Effect of a School-Based Supervised Tooth Brushing Program In Mexico City: A Cluster Randomized Intervention

S Aída Borges-Yáñez*/ Roberto Carlos Castrejón-Pérez**/ María Esther Irigoyen Camacho***

Large-scale school-based programs effectively provide health education and preventive strategies. SaludARTE is a school-based program, including supervised tooth brushing, implemented in 51 elementary schools in Mexico City. ***Objectives****: To assess the three-month efficacy of supervised tooth brushing in reducing dental plaque, gingival inflammation, and bleeding on probing in schoolchildren participating in SaludARTE.* ***Study Design****: This was a pragmatic cluster randomized intervention, with two parallel branches. Four randomly selected schools participating in SaludARTE (n=200) and one control school, which did not participate in the program (CG) (n=50), were assessed. Clusters were not randomly allocated to intervention. The main outcomes were as follows: mean percentage gingival units with no inflammation, dental surfaces with no dental plaque, and gingival margins with no bleeding. The independent variable was supervised tooth brushing at school once a day after a meal. Guardians and children responded to a questionnaire on sociodemographic and oral hygiene practices, and children were examined dentally. Mean percentage differences were compared (baseline and follow-up).* ***Results****: A total of 75% of guardians from the intervention group (IG) and 77% from the CG answered the questionnaire. Of these, 89.3% were women, with a mean age of 36.9±8.5 years. No differences in sociodemographic variables were observed between groups, and 151 children from the IG and 35 from the CG were examined at baseline and follow-up. Mean percentage differences for plaque-free surfaces (8.8±28.5%) and healthy gingival units (23.3%±23.2%) were significantly higher in the IG.* ***Conclusion****: The school-supervised tooth brushing program is effective in improving oral hygiene and had a greater impact on plaque and gingivitis than on gingival bleeding. It is necessary to reinforce the oral health education component of the program.*

Key words*: tooth brushing, school program, gingival bleeding, dental plaque, oral health education.*

INTRODUCTION

Adequate oral health depends on establishing significant tooth brushing routines to prevent gingivitis and dental caries and controlling the consumption of sugared foods. Elementary schools are a potential target for these interventions to support children in developing healthy behaviors in an independent manner. [1] [2] Large-scale school-based programs are effective for reducing preventable diseases through cost-effective interventions. An example is the "*Fit for School*" program, which promotes hand washing and daily tooth brushing. [3] Previous school-based prevention programs have shown a reduction in the prevalence of gingivitis [4] and gingival bleeding in 3- to 12-month periods.[2-8] A systematic review found a reduction in plaque (32%) and gingival bleeding in nearly every investigation. [9]

The prevalence and severity of caries in Mexican children has decreased; however, it is necessary to support preventive actions at the school level. [10] In 2013, the Secretariat of Public Education and the Government of Mexico City in Mexico implemented the *SaludARTE* program in 83 primary schools in marginalized areas in Mexico City. The program promotes self-care and artistic and civic expression through supplementary education. After school, children

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receive healthy meals, nutritional counseling to prevent obesity, and health education, and perform general and oral hygiene practices (supervised tooth brushing) and physical and cultural activities from Monday to Friday for three hours daily.

The purpose of this investigation was to assess the short-term (three-months) efficacy of supervised tooth brushing for reducing dental plaque, gingival inflammation, and gingival bleeding in schoolchildren participating in the *SaludARTE* program during the academic year 2013-2014 and to compare them with children from a school that was not participating in the program.

MATERIALS AND METHOD

The study was a pragmatic cluster randomized intervention with a parallel design with two arms. There were two study populations, 13000 children aged six to 13 years old from 51 public elementary schools in 15 districts in Mexico City participating in the S*aludARTE* program during the academic year 2013-2014 (intervention group), and 2100 children aged six to 13 years old from six public elementary schools in one district in Mexico City that was not participating in the *SaludARTE* program (control group).

Inclusion criteria for the IG were as follows: children, whose parents or guardians signed an informed consent, 6-13 years old, participating in *SaludARTE*.

Exclusion criteria for the IG were as follows: children who attended the schools participating in the *SaludARTE* program but were not participating in the program, and children with systemic diseases or wearing orthodontic appliances.

Inclusion criteria for the CG were as follows: children, whose parents or guardians signed an informed consent, 6-13 years old, not attending a *SaludARTE* school.

Exclusion criteria for the CG were as follows: children with systemic diseases or wearing orthodontic appliances.

Elimination criteria were as follows: children who stopped participating in the program (IG), those who did not agree to participate in the second evaluation, or those who did not attend classes on the days of the clinical evaluation.

Sample size was calculated based on a test for two means in a repeated measures design. [11] Group sample sizes of 169 and 35 achieve 80% power to detect a mean difference of 0.20 gingival units with no inflammation between the two groups in a design with two repeated measurements and an alpha level of 0.050. A dropout rate of 20% was expected, and the sample sizes were increased to 200 children in the intervention group and 50 in the control group.

The sampling unit was the school, and four schools were randomly selected in the intervention group (sampling frame = 51 schools participating in *SaludARTE*). One school not participating in *SaludARTE* was selected among six public schools (2100 children) from one district in Mexico City participating in the "Bright Smiles Bright Futures" program sponsored by Colgate™. The clusters were not randomly allocated to the intervention. The sample size for each school was 50 children. Schools were the units of randomization, and children were the units of analysis. The intervention occurred at a cluster level.

Authorization to perform the investigation was requested from the authorities of the selected schools in both groups. The *SaludARTE* coordinators, teachers, parents or guardians, and children from both groups were informed about the purpose of the study. Informed consent forms and questionnaires were delivered to the persons responsible for the children. The children who agreed to participate and whose parents or guardians signed the informed consent form were interviewed and examined at school at baseline and 12 weeks later. After the second clinical evaluation, the parents or guardians received a written oral health diagnosis of their children. Figure 1 shows the flow chart of the study.

The independent variable was the supervised tooth brushing (Bass tooth brushing technique) performed at school once a day for two minutes after a meal with fluoridated toothpaste (*Colgate Máxima Protección Anticaries MFP*™ with sodium monofluorophosphate 0.76%) and a child extra-soft bristles toothbrush.

The following information was obtained from a questionnaire answered by the guardian: the child's gender and age; the guardian's age, marital status, educational level, occupation, and their relationship to the child; the child's social security; the frequency of the child's daily tooth brushing at home (does not brush / once before going to school / once before going to sleep / once at any time / twice / three or more); the child's tooth brushing at home at night; the person who brushes the child's teeth; and the child's utilization of dental services in the previous 12 months. The children were interviewed at school, and the following variables were included: self-perception of oral health, frequency of daily tooth brushing at home, tooth brushing before going to bed, tooth brushing before going to school, tooth brushing supervised by an adult, and toothache in the past twelve months. The questionnaires were tested for internal consistency, and the questionnaire for guardians had a Cronbach's Alpha Value of 0.9148 (50 items). The questionnaire for children had a Cronbach's Alpha Value of 0.4978 (17 items).

Dependent variables

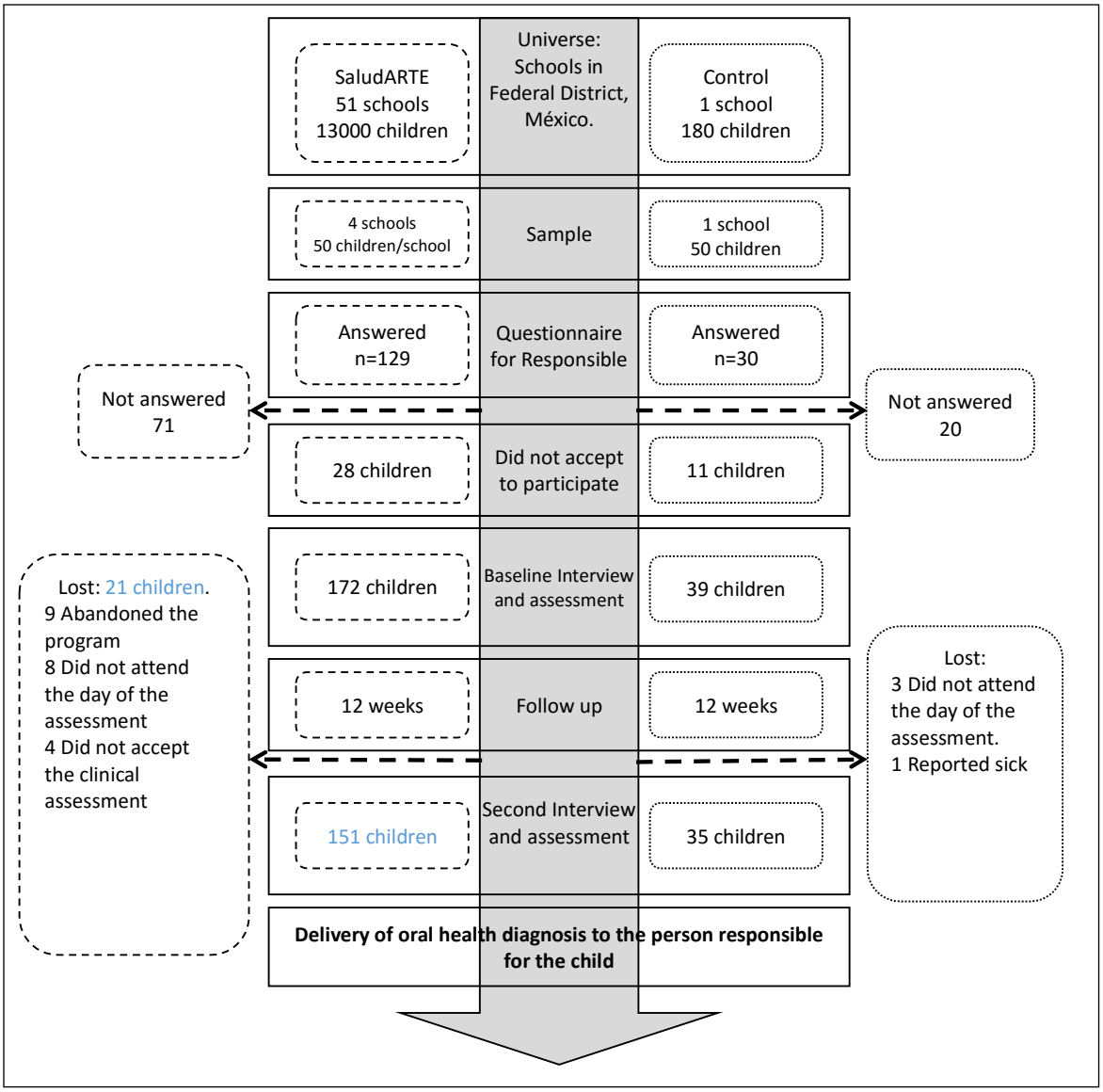
The main outcomes were the mean percentage of surfaces with no dental plaque, mean gingival units with no inflammation, and mean gingival margins with no bleeding.

Dental plaque: Soft deposits covering the four surfaces of all teeth were assessed using the Green and Vermillion criteria (percentage of surfaces without dental plaque, percentage of surfaces with dental plaque covering up to one-third, covering between 1/3 and 2/3, and covering more than 2/3 of the surface). [12]

Gingivitis: Gingival inflammation of the vestibular and lingual surfaces of the gingival margins and interdental papilla of completely erupted teeth (gingival unit) was assessed using the Modified Lobene Gingival Index (percentage of gingival areas with absence of inflammation / localized mild inflammation / generalized mild inflammation / moderate inflammation / severe inflammation). [13]

Marginal gingival bleeding: Bleeding in the gingival crevice, measured according to the Gingival Marginal Bleeding Index, [14] was evaluated using the World Health Organization periodontal probe inserted two millimeters into the gingival margin and displaced along the crevice in six areas of the teeth. After 30 seconds, the highest score for each tooth was recorded (percentage of teeth with no bleeding, marginal bleeding in one site, or excessive marginal bleeding).

Figure 1. Flowchart of the study



Intervention

The Mexican Dental Association Foundation (FADM) proposed the inclusion of a dental tooth brushing program to the education authorities in Mexico City. The program was designed and implemented in all *SaludARTE* schools by the FADM.

After the children finished their meal, the supervisor from *SaludARTE* delivered personalized child toothbrushes, provided fluoridated toothpaste, and supervised the activity. Tooth brushing was performed for two minutes; thereafter, the toothbrushes were collected and stored in containers. The complete tooth brushing activities lasted ten minutes. Teachers and supervisors from *SaludARTE* were trained by FADM staff and taught the children the tooth brushing technique. Due to the short amount of time assigned for this activity, oral health education was offered sporadically during the workshops on food, nutrition, and hygiene habits. A supervisor conducted surveillance visits to all the schools participating in *SaludARTE*.

Control Group

Children from the CG received one lecture about tooth brushing and other caries prevention methods.

Clinical evaluation for the IG was performed after mealtime at school in a separate room, because the CG was performed during school hours. None of the children brushed their teeth before the dental examination. The examination was performed with the child resting on a table and the examiner sitting on his/her head side. [15] A headlamp, a #5 reflection dental mirror and a PCP11.5 probe (HU-Friedy™ Chicago, IL, USA) were used to assess plaque and gingival bleeding. Infection control barriers were used.

Three standardized Dental Surgeons performed the clinical evaluation, and the kappa values were as follows: 0.90 for dental plaque, 0.85 for gingivitis, and 0.90 for gingival bleeding. A pilot test was performed in one school not participating in the investigation.

The examiners were not blinded due to the ongoing activities conducted in *SaludARTE* during the examinations. The control group was examined in the mornings or afternoons and

the intervention group was only examined during the afternoons. However, the statistical analysis was blinded. The persons supervising and performing the tooth brushing program at the schools did not know which schools were selected.

When dental problems requiring immediate care were identified, a written note describing the issue and instructions to request attention at the Dental School, Universidad Nacional Autónoma de México (UNAM) was sent to the person responsible for the child. The Ethics and Research Committee of the Dental School, UNAM, approved the research protocol (CIE/03/19/03/2014). The research was conducted in full accordance with the World Medical Association Declaration of Helsinki.

Statistical Analysis

Results are presented at the individual level. The distributions of dental plaque, gingival inflammation, and marginal bleeding were compared at baseline between the groups (Mann-Whitney test). To determine whether there were differences between the groups after 12 weeks, the mean percentage differences were compared with parametric (T-test) and non-parametric tests (Mann-Whitney test) for all categories of the outcome variables in both groups with a significance level of 0.05. [16]

Data were analyzed at the patient level. To account for the clustering effect, intracluster correlation coefficients (ICC) were estimated. The ICC is a measure of the similarity of clustered data, which is the product of dividing the within-cluster variance by the sum of the within-cluster and between-cluster variances.[17] The design effect $(1 + (n - 1)\rho)$ [16] was estimated with the ICC (ρ) and the mean size of the cluster (n). To calculate P-values, statistics based on the t-test were divided by the square root of the design effect. If the clustering effect is not accounted for, the P-values will be misleadingly excessive. [18]

RESULTS

At baseline, the questionnaire was completed by 129 (75%) parents/guardians of the children from the intervention group, and 30 (77%) from the control group. In addition, 211 children (172 in the IG and 39 in the CG) were interviewed and underwent dental examinations. At follow-up, 186 children (151 from the intervention group and 35 from the control group) were evaluated (Fig. 1).

The distribution of the children by cluster was as follows: for each of the four schools participating in *SaludARTE*, there were 46, 42, 40, and 44 children who agreed to participate (mean=43, SD=2.6) and were examined at baseline. At follow-up, 45, 28, 39, and 39 children were examined (mean=38, SD=7.1). In the control group, 39 children were examined at baseline, and 35 at follow-up.

The mean age of the parents and guardians was 36.9±8.5 years, with no differences between the groups (p=0.49). The percentage of women was 89.3% (n=142). The distribution by sex was similar in both groups (p=0.89). No differences were found in the distribution by marital status; 76.8% were married or living in cohabitation (p=0.95). Most guardians were mothers (84.5%), followed by fathers (7.7%) (p=0.72). The proportion of guardians who completed secondary or high school education was 79.9% (p=0.19). The most common occupation was domestic work (54.8%) (p=0.49). Although the percentage of children who had access to social security services was only 31.1%, 33.8% of the children were declared to be affiliated to "Popular Insurance" (p=0.30) (Table 1).

No differences in the distribution of the guardians' responses about the tooth brushing practices of their children were observed. Tooth brushing at home twice a day was reported by 59.7%, 11% brushed once a day (before going to school), 13% brushed once a day before going to bed, 10.4% brushed once a day (at any time), and 5.2% three or more times a day. Only 1 person reported that the child did not brush (0.6%) (p=0.28). Approximately 78.1% of the children brushed their teeth at night before going to bed (p=0.41). Twenty six percent of guardians supervised the child while they were brushing (p=0.35). Furthermore, 60.5% of the children had used dental services in the previous twelve months (Table 2).

At baseline, 38.9% of the children were males, with similar distributions in both groups (p=0.76). The mean age was 8.8±1.8 years (p=0.73). Almost half the children (45.5%) reported good or very good self-perception of oral health (p=0.52). However, 10% of the children declared that they frequently suffered toothaches (p=0.74) (Table 3).

At follow-up, 186 children were interviewed and examined, and there was an 11.8% nonresponse rate (12.2% IG, 10.3% CG) (Fig. 1). The distribution by sex was similar between the groups, and 45.7% in the control group and 39.2% in the intervention group were males (p=0.47).

Efficacy of the Program

At baseline, the mean percentages of surfaces free of dental plaque were 58.8%±18.8% in the control group and 50.1%±24.7% in the intervention group (p=0.10). The overall mean percentage of surfaces with plaque covering up to 1/3 was 36.2%±15.9% and was similar in both groups (p=0.21). No differences were observed in the mean percentages of surfaces with plaque (overall=10.9%±12.9%) covering between 1/3 and 2/3 (p=0.28) and of surfaces with plaque covering more than 2/3 (overall= 1.2%±4.1%) (p=0.06) (Fig. 2).

The mean percentages of units without gingivitis was 65.4%±15.8% in the control group and 58.7%±23.1% in the intervention group (p=0.17). No significant differences were observed in the mean percentages of gingival units with mild localized gingivitis (overall mean percentage = 36.2%±19.3%) (p=0.34), mild generalized gingivitis (overall mean percentage= 3.6%±6.7%) (p=0.47), moderate gingivitis (overall mean percentage=0.22%±1.3%) (p=0.59), and severe gingivitis (overall mean percentage= 0.008%±0.11%) (p=0.17) between the groups (Fig. 3).

There were no differences in the distribution of marginal bleeding between the groups in the three categories. The overall mean percentage of gingival margins with no bleeding was 49.1%±22.1% (p=0.56), bleeding at one site was 46.3%±18.4% (p=0.47), and excessive bleeding was 4.6%±9.3% (p=0.76) (Fig. 4).

After 12 weeks, the mean percentage of surfaces free of plaque decreased in the control group (-8.2±24.3%) and increased in the intervention group (8.8±28.5%) (p=0.007). Significant differences in the mean percentage of surfaces with plaque covering up to 1/3 were observed between the control group (6.9%±20.1%) and the intervention group (-1.1%±22.9%) (p=0.031). The mean percentage of surfaces with plaque covering between 1/3 and 2/3 increased in the control group (0.55%±8.9%) and decreased in the intervention group (-6.7%±12.9%) (p=0.006). The mean percentage of surfaces with plaque covering ≥2/3 was 0.65%±1.5% in the control group and -0.99%±4.2% in the intervention group (p=0.02) (Fig. 5).

Table 1. Distribution of sociodemographic variables of parents or guardians of children and child's social security by study group. *SaludARTE* schools and control school, Federal District, México 2014.

Variables		Group						
		Control		*SaludARTE*		Total		p
		n	%	n	%	n	%	
Gender	Male	3	10.0%	14	10.9%	17	10.7%	.89
	Female	27	90.0%	115	89.1%	142	89.3%	
	Total	30	100%	129	100%	159	100%	
Marital Status	Single	2	7.4%	10	8.7%	12	8.5%	.95
	Married or cohabiting	21	77.8%	88	76.5%	109	76.8%	
	Widowed	2	7.4%	6	5.2%	8	5.6%	
	Divorced or separated	2	7.4%	11	9.6%	13	9.2%	
	Total	27	100%	115	100%	142	100%	
Relationship to the child	Mother	25	86.2%	106	84.1%	131	84.5%	.72
	Father	3	10.3%	9	7.1%	12	7.7%	
	Grandmother	1	3.4%	6	4.8%	7	4.5%	
	Other (uncles/aunts, siblings)	0	0.0%	5	4.0%	5	3.2%	
	Total	29	100%	126	100%	155	100%	
Education	Knows how to read or incomplete elementary school	5	18.5%	8	6.8%	13	9.0%	.19
	Complete elementary school or incomplete secondary school	4	14.8%	12	10.3%	16	11.1%	
	Complete secondary school or incomplete high school	10	37.0%	47	40.2%	57	39.6%	
	Complete high-school or bachelor's degree	8	29.6%	50	42.7%	58	40.3%	
	Total	27	100%	117	100%	144	100%	
Occupation	Housewife (domestic work)	14	46.7%	71	56.8%	85	54.8%	.49
	Independent dealer	3	10.0%	15	12.0%	18	11.6%	
	Student	0	0.0%	5	4.0%	5	3.2%	
	Employee	11	36.7%	29	23.2%	40	25.8%	
	Retired	0	0.0%	1	0.8%	1	0.6%	
	Other	2	6.7%	4	3.2%	6	3.9%	
	Total	30	100%	125	100%	155	100%	
Child's social security	Social Security	11	36.7	37	29.9%	48	31.1%	.30
	None	13	43.3%	41	33.1%	54	35.1%	
	Popular Insurance	6	20.0%	46	37.1%	52	33.8%	
	Total	30	100%	124	100%	154	100%	

Note: Totals do not add 159, some questions were not answered.

Table 2. Distribution of toothbrushing practices and utilization of dental services reported by parents or guardians by study group. *SaludARTE* **schools and control school, Federal District, México 2014.**

Variables		Group						
Individual Level		**Control (N=30)**		*SaludARTE (n=129)*		**Total (n=159)**		**p**
		n	**%**	**n**	**%**	**n**	**%**	
Frequency of daily toothbrushing at home	None	0	0	1	0.8	1	0.6	.28
	Once (before going to school)	6	20.7%	11	8.8%	17	11.0%	
	Once (before going to sleep)	2	6.9%	18	14.4%	20	13.0%	
	Once (anytime)	1	3.4%	15	12.0%	16	10.4%	
	Twice	19	65.5%	73	58.4%	92	59.7%	
	≥3 times	1	3.4%	7	5.6%	8	5.2%	
	Total	29	100%	125	100%	154	100%	
Toothbrushing at home at night	No	8	27.6%	25	20.5%	33	21.9%	.41
	Yes	21	72.4%	97	79.5%	118	78.1%	
	Total	29	100%	122	100%	151	100%	
Who brushes the child's teeth	Child	18	60.0%	87	72.5%	105	70.0%	.35
	An Adult	0	0.0%	3	2.5%	3	2.0%	
	Child supervised by an adult	11	36.7%	28	23.3%	39	26.0%	
	No one	1	3.3%	2	1.7%	3	2.0%	
	Total	30	100%	120	100%	150	100%	
Utilization of dental services last 12 months	Yes	8	28.6%	52	41.9%	60	39.5%	.19
	No	20	71.4%	72	58.1%	92	60.5%	
	Total	28	100%	124	100%	152	100%	

Note: Totals do not add 159, some questions were not answered.

Table 3. Distribution of children by gender, mean age, self-perception of oral health and toothache by study group. *SaludARTE* **schools and control school, Federal District, México 2014.**

Variables		Group						
Individual Level		**Control (N=39)**		*SaludARTE (n=172)*		**Total (n=211)**		**p**
Mean (SD) age (years)		9.3(1.7)		8.7(1.9)		8.8 (1.8)		.73
		n	**%**	**n**	**%**	**n**	**%**	
Gender	Male	16	41.0%	66	38.4%	82	38.9%	.76
	Female	23	59.0%	106	61.6%	129	61.1%	
	Total	39	100%	172	100%	211	100%	
Self-perception of oral health	Very good – good	20	51.3%	76	54.2%	96	45.5%	.52
	Regular	15	38.5%	64	37.2%	79	37.4%	
	Bad – very bad	2	5.2%	12	6.9%	14	6.6%	
	Doesn´t know	2	5.1	20	11.6%	22	10.4%	
	Total	39	100%	172	100%	211	100%	
Toothache in the last twelve months	Many times	3	7.7%	18	10.5%	21	10%	.74
	Occasionally	12	30.8%	65	37.8%	77	36.5%	
	Never	17	43.6%	70	40.7%	87	41.2%	
	I don't remember	6	15.4%	16	9.3%	22	10.4%	
	Doesn't know	1	2.6%	3	1.7%	4	1.9%	
	Total	39	100%	172	100%	211	100%	

Figure 2. Baseline mean percent surfaces with dental plaque by category and group. SaludARTE elementary schools and control school, Federal District, Mexico 2014.

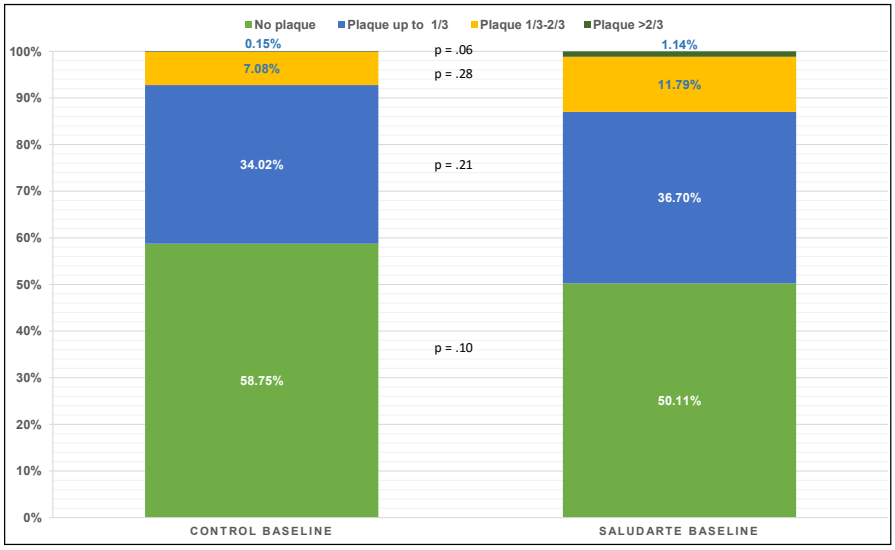


Figure 3. Baseline mean percent gingival units with inflammation by category and group. SaludARTE elementary schools and control school, Federal District, Mexico 2014.

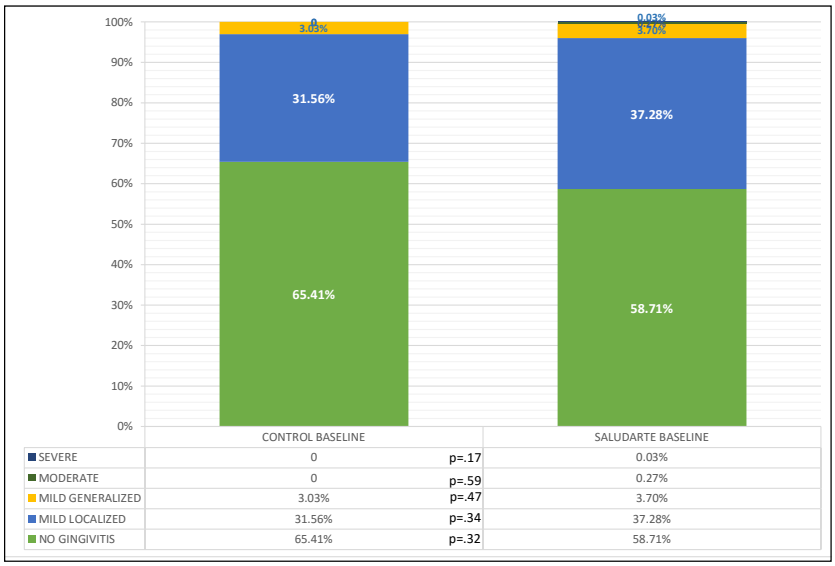


Figure 4. Baseline mean percent teeth gingival margins with bleeding by category and group. SaludARTE elementary schools and control school, federal District, Mexico 2014.

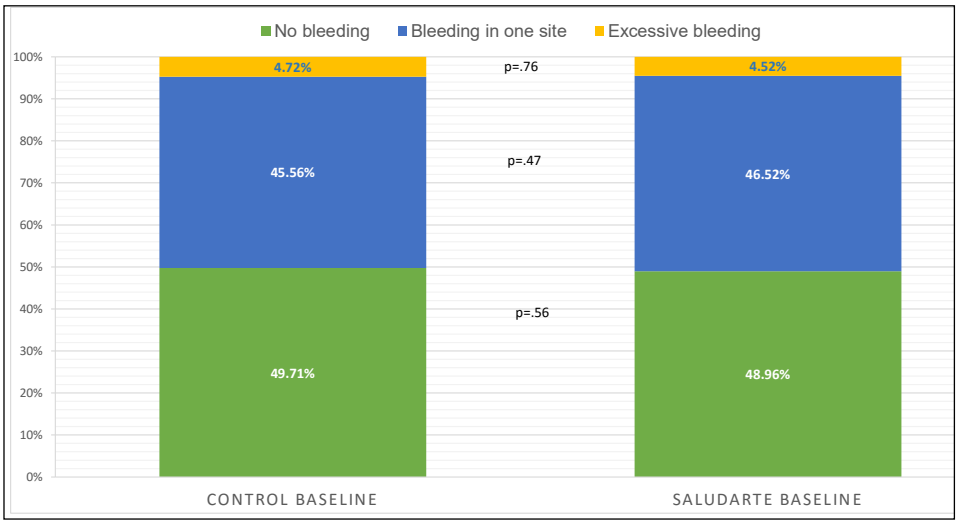
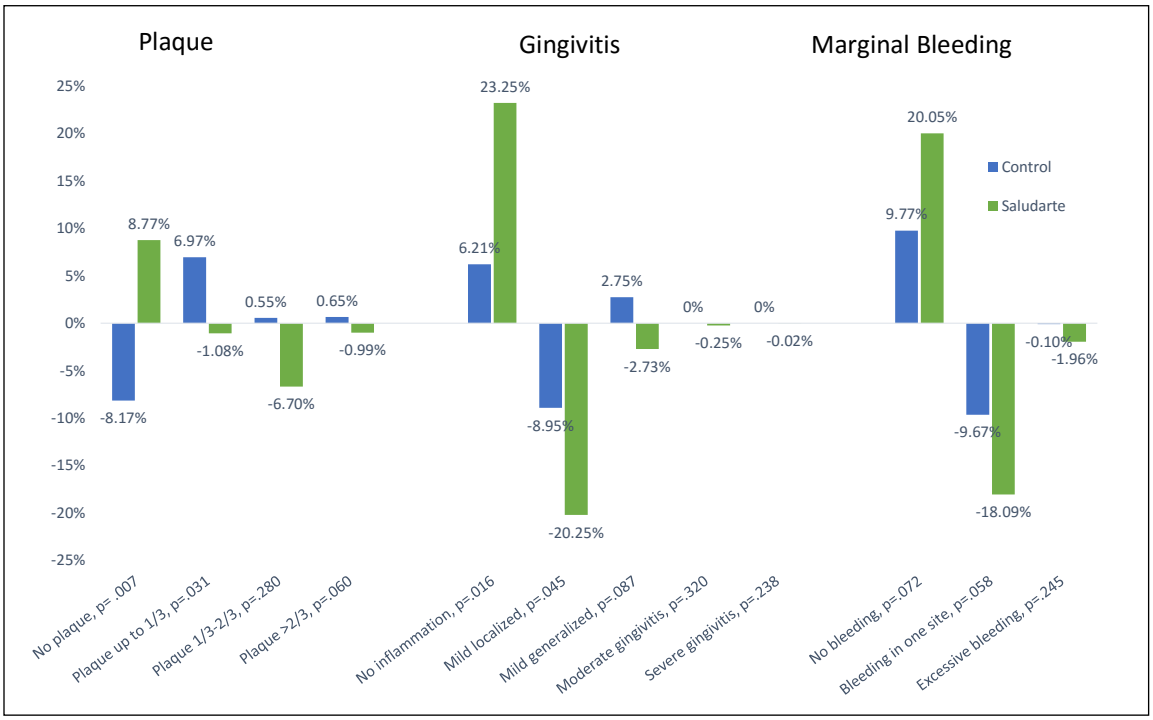


Figure 5. Mean percent differences of dental surfaces with plaque, mean percent of gingival units with gingivitis, and mean percent of gingival margins with bleeding. Intervention and Control Group. DF, Mexico, 2014.



The mean percentage of gingival units free from inflammation increased in both groups and was higher in the intervention group (23.3%±23.2%) than in the control group (6.2±21.9%) (p=0.016). Furthermore, the decrease in the mean percentage of units with mild localized inflammation was higher in the intervention (-20.3%±21.9%) than in the control group (-8.9%±23.9%) (p=0.045), whereas the mean percentage of units with mild generalized inflammation increased by 2.8%±9.9% in the control group and decreased 2.7%±7.1% in the intervention group (p=0.087). For moderate and severe gingivitis, changes in both groups were similar and close to 0% (p=0.32 and p=0.238, respectively) (Fig. 5).

The mean percentage differences in gingival margins with no bleeding were 20.1%±24% in the intervention group and 9.8%±20.7% in the control group (p=0.072). The mean percentage decreases in gingival margin bleeding at one site were -18.1%±23.4% in the intervention group and -9.7%±20.7% in the control group (p=0.058). No differences were observed in the mean percentage of excessive bleeding between the control group and the intervention group (p= 0.245) (Fig. 5).

DISCUSSION

Supervised tooth brushing at school was effective in reducing dental plaque and gingivitis. The mean percentages of surfaces free from dental plaque and of gingival units without inflammation were significantly increased compared with those in the control group. Previous studies of supervised tooth brushing in schoolchildren also showed positive results.[7, 8, 19, 20]

The overall improvement in dental plaque conditions was approximately 17.6% (8.77% + 1.1% + 6.7% + 1%). It has been reported that the maximum reduction of plaque that may be achieved is 40%-55%. [21] In this study, the three-month follow-up period was likely not sufficient to achieve larger changes in dental plaque. A systematic review showed that an evaluation at six months might reveal important reductions in plaque levels. [20]

Regarding gingivitis, the change was greater in units with no inflammation and with mild localized gingivitis, and the differences from mild generalized to severe gingivitis were smaller. However, compared to dental plaque, the increase in the percentage of children with gingival units free from inflammation was higher. Similar results were also found in a study conducted in Iran. [19] These differences between dental plaque and gingivitis may be explained by the observation that the efficient removal of dental plaque requires better tooth brushing ability, whereas gingivitis and gingival bleeding due to dental plaque accumulation decrease rapidly by brushing teeth.

Tooth brushing is the focus of the oral health program in *SaludARTE*, and because of the comprehensive approach of *SaludARTE,* we expect that over the medium to long term, the children will acquire healthier oral hygiene habits. However, it is advisable to reinforce the tooth brushing program by increasing the oral health education sessions, which can easily be included in the health promotion activities of *SaludARTE*. It has been demonstrated that after six months to four years of implementing school oral health educational programs, positive changes in knowledge, attitudes, and practices occur. [22-25]

The assessment of short-term efficacy is an opportunity to provide information for decision-making and improve the oral health component of the *SaludARTE* program. Moreover, the assessment of hygiene conditions allows for a more specific estimate of the tooth brushing program's impact.

Despite the 11.8% nonresponse rate, the sample fulfilled the sample size calculated at baseline. Although, we did not consider the cluster design when calculating the sample size, we estimated

the power of the sample size (test for two means in a cluster randomized design and unequal size groups). [26] We used the coefficient of variation of cluster sizes (0.19), the difference observed in the mean sites with no inflammation after the intervention between groups (17.1%), the standard deviation of the number of sites with no inflammation in both groups after the intervention (14.6%), and the intracluster correlation coefficient (ICC) (0.07).[17] To calculate the ICC, we used the mean *difference in sites without inflammation* in the intervention group. The estimated power was 0.95, [26] indicating that there was sufficient power in the sample size to detect a difference of 17%.

Limitations of the study

Some limitations were technical and logistical that delayed implementation of the tooth brushing program or interrupted it temporarily, such as a quarantine in one school due to an epidemic outbreak, the construction of classrooms in another school, and changes of *SaludARTE* program supervisors at the schools. We observed that some children only attended the program intermittently (between two and four days a week). This percentage was estimated as 15%, which may have decreased the efficacy of the program. Furthermore, the follow-up period was most likely not sufficient to achieve larger reductions in the most severe categories of assessed conditions. A longer follow-up is required to verify whether changes in the conditions will be increased and maintained.

Another limitation of this study was the low internal consistency (0.4978) of the questionnaire for children. Previous studies have reported that children younger than seven years old do not have sufficient cognitive skills to be systematically questioned (32.2% of children in the study were ≤7 years old) and recommend that questionnaires about daily activities and health issues for children 7-10 years old be answered by parents or caretakers. In our study, we included similar questions in both questionnaires; the information provided by guardians and parents, which was highly reliable, was the information reported in this study. [17]

By contrast, because it was not possible to randomly allocate participants to the intervention, the observation that some children had intermittent participation in the tooth brushing program might have affected the external validity of the study. Nevertheless, cluster selection in the intervention group was at random, and at baseline, the participants in both groups had similar sociodemographic and oral hygiene conditions. Furthermore, it is important to note that tooth brushing activities were performed in all schools and are supported by the education authorities; therefore, only exceptional conditions interrupted the activities.

Blinding was only possible for the analysis, and this might have compromised the internal validity of the study. However, as discussed earlier, blinding was not possible because of the ongoing activities of the *SaludARTE* program during the afternoons. However, other issues, such as the standardization of examiners, the internal consistency of the questionnaire for parents, the statistical power of the sample size, the similar response rates in both groups and accounting for the clustering effect in the analysis, showed that the internal validity was acceptable. By contrast, no risk of contamination of the intervention effect was expected because there were two study populations.

CONCLUSION

The school-supervised tooth brushing program was effective in improving oral hygiene conditions in children. The program had a greater impact on the reduction of plaque and gingivitis than on the reduction of gingival bleeding. It is necessary to strengthen oral health education in the nutritional and hygiene workshops of the *SaludARTE* program.

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