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Effect of educational strategy combined with ART on oral health-related quality of life: a controlled clinical trial

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Abstract: This study aimed to assess whether complementing atraumatic restorative treatment (ART) with oral health educational strategies (OHES) improves the perception of oral health-related quality of life (OHRQoL) and clinical oral outcomes. A controlled clinical trial included 93 six- to eight-year-old students from five public schools of Piracicaba, Saltinho, and Charqueada municipalities (State of São Paulo, Brazil) divided into 3 groups (31 children each) which received: OHES (caries-free), ART (dental caries), and ART plus OHES (dental caries). OHRQoL (CPQ8-10-ISF:16), dental caries, biofilm control, and gingivitis were assessed before and 1 month after interventions by one calibrated examiner. OHES consisted of an educational interactive activity performed once a week for four weeks. Data were analyzed using mixed model ANOVA, Chi-square, and Sign tests. After 1 month of follow-up, improvement in gingivitis status, OHRQoL total score, and Functional Limitations, Emotional Well-Being and Social Well-Being domains scores were found in all groups ($p < 0.05$). The improvement in biofilm control was observed only in the OHES group ($p < 0.001$; power = 0.98), while a decrease in Oral Symptoms scores was observed only in ART+OHES group ($p < 0.001$; power = 0.99) and a significant change in the perception of oral health was observed in the two groups that received ART ($p < 0.05$). In conclusion, improvement in overall OHRQoL and oral status was observed in all children, although the effect of including health educational strategies in the treatment plan was determinant for the perception of an improved oral health after restorative treatment.

Keywords: Child; Dental Caries; Health Education; Oral Hygiene.

Introduction

Children and adolescents are affected by several oral and orofacial disorders that have the potential to limit their physical function, psychosocial well-being, and quality of life.[1] Dental caries is considered the most prevalent disease affecting children worldwide and it impacts their masticatory, phonetic, and social functions, as well as their quality of life.[2-5] Caries has a multifactorial etiology that includes diet, socioeconomic status, home environment, lack of adherence to preventive measures

by children and their families, and poor access to dental care and health promotion measures.[5-8]

The school is an important setting for the promotion of health education activities that can be offered to schoolchildren and their parents, school staff, and the community.[7] Such strategies can encompass physical and mental health aspects aimed at providing learning experiences on health topics, developing personal skills, and promoting healthier behaviors.[9,10,11] Oral health programs can be especially relevant in primary school, a convenient place for changing unhealthy behaviors, particularly of groups in which healthy habits have not yet been established.[12]

Atraumatic restorative treatment (ART) has been recommended by the World Health Organization (WHO) and the Pan American Health Organization (PAHO) as a minimal intervention procedure applicable at the public health level to manage dental caries.[6,13,14] It is also a protocol recommended by the Ministries of Health in Latin America for schoolchildren aged 6 years and older.[14,15] Minimal intervention dentistry for managing dental caries has also been considered an important approach to reduce the impact of dental caries on oral health-related quality of life (OHRQoL).[14] Although some previous interventional studies have shown the impact of traditional/standard dental treatment and ART on OHRQoL and clinical outcomes of children and adolescents,[7,16-20] knowledge on the impact of complementing ART with oral health educational strategy (OHES) in the public health context is limited, and to our knowledge, there is a lack of controlled studies.

Health educational strategies should be tailored to their target population to be effective for capacity building and behavior change; educational interventions have been considered an important tool in the health care system as an integral part of complementary health promotion in public health.[21-25] Clinically, OHES also showed an important effect in improving children's well-being during dental treatment.[26]

Thus, this study aimed to assess whether combining OHES and ART improves the perception of OHRQoL and clinical oral outcomes. The hypothesis tested was that the combined approach improves biofilm and gingivitis control and perceived OHRQoL in a sample of schoolchildren to a larger degree.

Methodology

Study design

This was a controlled clinical trial approved by the Ethics Committee of the Piracicaba Dental School, University of Campinas – FOP-Unicamp (Protocol no. 136/2014), which has been previously registered at ClinicalTrials.gov (CJK-2014-ART, date of registration: January 28, 2016). The children signed an assent term, and their parents/guardians signed a consent form agreeing with the procedures of the study.

The study included a final sample of 93 six- to eight-year-old students from five public schools of Piracicaba, Saltinho, and Charqueada municipalities (State of São Paulo, Brazil). The populations of these cities range from 7,000 to 365,000 inhabitants, and their Human Development Indexes (HDI) range from 0.74 to 0.79.[27] The conduction of this study was also based on the recommendations of the SPIRIT protocol (Standard Protocol Items: Recommendations for Interventional Trials).[28]

Participants

The sample size was calculated based on the results of a previous cross-sectional study that evaluated the impact of ART on the OHRQoL of schoolchildren using the 25-item version of the Child Perceptions Questionnaire (CPQ_{8-10}).[18] Considering the mean difference found in social well-being scores between children with (14.13 ± 12.32) and without dental caries (5.20 ± 5.13), a power test of 0.80, a confidence level of 95%, and a possible dropout rate of 20% (*i.e.*, a correction factor of 1.226), the required sample size was defined as 22 individuals in each group.

Five hundred twenty-one children were initially invited. The inclusion criteria were children aged six to eight years old. The exclusion criteria were presence of any tooth with a diagnosis of irreversible pulp involvement, since these teeth cannot be treated by ART, presence of tooth decay in incisors and/or canines (which can negatively impact the dental aesthetic and consequently the OHRQoL), chronic treatment for systemic diseases such as asthma,

respiratory and/or food allergies, neurological disorders, epilepsy, among others, and children who did not attend all stages of the study. The excluded children were referred to the Pediatric Dentistry Clinic of the Piracicaba Dental School, University of Campinas, Piracicaba (State of São Paulo, Brazil), to receive dental treatment. Details about the sample distribution are shown in Figure 1. After applying the exclusion criteria, 93 children composed the final sample.

The sample was divided into three groups. Sixty-two children with at least one decayed primary molar in dentin were consecutively assigned to groups and submitted to ART (n = 31) and OHES+ART (n = 31). Thirty-one caries-free children received only OHES. Children from the same classroom were assigned to the same group and received the same procedures to avoid exchange of information within groups.

Clinical evaluation and ART

The clinical evaluations were carried out at the school, before recess, in the following times: baseline (all groups) and one month after the interventions.

The procedures for the evaluation of dental caries, biofilm, gingivitis, as well as OHES and ART interventions were conducted as previously described.[12,26] Dental caries was diagnosed according to WHO criteria[20] by one calibrated examiner (JRSH) who was trained by the *lux* method, which consists of the projection of images showing different possible variations of presence and severity of dental caries, thus comparing the examiner with a gold standard record.[11,20,25] The examinations took place at the school, outdoors in indirect daylight. Dental biofilm and gingivitis were visually inspected. Buccal surfaces of the primary and/or permanent upper incisors were examined to detect biofilm (dye was not applied); the scores ranged from 0 to 4, according the number of incisors affected.[29] Alterations in gingival shape and color of upper incisors were considered clinical parameters, with scores ranging from 0 to 4.[30] In both cases, the higher the score, the worse the clinical outcome.

The proposed OHES were developed and standardized according to children's cultural characteristics and considering their age and

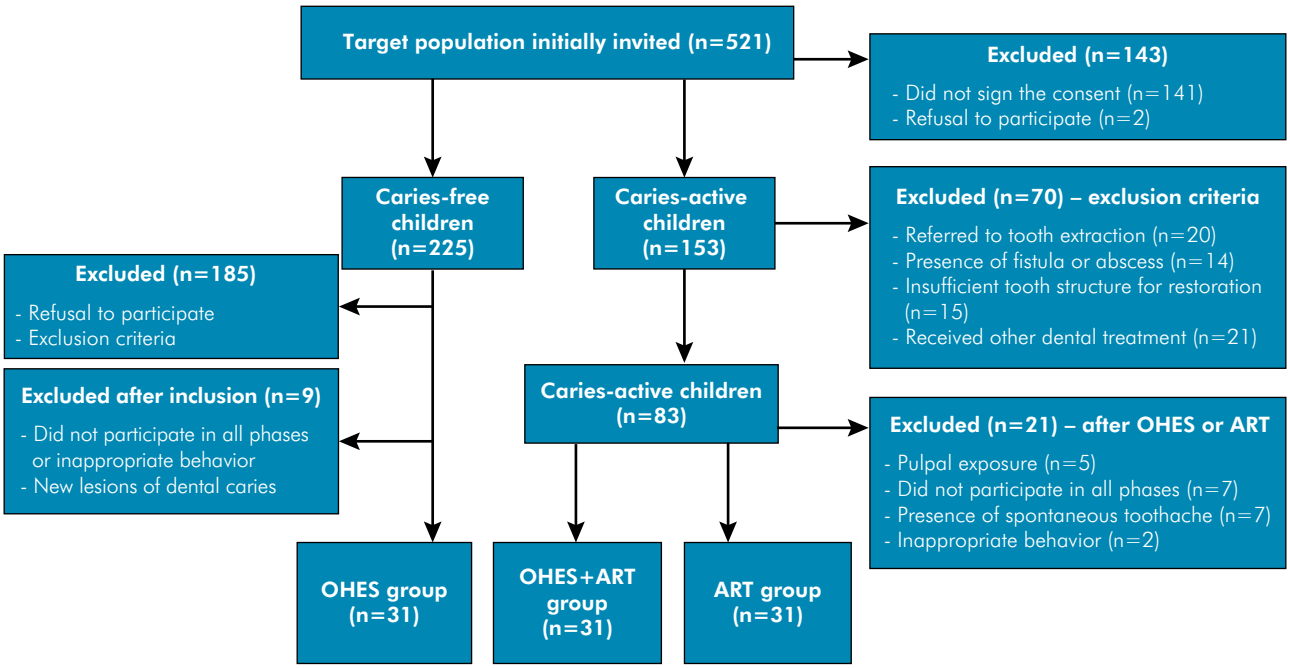

Figure 1. Flowchart of sample selection, allocation in groups, and description of the interventions (OHES: oral health educational strategy; ART: atraumatic restorative treatment).

language aiming at providing learning experiences on oral health topics by one of the authors (FLM, Public Health specialist).[31,32] The strategy consisted of four consecutive sessions (20 minutes each), performed once a week at the school, which included a maximum of 10 children per session. The sessions were based on active learning methodology, interaction, and reinforcement[31,32] and consisted of presentation of oral structures using pictures (1st session), delivering information on etiological factors of dental caries and self-visualization of oral structures (2nd session), oral hygiene instructions using dental models and supervised toothbrushing (3rd session), and delivering explanations about ART procedures (4th session).

The sessions were provided to the OHES and OHES+ART groups by the same trained researcher (CNF). One week after the 4th educational session, the OHES+ART group received the dental treatment. The ART group received the OHES one month after completion of dental treatment for ethical reasons.

ART was performed by one trained and blinded pediatric dentist (KGS) using a protocol specifically developed for this approach,[33] which consisted of one to two sessions (maximum) performed in two weeks.[12,26] Only hand instruments were used for opening and cleaning the cavities in primary molars. Cleaned cavities were restored with a high-viscosity glass-ionomer (Ketac Molar Easymix®; 3M ESPE, São Paulo, Brazil). ART was performed at school using folding chairs that were adapted to simulate a dental chair placed near a window with natural light.

At this stage, caries-active children were excluded in the case of tooth exfoliation and/or tooth restoration after inclusion, pulp exposure during excavation, inappropriate behavior and/or refusal to receive the ART procedure. Also, previous caries-free children that developed caries were excluded. These details are shown in Figure 1.

Oral health-related quality of life

OHRQoL was assessed by applying the validated Brazilian short-form version of the CPQ_{8-10}, which consists of 16 items (CPQ_{8-10}-ISF:16) and four domains,[34] by one trained interviewer (CNF). The questionnaire was applied as an interview considering that young children are capable of providing their own perceptions of oral health impacts, as stated previously.[35]

The questions were about the frequency of events in the previous 4 weeks in relation to the child's oral/orofacial condition, considering the following domains: oral symptoms, functional limitations, emotional well-being, and social well-being. A Likert-type scale was used with the following response options: 'never' = 0; 'sometimes' = 1; 'every day or almost every day' = 3 (higher scores indicate higher impact on OHRQoL). Children answered the scale at the following time points, depending on the group: at baseline (all groups), 1 week after interventions, and 1 month after interventions.

Participants were also asked to provide a global assessment of their oral health and overall well-being using questions that preceded the CPQ scale. At baseline, they answered the question '*How much do your teeth or mouth bother you in your everyday life?*' with a 3-point response scale: not at all, a little, and a lot. At baseline and follow-up, the following question was also answered: '*When you think about your teeth and mouth, would you say that they are…*' with a 3-point response scale: excellent, average, and poor.

In addition, the self-perceptions of changes in oral health at follow-up were assessed using the question: "*Compared to the first time you answered the questionnaire, you think that the health of your mouth and teeth ….*" with a 3-point response scale: worsened, stayed the same, and improved. Such transition judgments are often used as a 'gold standard' in evaluations of the sensitivity to change in OHRQoL measures.[36] One advantage of these judgments is that they are not affected by the mood of the individual.

Statistical analysis

Data were statistically analyzed by one of the authors (PMC, Applied Statistics specialist) using SPSS 24.0 (IBM Corp., NY, USA) and considering an alpha level of 5%. Descriptive statistics consisted of means and standard deviations, medians and interquartile ranges, and graph analysis of the OHRQoL scores (radar charts). Normality was checked using the Shapiro-Wilk test.

A two-way mixed model ANOVA was used to assess the differences between independent groups over time, testing the effect of *time* (two points: baseline and 1 month after intervention) and *time*group* interaction on the dependent variables: OHRQoL (scores of each domain and total score), biofilm accumulation, and gingivitis scores. This analysis also provided the effect size (partial Eta squared) and the power of the test for further interpretation. The variances of the differences between the levels of the within-subject factor and homogeneity assumptions were tested previously (Mauchly's sphericity test and Levene's test, respectively). In addition, Box's test for equality of covariance matrices was performed. When necessary, a correction was applied. If an interaction effect was found, we proceeded to the simple main effect analysis by using one-way repeated measures ANOVA to check the changes over time within each group.

The Chi-square and Sign tests were used to compare the global ratings differences between groups and between baseline and follow-up, respectively.

Results

The mean (standard deviation) age of the 93 participants (31 children in each group) ranged from 6.7 (0.5) (OHES and ART groups) to 6.8 (0.7) (OHES+ART group) years. Males were the majority in the OHES (51.6%) and OHES+ART (54.8%) groups, while in the percentage of girls in ART was 51.6%.

Table 1 shows that OHRQoL total score decreased over time in all groups ($p < 0.05$), as did the Functional Limitations, Emotional Well-being, and Social Well-being domain scores. However, an interaction effect of *time*group* was found for the Oral Symptoms domain ($F = 3.663$; $p = 0.030$); testing for a simple main effect, a significant decrease in the Oral Symptoms domain score was found only in the OHES+ART group ($p < 0.001$; partial *eta* squared = 0.474; power = 0.999).

The radar charts emphasize the decrease in CPQ_{8-10}-ISF:16 scores (improvement in OHRQoL) over time in all groups (Figures 2a, 2b, and 2c). This reduction in CPQ scores was less evident on the OHES group since it was composed of caries-free children with lower baseline scores.

Table 1. Follow-up description of samples according to CPQ8-10-ISF:16 scores and the interaction effect of *time*group*: a two-way mixed model ANOVA.

Follow-up time	OS	FL	EWB	SWB	OHRQoL total score
	Mean (SD)				
Baseline					
OHES	2.4 (1.5)	1.0 (1.2)	0.9 (1.7)	0.8 (1.2)	5.1 (4.2)
OHES+ART	2.9 [A] (1.6)	1.7 (1.8)	2.2 (2.6)	1.7 (2.0)	8.5 (6.6)
ART	2.7 (1.8)	1.8 (2.0)	1.7 (1.9)	1.0 (1.3)	7.1 (5.6)
1-month after intervention (OHES and/or ART)					
OHES	1.9 (1.4)	1.0 (1.6)	0.5 (1.2)	0.6 (1.6)	4.1 (4.8)
OHES+ART	1.6 [B] (1.2)	1.2 (1.6)	1.0 (1.5)	0.7 (1.0)	4.4 (4.2)
ART	2.3 (2.0)	1.1 (1.9)	1.0 (2.0)	0.9 (1.5)	5.3 (6.2)
Results of the Two-way Mixed Model ANOVA			F (p-value)		
Time effect	20139 (< 0.001)	4092 (0.046)	11669 (< 0.001)	5273 (0.024)	14804 (< 0.001)
Time*group interaction effect	3663 (0.030)	1108 (0.335)	1155 (0.320)	2393 (0.097)	2308 (0.105)

OS: oral symptoms; FL: functional limitations; EWB: emotional well-being; SWB: social well-being; SD: standard deviation; OHES: oral health educational strategy group; OHES+ART: oral health educational strategy and atraumatic restorative treatment group; ART: atraumatic restorative treatment group; OHRQoL: oral health-related quality of life. A ≠ B ($p < 0.001$; one-way ANOVA repeated measures/simple main effect). Numbers in bold are significant p-values.

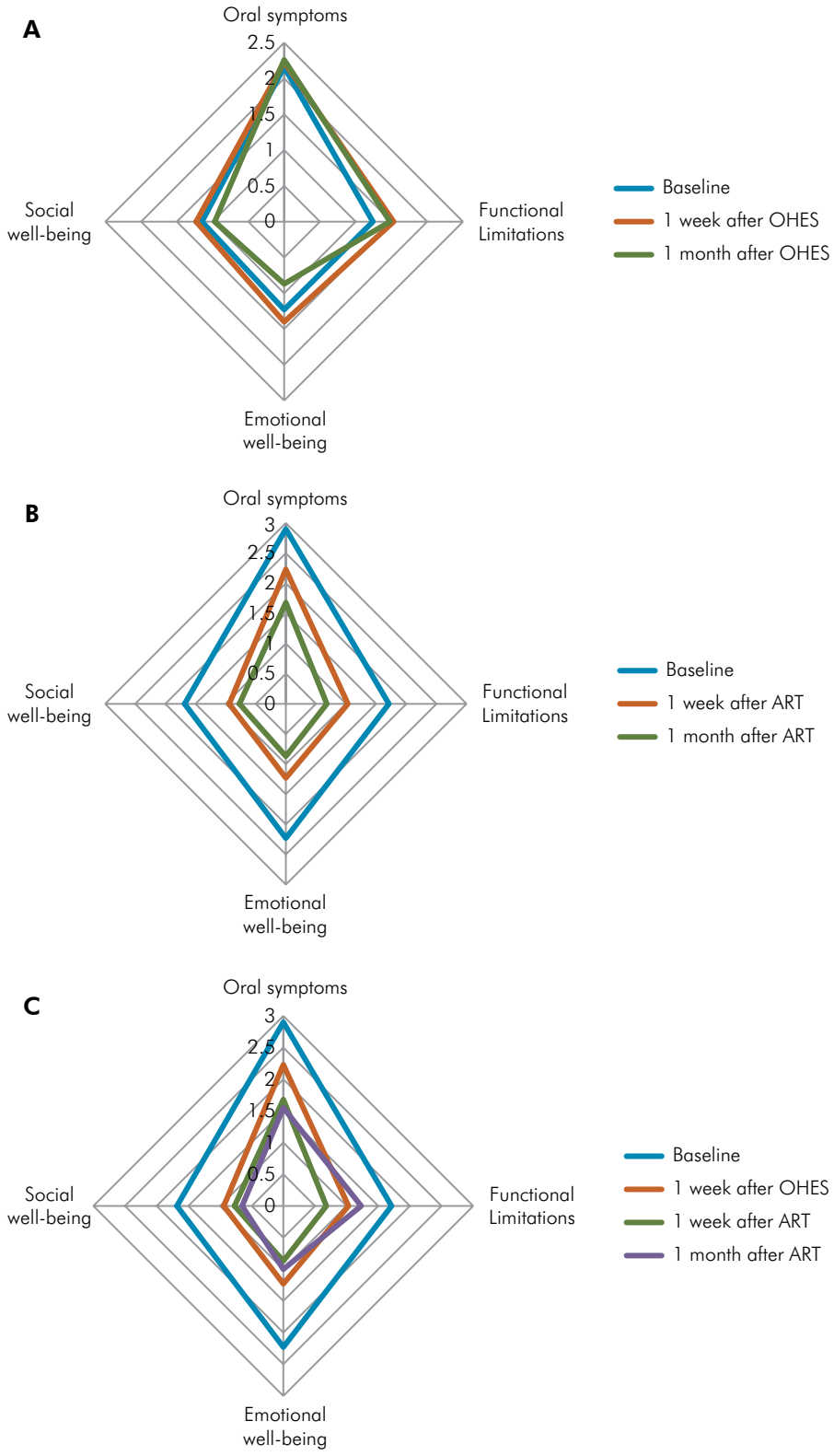

Figure 2. A. Radar chart describing the CPQ8-10-ISF:16 scores reached by the OHES group on each time point. **B.** Radar chart describing the CPQ8-10-ISF:16 scores reached by the ART group on each time point. **C.** Radar chart describing the CPQ8-10-ISF:16 scores reached by the OHES+ART group on each time point.

Table 2. Frequency [n (%)] of global oral health and overall well-being responses according to groups and follow-up time.

Variable	*"How much do your teeth or mouth bothers you in your everyday life?"*		*"Compared to the first time you answered the questionnaire, you think that the health of your mouth and teeth…"*	
	Baseline		One month after OHES	
OHES (n = 31)	Not at all	17 (55)	Improved	16 (52)
	A little	13 (42)	Stayed the same	13 (42)
	A lot	1 (3)	Worsened	2 (6)
	Baseline		One month after OHES + ART	
OHES + ART (n = 31)	Not at all	10 (32)	Improved	24 (77)
	A little	13 (42)	Stayed the same	7 (23)
	A lot	8 (26)	Worsened	0 (0)
	Baseline		One month after ART	
ART (n = 31)	Not at all	17 (55)	Improved	26 (84)
	A little	9 (29)	Stayed the same	5 (16)
	A lot	5 (16)	Worsened	0 (0)
	p-value*	0.0774	p-value*	0.0172

OHES: oral health educational strategy group; OHES+ART: oral health educational strategy and atraumatic restorative treatment group; ART: atraumatic restorative treatment group. *Chi-square test.

Table 3. Frequency [n (%)] of global oral health responses according to groups and follow-up time.

"When you think about your teeth or mouth, would you say that they are…"			
OHES (n = 31)	Baseline	One month after OHES	p-value*
Excellent	18 (58)	22 (71)	
Average	12 (39)	6 (19)	1.000
Poor	1 (3)	3 (10)	
OHES+ART (n = 31)	Baseline	One month after OHES+ART	
Excellent	15 (48)	26 (84)	
Average	12 (39)	4 (13)	0.019
Poor	4 (13)	1 (3)	
ART (n = 31)	Baseline	One month after ART	
Excellent	15 (47)	22 (71)	
Average	14 (45)	9 (29)	0.057
Poor	2 (6)	0 (0)	

OHES: oral health educational strategy group; OHES+ART: oral health educational strategy and atraumatic restorative treatment group; ART: atraumatic restorative treatment group. *Sign test.

Table 2 shows that although the percentage of children who reported being bothered with their teeth/mouth did not differ between groups at baseline, after treatment, significantly more children that received ART considered that their oral health 'improved' (OHES+ART = 77%; ART = 84%; $p < 0.05$).

In addition, Table 3 shows a significant change in the global ratings of oral health in the OHES+ART group, as 84% of children considered their teeth/mouth health status to be "excellent" after treatment (compared to 71% of the other two groups) ($p < 0.05$).

Table 4 shows a significant interaction of *time*group* for biofilm accumulation, indicating that the time effect over biofilm was dependent on the group; thus, a simple main effect was carried out showing that

Table 4. Follow-up description of samples according to biofilm and gingivitis scores and the interaction effect time*group: a Two-way Mixed Model ANOVA.

Follow-up time	Group	Biofilm score	Gingivitis score
		Mean (SD)	
Baseline	OHES	1.8 [A] (1.7)	1.1 (1.5)
	OHES+ART	1.1 (1.5)	0.7 (1.4)
	ART	1.0 (1.6)	0.7 (1.4)
1-month after intervention (OHES and/or ART)	OHES	0.6 [B] (1.1)	0.2 (0.8)
	OHES+ART	0.5 (1.0)	0.3 (0.2)
	ART	0.9 (1.4)	0.6 (1.2)
Results of the two-way mixed model ANOVA		F (p-value)	
Time effect		13961 (< 0.001)	14878 (< 0.001)
Time*group interaction effect		3752 (0.027)	2128 (0.125)

SD: standard deviation; OHES: oral health educational strategy group; OHES+ART: oral health educational strategy + atraumatic restorative treatment group; ART: atraumatic restorative treatment group. A ≠ B ($p < 0.001$; one-way ANOVA repeated measures/simple main effect). Numbers in bold mean significant p-values.

the decrease in biofilm accumulation was significant in the OHES group with a large effect size ($p < 0.001$; partial *eta* squared = 0.354; power = 0.975) compared to the other groups. For the gingivitis score, a significant *time* effect was observed, meaning that the gingivitis score decreased after the interventions in all groups ($F = 14.878$; $p < 0.001$).

Discussion

Although an improvement in the overall OHRQoL and gingivitis control was observed in all children undergoing dental treatment and/or educational activities, the perception of oral health was improved in the group of children submitted to ART who also participated in the sessions of oral health education. The findings emphasize the importance of health education in providing children with knowledge and awareness about their own oral health and, ultimately, promoting healthier behaviors.

The three inteventions were able to positively impact the OHRQoL of schoolchildren with or without dental caries as measured by the CPQ_{8-10}-ISF:16, agreeing with previous studies that showed a reduction in oral health problems and an increased satisfaction with oral health in individuals who received dental treatment.[7,16-19] To control for the 'Hawthorne effect', in which the several follow-ups could influence the child's self-motivation and perception of the care received,[37] the design of the study included two groups to control the effect of including OHES in dental treatment. Indeed, the frequent contact between the schoolchildren and the oral health team could have positively affected their self-perception about oral health, making them prone to feel 'under control' and motivated.[16,17,20] In young adults, a positive impact of oral health education performed at school on OHRQoL was also observed, especially regarding daily activities.[25]

The observed change in overall OHRQoL over time also reflects the symptomatic relief of the child's dental problems,[16,20] as even short-term effects on functional limitations may reveal an improvement in masticatory functions as a result of dental restorations. These findings agree with previous studies that showed the impact of dental procedures on OHRQoL,[6,16,18,19,20] including those performed while the children were under general anesthesia.[38]

The importance of including OHES in the treatment plan was evidenced by examining the improvement in the Oral Symptoms scores found in the OHES+ART group. In addition, a higher percentage of children from this group also considered the health of their

teeth/mouth as "excellent" after treatment, meaning that they probably acquired sufficient awareness to understand the benefits of dental treatment.[16] As OHES sessions were designed to increase knowledge on the relationship between health, disease, and quality of life,[7,10] the strategy provided understanding of their own oral problems and symptoms and the extent to which these symptoms may 'bother' and affect their daily activities, which were not sufficiently perceived before dental treatment. However, it is important to mention that contact with the health team was more frequent and intense with the OHES+ART group, totaling 5 or more sessions including OHES and ART procedures, which may have also favored this group.

One study that compared different types of oral health education approaches (conventional, game-based, and drama) showed that all were effective in improving clinical oral outcomes.[32] However, in this study, while the gingivitis score decreased after 1 month of follow-up in all groups, independent of the type of treatment received, the decrease in biofilm accumulation was only significant in the OHES group in a short follow-up period, that is, among caries-free children. This finding suggests that children with a higher risk of tooth decay may encounter greater difficulty in biofilm control, either with toothbrushing or in changing dietary habits.[21] In this way, the greater biofilm accumulation observed even after OHES and/or ART may be related to unhealthy habits that should be changed, which can lead to a greater susceptibility to the development of dental caries.[39]

The findings emphasize the importance of the *minimal intervention dentistry* that recognizes the patient-centered care approach as the best way to control caries disease and enable the patient to manage his/her own oral health.[8,14] The earlier the enrollment in preventive programs, the better the prevention of oral diseases despite the family's social status.[9,37] Implementing *minimal intervention dentistry* in the public dental sector would facilitate the management and "healing" of the condition in its early stages, minimizing the need for later complex restorations, preserving the natural teeth, and creating opportunities for oral care self-management, as the focus is on prevention.[36,37] The results of this study also emphasize the importance of delivering information, developing personal skills, and establishing healthy habits in a population (children) with no previous habits.

The study had some limitations and strengths that should be mentioned. The schoolchildren were enrolled in public schools from lower socioeconomic areas, which may limit the generalization of the findings. In addition, the follow-up period was relatively short (one month after finishing the interventions), and a longer follow-up time would be useful to ascertain long-term differences among groups. Current findings have shown that oral health education should be consistently repeated to ensure positive changes over time.[40] The strengths of the study include the controlled clinical trial design with sufficient sample size and the use of validated and robust measures of OHRQoL. The CPQ8-10-ISF:16 (in preparation for submission) is a communication tool of this research group.

Conclusions

Improvement in overall OHRQoL was observed in all children, although the effect of including health educational strategies in the treatment plan was determinant for the greater perception of improved oral health after ART. Gingivitis score decreased in the follow-up period in all groups of schoolchildren, whether or not they participated in the OHES, while the decrease in biofilm accumulation was significant only in caries-free children who participated in the OHES.

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