

Effectiveness of an oral health education intervention among 6–12-year-old children: A cluster randomized controlled trial

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Objectives: Literature on the effectiveness of theory-based oral health education on the oral hygiene of children is limited. We aimed to determine the effectiveness of an health behaviour theory-based school oral health education intervention on 1) oral hygiene and 2) oral health-related knowledge, attitude and practices among 6–12-year-old children in Kerala, India. **Methods:** Cluster randomized controlled trial. Sixteen class divisions (clusters) were randomized into intervention and control groups of 225 and 228 children respectively. Primary and secondary outcomes were plaque score as measured using the simplified oral hygiene index (OHI-S) and oral health-related knowledge, attitude and practices respectively. The intervention group received structured oral health education classes for three months and materials including pamphlets. Children in the control group were not given the classes or materials. **Results:** Post-intervention OHI-S scores in the intervention group and control groups were 1.65 and 2.17 respectively (difference = -0.52, 95%CI -0.86, -0.18). All the secondary outcomes improved in the intervention group compared to the control group. **Conclusions:** The intervention improved the oral hygiene status, oral health-related knowledge, attitude and practices of the children. Longer term follow-up and economic appraisal are needed to help policymakers plan and develop OHEI based on health behaviour theories.

Keywords: Children, India, Kerala, cluster randomized controlled trial, oral health education

Introduction

Oral health plays a significant role in the development of overall health status and quality of life of children (Guarnizo-Herreño and Wehby, 2012). Poor oral health among children can cause pain, discomfort, irritability, poor growth, disturbed sleep, diminished learning ability and reduced self-esteem (Sheiham, 2006). Children with poor oral health are more likely to miss school hours and perform poorly in school (Jackson *et al.*, 2011). The most common oral health problems in children are dental caries and gingivitis (Suresh *et al.*, 2021a). Improving the oral hygiene (OH) of children could help to prevent gingivitis (Damle *et al.*, 2014).

Oral Health Education Intervention (OHEI) is a method of public health intervention to improve oral health-related knowledge to support good oral health behaviours which in turn will improve oral health (Nakre and Harikiran, 2013).

Three systematic reviews (SR) on the effectiveness of OHEI had given contrasting results. Brown (1994) and Kay and Locker (1996) reported that OHEI improved the knowledge of the participants, but not their attitudes and practices whereas Nakre and Harikiran (2013) concluded that OHEI were effective in improving the oral health-related knowledge, attitudes and practices of participants. The first two SRs followed a strict inclusion criterion,

while the third SR included case-control studies along with randomized controlled trials (RCT). These SRs also noted the scarcity of well-conducted RCTs in OHEI.

An SR of OHEI on various target groups concluded that school children were the best group to provide OHEI (Kesavan and Vinita, 2011). The most appropriate time to provide OHEI to children is 6–12 years, the first permanent tooth erupts by six years (Suresh *et al.*, 2021b). The children in this age group have logical thoughts, (Glogster, 2007) beliefs in their skills and feel pride in their accomplishments (Verywell, 2022).

More than the duration of intervention, repetition of sessions of OHE classes was more effective and OHEI ranging from three months to two years had a positive effect with children (Menon, 2021). Habbu and Krishnappa's (2015) SR reported that most OHEI for children improved their knowledge, but their attitudes and behaviours towards oral hygiene did not improve. OHEIs may change behaviours if they are guided by health behaviour theories. Health behaviour theories provide a systematic approach to tailor, target, implement and evaluate health education programs that will enhance the likelihood of success (Sanaeinasab *et al.*, 2019). An OHEI program based on the health belief model (HBM) was effective in improving the oral health behaviour of 6–12-year-old children (Sanaeinasab *et al.*, 2022).

A systematic review of school OHEI found that none were guided by health behaviour theories. (Gambhir *et al.*, 2013). In India to the best of our knowledge, to date, no study has evaluated the effectiveness of health behaviour theory-based school OHEI on OH for 6-to 12-year-old children. This study aimed to determine the effectiveness of a health behaviour theory-based school OHEI on 1) OH and 2) oral health-related knowledge, attitude and practices among 6–12-year-old children.

Methods

This cluster randomized controlled trial, single-blinded (outcome assessor was blinded), 2-arm trial was registered in the Clinical Trials Registry – India [REF/2018/01/016755]. Cluster randomization was chosen for practical reasons. The trial took place between January 2018 and February 2019 in the Thiruvananthapuram educational district of Kerala state. The study involved children studying in one to seven standards (aged 6–12-years) of Government schools.

The sample size was calculated according to the study design (Noordzij *et al.*, 2010) and the primary outcome variable; the OH (recorded using the Simplified Oral Hygiene Index, OHI-S). At 5% level of significance and 80% power, expecting a reduction in mean OHI-S score by 0.38 (SD=0.85) in the control group and 0.75 (SD=1.26) in the intervention group (Chandrashekar *et al.*, 2012), the sample size required was calculated as 135 per group. After assuming an arbitrary design effect of 1.5 and 10% loss to follow up the required sample size was determined as 450 (225 per group).

Inclusion criteria for schools included schools for general education and co-education, with standards one to seven and at least 10 students studying in each standard. Inclusion criteria for children included age of 6-12 years and child assent and parental consent.

Twenty-seven government schools in the district met the inclusion criteria. Participants were selected using multistage cluster sampling; selecting schools in the first stage and class divisions (CD, the clusters) in the second. The total number of eligible children in the 27 schools was 11468 as per the school records and the total number of CDs was 397. As the mean number of children per CD was 29, 16 CDs were selected. Only one CD was selected from each school.

School and class divisions were selected randomly using computer-generated numbers, stratifying to include 6 urban and 10 rural CDs. Parents of all 465 children in the selected 16 CDs consented to the baseline survey. Parents of 12 (2.6%) children did not consent to intervention so the remaining 453 children were included for intervention and follow-up. The trial statistician randomized the 16 clusters into intervention and control clusters with three urban and five rural clusters in each group. This yielded 225 children in the intervention and 228 in the control group (Figure 1).

Given the participants' age we selected the relatively simple health belief model (HBM) to guide the development of the OHEI (Glanz *et al.*, 2008) (Table 1).

The study was conducted in three stages. Stage 1 (baseline data collection) included a baseline survey of a structured interview and clinical oral examination by three trained dentists. The clinical oral examination

recorded children's OHI-S, the primary outcome variable (Greene and Vermillion, 1964). The possible range of the OHI-S score is 0-6, with lower scores indicating better OH. Scores may be classified as good (0.0 to 1.2), fair (1.3 to 3) or poor (3.1 and 6).

The baseline interview enquired about general information and socio-demographic and three secondary outcome variables: oral health-related knowledge (OHRK), oral health-related attitude (OHRA) and oral health-related practice (OHRP). The socio-economic status (SES) of the children was calculated based on the job status of their parents. The minimum score possible was one and the maximum score possible was four. Scores were classified as low (1 to 2), medium (2.1 to 3) and high (3.1 to 4). The OHRK score was assessed based on the children's knowledge on causes, symptoms and prevention of dental caries, symptoms and prevention of gum diseases, harmful effect of tobacco and relationship of oral health and general health. The OHRA score was based on the children's response regarding the need to keep the teeth clean, need for regular dental check-up and what they would do if they had tooth pain or bleeding gums. The OHRP considered the children's tooth cleaning frequency, the materials they used for teeth cleaning, frequency of tooth brushing, time and method of tooth brushing, frequency of toothbrush changing, whether they cleaned their tongue and the material used, their mouth washing habits after eating, frequency of sweet and soft drink intake, their visit to dentist and tobacco use. The minimum score possible for these secondary outcome variables was zero and the maximum possible scores were seven for OHRK, four for OHRA and 14 for OHRP. The primary outcome variable OHI-S score, and the secondary outcome variables OHRK, OHRA, and OHRP were continuous variables.

In stage 2 (the intervention phase) the intervention group received three sessions of OHE classes by a dentist (NS) one month apart and OHE materials. The OHE classes were in the local Malayalam language in classrooms with the help of a simple 20-minute video. Topics included the importance of teeth including deciduous teeth; caries, gum disease, dietary habits for good oral health, oral hygiene instructions including toothbrushing and tongue cleaning technique, detrimental effects of tooth cleaning with materials like charcoal, the importance of washing mouth after meals and snacks; what to do and what not to do if you experience tooth pain or bleeding gums; harmful effects of tobacco; and importance of regular dental check-ups. After each class, the children were divided into four to five groups and each group was given a demonstration and hands-on training in tooth brushing with the Modified Bass technique (Poyato-Ferrera *et al.*, 2003) and tongue cleaning techniques in the same classroom. The OHE materials included charts, pamphlets and brushing charts prepared in the local language with attractive pictures and cartoons. Charts and pamphlets contained all the main points covered in the OHE class along with the brushing technique; shedding time of deciduous teeth and eruption time of permanent teeth. The charts were pasted on the walls of the classrooms to remind children about the main points of the OHE classes. Pamphlets were sent to parents via their children and distributed among the class teachers.

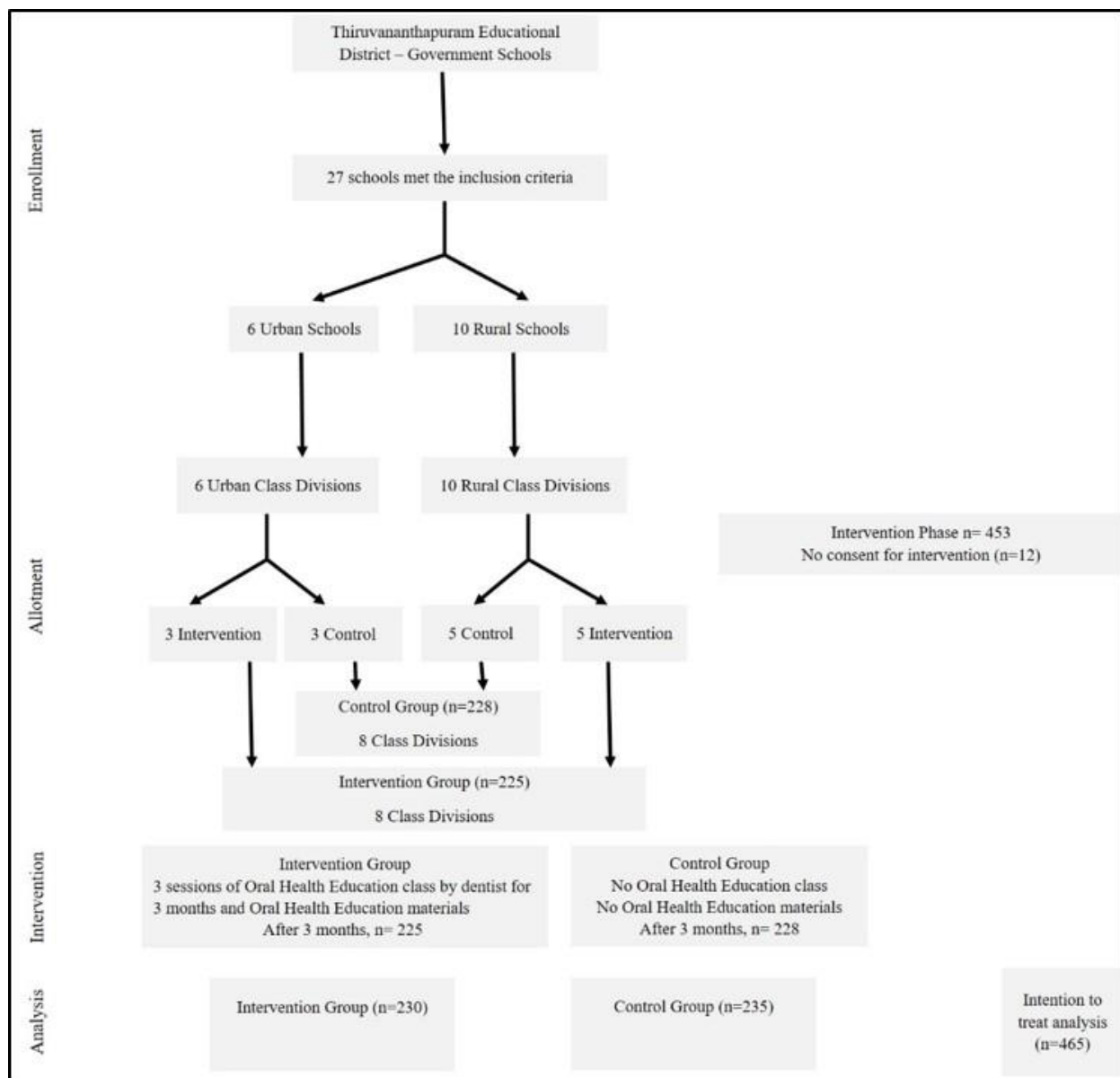


Figure 1. Trial profile.

Table 1. Development of the health belief model guided OHEI.

Concept	Definition	Action
Perceived susceptibility	Belief about the likelihood of experiencing a risk or getting a condition or disease	Children were made aware that their poor oral health behaviours had affected their oral hygiene and made them more susceptible to tooth decay and gum diseases.
Perceived severity	Belief about how serious a condition may become if not treated (clinical and social sequelae)	Children were made aware regarding <ul style="list-style-type: none"> • Tooth decay and gum diseases – its clinical sequelae • How oral diseases affect general health • Importance of teeth and consequences of tooth loss
Perceived benefits	Belief in efficacy of the advised action to reduce risk	Children were made aware that good oral health behaviours would improve their oral hygiene and make them less susceptible to tooth decay and gum diseases.
Perceived barriers	Belief about the tangible and psychological costs of the action	Children's misinformation regarding oral health behaviours were corrected. Parents and teachers were given pamphlets containing oral health information regarding oral health behaviours.
Cues to action	Strategies to activate "readiness"	Brushing charts reminded the children about twice daily tooth brushing. Class teachers helped to motivate and encourage children about twice daily brushing.
Self-efficacy	Confidence in one's ability to act	Children were given training on <ul style="list-style-type: none"> • Tooth brushing technique • Tongue cleaning technique

Monthly brushing charts were developed with boxes for the children to record their tooth brushing to remind them about twice-daily tooth brushing. One month after every OHE class, the class teachers checked brushing charts. If children had used the brushing chart effectively and marked ticks the teacher would appreciate the children and award a “Good” comment in their chart. Children who had brushed twice daily for the whole month, would additionally receive a ‘star’ mark of encouragement. The control group received neither OHE class nor materials.

The post-intervention data collection started three months after the intervention and included clinical oral examinations by a new group of three trained dentists. We were able to collect follow-up data for all the children after two visits to each school.

After the post-intervention data collection, children in the control group were given one OHE class and received a demonstration and hands-on training in tooth brushing and tongue cleaning. They also received all the OHE materials developed as part of the program.

In data analysis, baseline characteristics of clusters and participants were summarised using means and standard deviation (SD). The post-intervention data analyses observed intention-to-treat with baseline data of 12 children who did not participate in the intervention used as post-intervention scores. Post-intervention differences between the intervention and control groups were estimated using Wald Chi-square tests from the Generalized Estimation Equation method to incorporate the clustered data. The primary (OHI-S score) and the secondary outcome variables (OHRK, OHRA, and OHRP) were all continuous variables.

The study was approved by the Institutional Ethics Committee (IEC) of a national Institute (SCT/IEC/1138/ December 2017). Permission from the education department was obtained. Participant information sheets were given to participants, informed consent was obtained from parents/ guardians and assent was obtained from the children.

Results

Characteristics of the 465 children are presented in Table 2. Slightly more participants in both groups were boys. Proportionately more participants in the intervention group attended schools in urban areas. Baseline OHI-S scores were 2.0 and 2.1 in the control and intervention groups respectively. Scores for oral health-related knowledge, attitudes and practices were also very similar across the two groups.

Parents/ guardians of 12 children did not provide consent to receive the intervention, leaving 453 children to be randomised. All 228 children in the control group and 225 children in the intervention group provided post-intervention data. Baseline scores for those who did not consent to the intervention were used in intention to treat analysis (Table 2).

Mean post-intervention OHI-S scores in the intervention and control group were 1.65 and 2.17 respectively (Difference = 0.52, 95%CI = 0.37, 0.68). Post-intervention OHRK, OHRA and OHRP scores also were higher in the intervention than the control group (Table 3).

Discussion

Three months after the intervention, the OH of the children who received OHEI was better than in the control group, suggesting that the OHEI program was effective. This benefit occurred even though the children had fair OH at the baseline. The mean OHI-S score of the intervention group at baseline was 2.01 (Table 2). This may have been possible because the intervention was developed and implemented based on the health behaviour theory. In earlier studies where OH improved the children had poor OH at baseline (Chandrashekar *et al.*, 2012).

Systematic reviews, including those on oral health have reported that OHEIs for children might increase childrens’ knowledge, but their attitudes and behaviours

Table 2. Characteristics of control and intervention groups.

		Control (n=235) %	Intervention (n=230) %
Sex	Male	58.3	59.6
	Female	41.7	40.4
Medium of education	English	51.9	50.0
	Malayalam	48.1	51.0
Location of school	Urban	35.7	50.4
	Rural	64.3	49.6
Socio-economic status	Low	58.3	62.8
	Middle	23.4	25.2
	High	18.3	12.6
		(Mean ± SD)	(Mean ± SD)
Age		10.66±1.00	10.19±0.79
Oral Hygiene Index Simplified		2.00±0.87	2.01±0.88
Oral Health-Related Knowledge		4.33±1.40	4.44±1.28
Oral Hygiene-Related Attitude		2.38±1.02	2.47±1.03
Oral Hygiene-Related Practice		7.73±1.46	7.93±1.37

Table 3. Outcome variables 3 months post-intervention.*

	Control group (n=235)	Intervention group (n=230)	
	Mean (SD)	Mean (SD)	Difference (95% CI)
Oral Hygiene Index Simplified	2.17 (0.88)	1.65 (0.81)	-0.52 (-0.86, -0.18)
Oral Health-Related Knowledge	5.01 (1.40)	6.72 (0.64)	1.71 (1.27, 2.14)
Oral Hygiene-Related Attitude	2.97 (1.02)	3.82 (0.54)	0.85 (0.64, 1.07)
Oral Hygiene-Related Practice	7.43 (1.57)	11.31 (1.50)	3.88 (3.37, 4.40)

* Baseline scores for those who did not consent to the intervention were used in intention to treat analysis

¹Standard error in Generalized Estimation Equation to account for clustered nature data.

are less likely to improve (Brown, 1994; Kay and Locker, 1996; Nakre and Harikiran, 2013; Habbu and Krishnappa, 2015). However, three months after the intervention, OHEI had improved the oral health-related knowledge, attitude and practices of the children. Again, this effectiveness may have resulted from the intervention being based on the health behaviour theory and being implemented with the support of teachers. Earlier studies have also reported that health education programs supported by health behaviour theories might enhance effectiveness (Sanaeinasab *et al.*, 2019). The topics included in the OHE classes and the way classes were conducted, covered all six concepts of HBM. A three-month study from Iran also used HBM to guide an OHE program for 6 -12-year-old school children. OHEI using the HBM was also effective in improving oral health behaviour (Sanaeinasab *et al.*, 2022).

The OHEI in this study employed live demonstrations, practice sessions and individual instructions to teach skills such as tooth brushing and tongue cleaning. Such practical education is likely more important than audio-visual aids (Leal *et al.*, 2002). The OHE materials might also have played a great role in improving the oral health-related practices of the children. Earlier interventions have used posters (Tolvanen *et al.*, 2009) and leaflets (Sadana *et al.*, 2017) but few report using monthly tooth brushing charts. OHEI for elementary school children may be most effective when children, teachers, and parents, are all involved (Bramantoro *et al.*, 2021). In our intervention teachers motivated and reminded children regarding twice-daily tooth brushing. Even though separate OHE classes were not taken for parents, pamphlets containing all the oral health information were sent to them through their children.

Strengths of this study include that planning and development of the intervention based on the health behaviour theory and that teachers and to a small extent parents were also participated. The limitations of the study were that children from private schools were not included and short follow-up period. Longer term follow-up and economic appraisal are needed to help policymakers plan and develop OHEI based on health behaviour theories.

In conclusion, this cluster randomized controlled trial showed that a health behaviour theory guided school OHEI was effective in improving the oral hygiene and oral health-related knowledge, attitudes and practices among 6–12-year-old children.

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