mouth Rinse program.

two trained examiners. The calibration of the two dentists whom trained by a public health expert using gold standard. Linear weighted Kappa values for intra-examiner and inter-examiner variability were 0.85 and 0.80, respectively. A clinical oral examination was conducted to assess dentition status at the baseline and annual follow-ups based on WHO criteria for dental caries [20]. The schoolchildren were examined using plane mouth mirrors and metallic periodontal probes under good day light to record Decayed (D), Missing (M) and Filled (F) teeth. The findings were recorded using the DMFT index and DMFS index. If at the point the examiners noted the total of 'zero' DMFT/DMFS in clinical oral examination, it defined as "caries free".

#### 2.4. Fluoride Mouth Rinsing

0.2% sodium fluoride (NaF) 900 ppmF (Wako Product Number 196-01975, USA) was used for the intervention in this study. The children were trained for mouth rinsing using normal water for three months to avoid the swallowing of fluoride solution. After obtaining the standard practice without swallowing and leaving solutions in cups, the prepared 0.2% NaF solutions were provided weekly to the schools by investigators.

A teacher was allocated to distribute fluoride solution to each class in each school. The class teacher distributed the plastic cups containing 10 ml of fluoride solution to participating children according to the schedule. Children rinsed for a minute according to the teacher's instructions. The class teachers directly supervised the mouth rinsing program and maintained the records for three years. The final assessment of caries risk was done to evaluate the effectiveness of the program in January 2014. The control group was also intervened as 'placebo' and so they performed regular mouth rinse activity with drinking water. Furthermore, they were repeatedly and annually educated on oral health including the frequency of tooth brushing, usage of tooth paste with fluoride, frequency of intake of sweet food, parents' involvement during tooth brushing knowledge on factors that influence tooth decay, information about nutrition intake and eating habits.

#### 2.5. Statistical analysis

The expected outcome of the study was that the mean DMFT and DMFS in the intervention group would be at a lower value than the control group after the weekly exposure to fluoride mouth rinsing.

**Table 1.** Socio-demographic background at baseline between two groups.

	FMR, n=198 n (%)	Control, n=217 n (%)
<b>Gender</b>		
Male	101 (51.0)	111 (51.2)
Female	97 (49.0)	106 (48.8)
<b>Location</b>		
Urban	70 (35.4)	83 (38.3)
Sub-urban	100 (50.5)	109 (50.2)
Rural	28 (14.1)	25 (11.5)
<b>Father's education level</b>		
University level	28 (14.1)	45 (20.8)
High school level	125 (63.2)	122 (56.2)
Below high school level	45 (22.7)	50 (23.0)
<b>Mother's education level</b>		
University level	29 (14.6)	40 (18.4)
High school level	134 (67.7)	148 (68.2)
Below high school level	35 (17.7)	29 (13.4)
<b>Family's income</b>		
High (> Rs. 20000)	23 (11.3)	29 (13.4)
Middle (Rs. 10000 – 20000)	72 (36.9)	59 (29.2)
Low (< Rs. 10000)	103 (51.8)	129 (57.4)
<b>Frequency of tooth brushing</b>		
Once a day	27 (13.6)	34 (15.7)
Twice a day	151 (76.3)	155 (71.4)
Three times and above a day	20 (10.1)	28 (12.9)
<b>Use of fluoride toothpaste</b>		
Yes	185 (93.4)	201 (92.6)
No	3 (1.5)	5 (2.3)
Don't know	10 (5.1)	11 (5.1)

FMR: Fluoride Mouth Rinse, n: number of participants, Family income: average monthly income of the Kandy district, 1 US \$ = Rs. 100, by X2 test ( $p < 0.05$ )

Therefore, the variables of study were exposure and no exposure of six year-old schoolchildren to 0.2% fluoride mouth rinse for three years and DMFT level and DMFS level in permanent dentition.

A statistical analysis was carried out using the statistical software SPSS 23.0 (SPSS, Chicago, IL, USA). Chi-square, independent t-test and ANOVA tests were performed between the mean differences between the intervention group and the control group at the baseline and the annual follow-ups. The level of statistical significance for all tests was set at  $p < 0.05$ .

#### 2.6. Ethical approval

The study design was approved by the Research Committee and Ethical Review committee of the Faculty of Dental Sciences, University of Peradeniya, Sri Lanka (Ethical clearance No. FDS-RERC/2009/13/Herath2). The study permission was also obtained

from the Zonal Education Authority of Kandy District, Central Province of Sri Lanka.

### 3. RESULTS

Four hundred and sixteen schoolchildren at age 6 were initially recruited for the study. However, one child was excluded from the study due to the absence of the consent form. Therefore, 415 schoolchildren were finally included in the study. Out of them, 198 children (male: 101, female: 97) were recruited for the intervention group and 217 children (male: 111, female: 106) for the control group. As shown in Figure 1, their socio-demographic background and fluoride level in drinking water were adjusted in both groups. Then, the intervention group was introduced to 0.2% NaF mouth rinse under the supervision of school teachers for consecutive three years. There were no dropouts from the study during the study. Although

**Table 2.** Percentage of caries free school children in the FMR and control groups.

Visits	FMR, n=198 n (%)	Control, n=217 n (%)
Baseline	178 (89.9)	205 (94.5)
1 <sup>th</sup> visit	165 (83.3)	194 (89.4)
2 <sup>nd</sup> visit	149 (75.3)	143 (65.9)
3 <sup>rd</sup> visit	154 (77.8)	137 (63.1)

FMR: Fluoride Mouth Rinse, n: number of participants, by independent t-test ( $p < 0.05$ )

there was a number of additional lateral entries to the S-FMR program, they were not included into the study. During the three years of the program, a clinical oral examination and oral health education (basic knowledge about dental diseases and oral hygiene care) were performed in both groups annually. The socio-demographic background of the study population at the baseline between the two groups is summarized in Table 1.

At the baseline, the mean ages of schoolchildren in the FMR group and the control group were  $6.17 \pm 0.41$  years and  $6.08 \pm 0.50$  years, respectively. There were no significant differences in mean age, proportions of male and female, and other socio-demographic data between the two groups. Over 75% of students in both groups show that their parents have above high school level education; 77.3% (father) and 72.3% (mother) in the FMR group and 77.0% (father) and 86.6% (mother) in the control group. However, the family income for the majority of the students shows low level in both groups.

All schoolchildren brushed their teeth at least once a day. Yet, the frequency of tooth brushing twice a day was 76.3% in the FMR group and 71.4% in the control group, which is the standard and recommended practice. Almost all schoolchildren (>90%) used fluoride toothpaste in both groups. The results of the percentage of caries-free in the FMR and control groups for consecutive four visits are shown in Table 2. The percentage of caries-free schoolchildren was calculated with permanent dentitions; if DMFT is equal to zero, this child was considered as a caries-free. No significant differences were observed in proportion of caries-free in both groups during the program. The caries-free level in the FMR group, which was less comparative to the control at the baseline and 1<sup>st</sup> visit, was higher than the control group since the 2<sup>nd</sup> visit. When compared after the FMR program, the intervention group (77.8%) shows higher percentage of caries-free than the control (63.1%). Table 3 shows the comparison of the FMR and the control groups based on DMFT and DMFS. At the baseline, the DMFT index in FMR and control groups were  $0.03 \pm 0.22$  and  $0.11 \pm 0.47$ , where the

DMFS level in the FMR and control groups were  $0.04 \pm 0.31$  and  $0.13 \pm 0.54$ , respectively. There were no significant differences in mean DMFT and DMFS between the two groups at the baseline and 1<sup>st</sup> visit. The mean number of DMFT and DMFS in the FMR group was significantly lower than that in the control group at the 2<sup>nd</sup> visit and 3<sup>rd</sup> visit.

As within groups, the mean DMFT and DMFS were significantly increased from baseline to the 3<sup>rd</sup> visit in the FMR group. In the control group, there was no significant difference from baseline to the 1<sup>st</sup> visit whereas there were significant differences during the 2<sup>nd</sup> and 3<sup>rd</sup> visits.

#### 4. DISCUSSION

Dental caries caused by multi-etiological factors is largely preventable with evidence-based preventive methods. However, the prevalence of dental caries among children has risen in developing countries in recent years because there are very frail preventive care projects compared with developed countries. Beside the increased burden of dental caries in Sri Lanka, the evidence-based fluoride mouth rinsing program in school has not been implemented yet. This is the first intervention study to evaluate the anti-caries effect of school based fluoride mouth rinsing (S-FMR) program among 6 years old Sri Lankan schoolchildren. The present study included 6 year-old 198 schoolchildren in the S-FMR program and 217 children who did not receive any fluoride application.

Table 2 included the timely caries-free status of permanent dentition in schoolchildren of both groups. The FMR group showed less reduction of the caries-free proportion than the control group, although there were no statistical differences between the two groups during the program. A higher proportion (77.8%) of the children in the FMR group remained caries-free at the end of the study compared to the control group (63.1%). This implies that the caries level in the FMR group was 22.2% and 36.9% in the control group. Furthermore, it is less than the reported prevalence of dental caries for 12 year-old Sri Lankan population which is 30.4% and the Kandy district population which is 35% [5].

Even though the present study did not carry out the computation of percentage reduction of dental caries due to S-FMR program, when compared with the results of a systematic review [22], it showed a comparable level of caries reduction which would be observed in permanent dentition ranging from 15% to 67%. When compared to the study carried out in Sarawak which was 24.2% [11], the caries-free percentage was very high in the present study as 77.8%. At the baseline, the mean DMFT and DMFS values in both groups were not statistically significant due to adjusting nearly equal recruitment of schoolchildren into the study from urban, semi-urban and rural areas. Moreover, they all were



**Table 3.** Mean number of DMFT and DMFS in two groups.

	DMFT (SD)		p-value	DMFS (SD)		p-value
	FMR	Control		FMR	Control	
<b>Baseline</b>	0.03 (0.22)	0.11 (0.47)	<b>0.965</b>	0.04 (0.31)	0.13 (0.54)	<b>0.992</b>
1 <sup>st</sup> Visit	0.32 (0.74)*	0.19 (0.62)	<b>0.067</b>	0.40 (0.96)*	0.26 (0.92)	<b>0.191</b>
2 <sup>nd</sup> Visit	0.44 (0.83)*	0.76 (1.01)*	<b>0.03</b>	0.54 (1.06)*	1.06 (1.48)*	<b>0.04</b>
3 <sup>rd</sup> Visit	0.64 (0.89)*	0.90 (1.02)*	<b>0.07</b>	0.85 (1.25)*	1.32 (1.61)*	<b>0.07</b>

FMR: Fluoride Mouth Rinse, n: number of participants, DMFT: decayed, missing, and filled permanent teeth, DMFS: decayed, missing, and filled permanent tooth surfaces, SD: Standard Deviation.

Mean values within each row are analyzed by using ANOVA test ( $p < 0.05$ ), NS: statistically not significant.

Mean values within each column are analyzed by using one way repeated ANOVA test ( $p < 0.05$ ), (\*): statistically significant.

from geographically comparable background, which reported to have very low fluoride level in the natural drinking water (0.078 ppmF) [11]. The previous studies also recommended that school based fluoride mouth rinsing should be implemented in areas of fluoride-deficient communities [10,21]. Furthermore, a study on a school based fluoride mouth rinsing program in Japan concluded that community-oriented health measure should be contributed to caries prevention of the permanent teeth in areas where water fluoridation is not available [22]. According to the National Oral Health Survey in 2015-16 [5], the FMR group in this study even though showed a similar DMFT level with 12-year-old Sri Lankan population which was 0.6 (1.6) it rather less than the Kandy district population (0.8). Furthermore, when compared to the study carried out in Sarawak [10], the DMFT value at the end of the program was significantly less. The mean DMFT and DMFS were significantly decreased in the FMR group than in the control group during the 2<sup>nd</sup> and 3<sup>rd</sup> visits, respectively.

This finding supported the previous studies which were performed in several communities [10,24,25]. In accordance with our findings, the present study demonstrated that weekly use of 0.2% NaF (900 ppm F) has a significant caries-preventive effect in children. Therefore, the S-FMR programs are regarded as a highly effective caries-preventive strategy. A previous systematic review concluded that supervised regular use of fluoride mouth rinse in daily or weekly or fortnightly basis with 0.05% NaF (230 ppm F) or 0.2% NaF (900 ppm F) in children and adolescents could achieve a satisfactory caries reduction in tooth surfaces [25]. On the other hand, Jagan et al reported that the effectiveness of fluoride mouth rinse with low concentration (0.05% NaF) is not significant on caries reduction [26].

Furthermore, its effectiveness is said to be more significant in caries prevention with the early introduction of fluoride mouth rinses to children [22]. In this study, children aged 6 years participated in the S-FMR program, as they are the age group that start to attend primary schools. The previous studies concluded that fluoride mouth rinsing programs should start at a younger age, and

continue up to the age of 12 years in order for more children to remain caries-free through their school years [25]. The measurements for FMR uses among preschoolchildren were performed in Japan, and reported FMR could be performed by preschoolchildren safely and efficiently [22]. This suggests that the S-FMR program should start at a younger age, such as the preschool period to further enhance the impact of the caries-preventive effects. In this study, basic knowledge of oral hygiene care such as the use of fluoridated toothpaste with correct tooth brushing was delivered via the oral health education in both groups during the follow-up visits. Low levels of oral health knowledge will hinder the sound understanding of oral health care, and result in a poor oral health outcome [27].

The previous review studies reported that daily use of fluoridated toothpaste had a significant caries-preventive effect in children [12,28,29]. The oral health situation would be enhanced by a combination of the S-FMR program together with provision of oral health education for further impressive results.

The limitation of this study includes the assignment of subjects to test and control groups which was known to the examiners (not performed to single or double blind), which is common to studies. Further, the diagnostic criteria applied are based on those stated by WHO (1997), in which the initial lesions (white spots) are not considered. In consequence, there may be under-registration. Nevertheless, this study could provide useful information about school-based weekly fluoride mouth rinsing programs in fluoride-deficient areas.

The positive benefit of weekly sodium fluoride mouth rinses on caries reduction would be a major population-based strategy to improve the oral health situation in Sri Lankan children. In addition, to get the maximum impact on caries prevention, the school-based fluoride mouth rinsing program could be combined with other additional preventive activities including reinforced use of fluoride toothpaste and supervised tooth brushing through oral health education to parents, guardians, school teachers as well as schoolchildren to further caries reduction.

## 5. CONCLUSION

Based on the findings of this study, we have found evidence that weekly 0.2% NaF mouth rinse had a significant tendency of preventing future caries incidence among children in permanent dentition.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

## AUTHOR CONTRIBUTIONS

CH: Proposal writing, program organizing, clinical examination, DMFT calculation, manuscript writing; TN: Concept, data gathering and recording DMFT calculation, data entry, manuscript writing;

KT: Data analysis, manuscript writing, critical review of manuscript; AA: Mouth wash preparation, mouthwash distribution, data recording, data entry; SR: Clinical examination, DMFT calculation, data recording, data entry; HO: Data analysis, manuscript writing, critical review of manuscript; HM: Concept, protocol, proposal writing, data analysis, critical review of manuscript; TM: Concept, protocol, critical review of manuscript.

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## Chandra HERATH

BDS, MS (Rest), FDS (Paed), RCS (Eng), Professor  
 Department of Community Dentistry  
 Faculty of Dental Sciences  
 University of Peradeniya  
 Peradeniya, Sri Lanka



## CV

Chandra Herath, is a Professor in Paedodontics. She joined the Faculty of Dental Sciences, University of Peradeniya, Sri Lanka in 1997 and obtained her Fellowship in Paediatric Dentistry from the Royal College of Surgeons, England in 2003. She has published over 15 research papers in local and international journals. She is the President elect of the Association of Specialists in Restorative Dentistry, Sri Lanka and the Joint Secretary of the South Asian Academy of Paediatric Dentistry. Her research interests are related to early childhood caries, dental trauma, developmental anomalies of teeth and children with special health care needs. She has immensely contributed to upgrading Paediatric Dentistry in Sri Lanka by developing undergraduate and postgraduate curricula, conducting workshops and delivering lectures for health care professionals and the general public.

## Questions

**1. Which of the following method is more cost-effective to the developing country to carry out the school-based study to prevent dental caries?**

- a. Water fluoridation method;
- b. Use of fluoride mouth rinses;
- c. Use of fluoride toothpastes;
- d. Milk fluoridation method.

**2. What is the effect of fluoride on teeth?**

- a. Demineralize the enamel;
- b. Discolor the enamel;
- c. Remineralize the enamel;
- d. No effect on enamel.

**3. What is the optimal level of fluoride in the fluoride mouth rinses to be used once a week?**

- a. 100-300 ppm;
- b. 300-500 ppm;
- c. 800-1000 ppm;
- d. > 1500 ppm.

**4. What is not an advantage of fluoride mouth rinsing program in school?**

- a. Cost effective;
- b. Time consuming;
- c. Can practice at community level;
- d. Less attention by participants.