




BMJ Open Effectiveness of an oral health curriculum in reducing dental caries increment and improving oral hygiene behaviour among schoolchildren of Ernakulam district in Kerala, India: study protocol for a cluster randomised trial

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To cite: Das H, Janakiram C, Ramanarayanan V, *et al*. Effectiveness of an oral health curriculum in reducing dental caries increment and improving oral hygiene behaviour among schoolchildren of Ernakulam district in Kerala, India: study protocol for a cluster randomised trial. *BMJ Open* 2023;**13**:e069877. doi:10.1136/bmjopen-2022-069877

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-069877>).

Received 05 November 2022
Accepted 08 February 2023



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ABSTRACT

Introduction Children's learning abilities suffer when their oral health is compromised. Inadequate oral health can harm children's quality of life, academic performance, and future success and achievements. Oral health problems may result in appetite loss, depression, increased inattentiveness, and distractibility from play and schoolwork, all of which can lower self-esteem and contribute to academic failure. An oral health curriculum, in addition to the standard school curriculum, may instil preventive oral hygiene behaviour in school students, enabling them to retain good oral health for the rest of their lives. Because most children attend school, the school setting is the most effective for promoting behavioural change in children. A 'health-promoting school' actively promotes health by enhancing its ability to serve as a healthy place to live, learn and work, bringing health and education together. Making every school a health-promoting school is one of the joint objectives of the WHO and UNICEF. The primary objective of this proposed study is to assess the effectiveness of an oral health curriculum intervention in reducing dental caries incidence and improving oral hygiene behaviour among high school children in grades 8–10 of the Ernakulam district in Kerala, India. If found to be effective in changing children's behaviour in a positive way, an oral health curriculum may eventually be incorporated into the school health curriculum in the future. Classroom interventions can serve as a cost-effective tool to increase children's oral health awareness.

Methods and analysis This protocol presents a cluster randomised trial design. It is a parallel-group comparative trial with two arms having a 1:1 distribution—groups A and B with oral health curriculum intervention from a dental professional and a schoolteacher, respectively. High schools (grades 8–10) will be selected as clusters for the trial. The minimum cluster size is 20 students per school. The total sample size is 2000 high school children. Data will be collected at three time points, including baseline, after 1 year (mid-term) and 2 years (final), respectively. The

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is the first cluster randomised clinical trial in the world evaluating the effectiveness of an oral health education curriculum for high school students.
- ⇒ Along with the dental professionals, schoolteachers are part of implementing the oral health curriculum intervention, making it sustainable.
- ⇒ The use of cluster-controlled design enables us to include a large sample size and a more significant number of schools, thus increasing the generalisability of the study findings.
- ⇒ Blinding may not be possible due to the nature of the intervention (education) and the study setting, that is, school.
- ⇒ Follow-up might be challenging for class 10 students who are set to take their board examinations.

outcome measures are Decayed, Missing and Filled Teeth Index; Oral Hygiene Index-Simplified; and knowledge, attitude and behaviour. Data collection will be done by clinical oral examination and questionnaire involving oral health-related knowledge, attitude and behaviour items.

Ethics and dissemination Ethical approval was obtained from the Institutional Ethics Committee of Amrita Institute of Medical Sciences and Research Centre (dated 19 July 2022, no: IEC-AIMS-2022-ASD-179).

Trial registration number Clinical Trial Registry of India (CTRI/2022/09/045410).

INTRODUCTION

Oral diseases in general and dental caries, in particular, are among the most serious public health issues due to their high prevalence and adverse effect on the quality of life.¹ Dental caries is a common chronic disease in children and one of the most frequent causes of loss of school hours.² On the other

hand, if inculcated early in life, good oral hygiene practices go a long way in maintaining optimal oral health. The WHO has made it a priority to promote children's oral health through health-promoting schools (HPS) in order to improve global oral health.³ Long-term input is needed to achieve behavioural changes in children, and the school environment is considered an ideal environment for advocating behavioural change through health education since most children attend schools.⁴ Moreover, schools can significantly impact children's health, education and general well-being.⁵

India confronts numerous obstacles in meeting oral healthcare demands. In 1940, 55.5% of school students in India had dental caries, which jumped to 68% in the 1960s and escalated to 89% in the following years.⁶ Seven out of every 10 Indian youngsters have untreated dental caries, according to the FDI World Dental Federation (FDI).⁷ Poor oral health can harm children's quality of life, academic performance and future achievements.⁸ Many children and parents in developing nations have limited awareness of the causes and prevention of the most frequent oral diseases.⁹ Oral health knowledge among Indian children is low when compared with their western counterparts.¹⁰ It has been found that inculcating preventive oral hygiene behaviour among schoolchildren (eg, through an oral health curriculum in schools) for the maintenance of good oral health throughout life can provide them with the knowledge to make judicious choices about how they live their lives and preserve their health.¹¹ The National Health Policy 2017 in India recommends integrating health education into the school curriculum and encouraging hygiene and safe health behaviour in the school environment as a part of school health.¹²

HPS is a concept in which schools strive to continually improve their ability to be healthy places to live, work and study. They aim to organise and strengthen health promotion and education efforts in schools to promote the health of students, teachers, families and the community as a whole.¹³ The initiative assists countries in developing health and education policies and school-based health improvement programmes. School health education is one of the most fundamental aspects of an HPS. Along with general health, oral health education can be taught separately or as a component of other subjects. Integrated approaches with active engagement have been demonstrated to generate long-term behaviour improvements.¹⁴ Due to the adoption of the HPS concept, several nations now provide health education in a curriculum structure. Many countries have created an oral health curriculum aimed at the oral health promotion of schoolchildren.^{15 16} The oral health curriculum has been included in new statutory guidance on health teaching for schools in England, which has been welcomed by the Faculty of General Dental Practice (UK).¹⁷

In India, the school health curriculum lacks an oral health component, and there are currently no structured oral health initiatives for schoolchildren. Children's lives

are shaped by their years in school, when they develop lifetime oral health-related behaviours, convictions and attitudes. During the school years, children are more receptive, and the earlier habits are set, the greater the influence. An oral health curriculum, if found to be effective in positively altering children's behaviour, could be incorporated into the school curriculum in the future.

Evidence gaps that need to be filled

Though many nations have developed oral health curriculums, there is insufficient research on the impact of these interventions on dental caries and oral hygiene behaviour. In addition, only a small number of studies have been published that show oral health education significantly reduces dental caries in permanent dentition.^{18–20} Dental caries experience measured by caries prevalence and DMFT (Decayed, Missing, Filled Teeth) Index or DMFS (Decayed, Missing, Filled Surface) Index are used to assess the impact of the educational interventions on controlling the disease. Most previous studies could not report a significant change in dental caries experience, except for studies combining oral health education with preventive treatments like topical fluoride application and fluoride mouth rinses.²¹ This combined approach might reduce caries activity and maintain a balance between the DMFT and DMFS scores.

Furthermore, most of the studies had long-term follow-ups to see if there was a significant change in controlling dental caries.^{22 23} Karuveetil *et al* conducted a study in 2020 that found significant improvements in oral health knowledge, attitudes and practices among Indian schoolchildren, as well as significant reductions in decayed primary teeth in lower primary and upper primary schoolchildren post-intervention of an oral health curriculum. However, the study had only 1-year duration, which is insufficient time to bring about changes in caries experience of permanent dentition, and was limited to a single school only.²⁴ Therefore, more evidence is needed to demonstrate the effectiveness of an oral health curriculum in lowering caries incidence and enhancing oral hygiene behaviour among students.

Studies have also compared the effectiveness of various instructors (health educators), showing a wide range of outcomes. Compared with social workers and teachers, direct health education delivery by dentists was found to be more effective in boosting KAB (knowledge, attitude and behaviour) levels in a study by Chachra *et al* in 2011.²² Based on better oral hygiene ratings, another study identified schoolteachers as ideal instructors for oral health education.²⁵ These findings suggest that finding the right health educator to teach schoolchildren about oral health presents a challenge.

Aim and objectives

Aim

To reduce dental caries incidence and improve oral hygiene among schoolchildren in Kerala, India.

Objectives

Primary objective

To assess the effectiveness of an oral health curriculum intervention in reducing dental caries increment in schoolchildren and improving their oral hygiene behaviour.

Secondary objective

To compare the effectiveness of oral health education imparted to schoolchildren between a dental health professional and a schoolteacher in reducing dental caries increment and improving oral hygiene behaviour.

Tertiary objective

To determine the oral health-related KAB of schoolchildren before and after intervention.

METHODS AND ANALYSIS

Study setting

The study will be conducted in high schools of Ernakulam district in Kerala, India. There are 128 Central Board of Secondary Education (CBSE) English-medium schools in Ernakulam, Kerala from which the participants will be recruited for the trial.

Study design

A cluster randomised trial design will be adopted with the intervention of the oral health curriculum delivered through two arms: groups A and B will receive the intervention from a dental professional and a schoolteacher, respectively. A parallel-group comparative trial will be designed with a 1:1 distribution between the two arms.

Study population

India’s school education system is divided into four levels: lower primary (ages 6–10 years), upper primary (ages 11–12 years), high school (ages 13–15 years) and higher secondary (ages 17 and 18 years). The target population for our study will be high school children from standard 8–10 of the age group 13–15 years. The recruitment of study participants is illustrated in figure 1.

School selection

English-medium high schools in Ernakulam, Kerala will be selected. Permission will be obtained from the school authorities, and cooperation from the teachers will be requested.

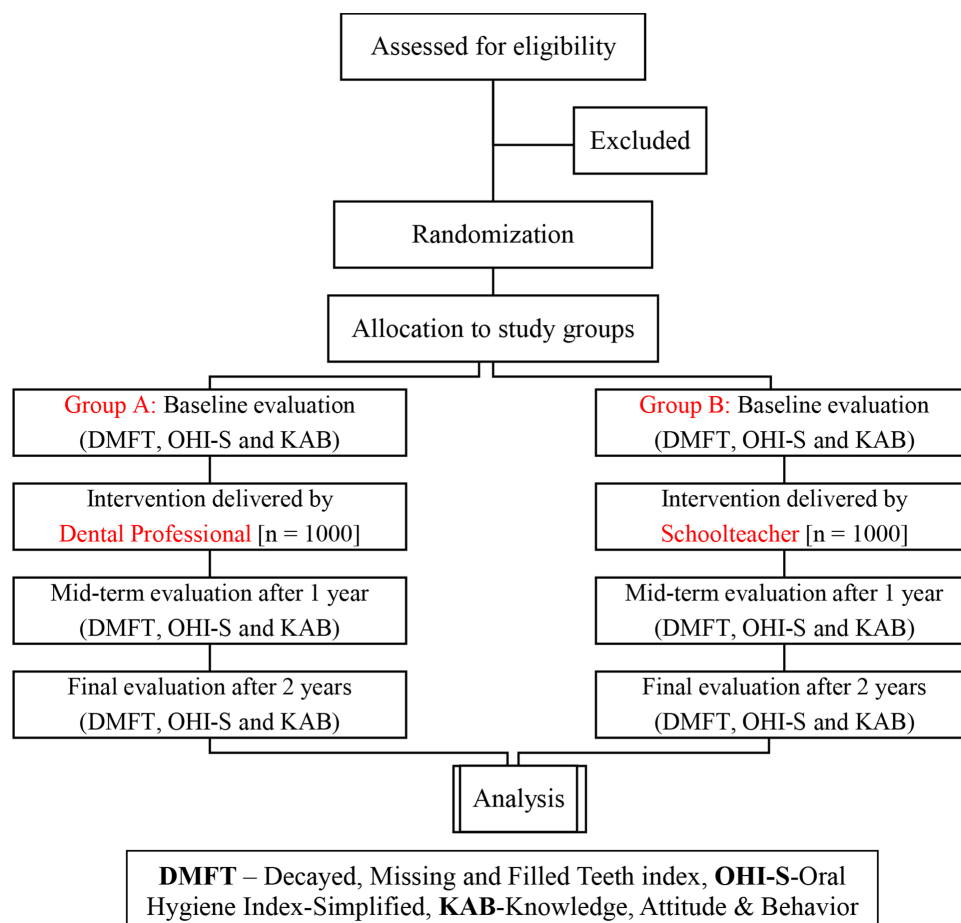


Figure 1 Recruitment flow chart.

Eligibility criteria

Inclusion criteria

- ▶ High school students aged 13–15 years (from 8 to 10 standard/grade) will be selected.
- ▶ Students who are willing to participate in the study and who have given the informed consent (parental consent/assent).

Exclusion criteria

- ▶ Students who are unwilling to participate in the study and do not provide informed consent (parental consent/assent).
- ▶ Students who do not speak English.
- ▶ Participants who are unable to hold a toothbrush due to physical challenges (which will prevent them from brushing their teeth properly).

Sampling strategy

A cluster sampling technique will be adopted for the study. The Ernakulam educational district will be selected as the study setting to get an accurate representation of urban and rural schools. Each school will be considered as a cluster. The minimum cluster size of 20 students per school is fixed. The selected schools will be randomised using computer-generated numbering system into two intervention groups, A and B, receiving the oral health curriculum from a dental professional and a school-teacher, respectively.

Sample size

The sample size was calculated based on the results of our primary outcome, that is, the mean difference in DMFT before and after intervention. Cluster Design-Two Groups-Unmatched Studies-Comparison of Means formula was used. The following parameters were used for estimation: mean difference: 0.22 (mean DMFT obtained from a previous study),²⁴ SD: ± 1.69 , size of cluster: 200, design effect: 1.5, power: 80%, alpha error: 5% and number of clusters 7; thus, the calculated sample was 1390. Considering 40% attrition/non-response rate due to the 2-year follow-up, the total sample was amended to 2000.

Study intervention and procedure

The study will be divided into five phases, including the intervention of oral health curriculum as demonstrated in figure 2.

Phase I: preparatory phase

- ▶ *Development of educational material:* educational material will be developed based on existing oral health curriculums from other countries in the English language.

It will be customised for Indian schoolchildren. The curriculum will be divided into modules with age-appropriate instructions for the students. Lesson plans with instructor instructions, hands-on demonstrations, handouts or master copies for each child will be included in each module and delivered following each session. The handouts will cover topics such as healthy teeth, primary and permanent dentition, tooth brushing and parts of teeth, decay chemistry, fluorides, flossing, dental appointments, tobacco use prevention, dental trauma management and healthy nutrition. The curriculum will include an instructor's information booklet that will provide thorough information on the causes, identification and prevention of various orodental diseases while bearing in mind schoolteachers who are new to the curriculum. The overall layout of the oral health curriculum is given in figure 3.

- ▶ *Advocacy meetings:* an advocacy meeting will be conducted with the school authorities, and the need and methodology of the study will be discussed with the principal, schoolteachers and caregivers. The expected cooperation will be explained and assessed before finalising the school's inclusion in the project. Written permission for the conduct of the programme will also be obtained from the school principal.
- ▶ *Information, education and communication aids:* age-appropriate lesson plans will be developed as per the topics needed for the curriculum. Demonstration of oral hygiene techniques will be included, and students will receive coloured handouts of each lesson plan.
 - *Tooth brushing:* supervised tooth brushing programme using the modified bass method.
 - *Flossing:* demonstration of flossing on tooth model.
 - *Demonstration of the mechanism of tooth decay by flannel graph:* demonstration of dental caries formation with the help of a flannel graph will be performed.
 - *Fluorides:* topical fluoride application will be demonstrated with models. Fluoride gel, trays and tooth models will be used to familiarise children with the process of fluoride application.
 - *Models of mouth guard, cigarettes and food pyramid* to be used to aid in health education.

Phase II: Baseline evaluation

The baseline survey will include KAB questionnaires and an oral examination performed by trained dental professionals who have undergone calibration. Questions will be explained to each participant to get familiar with the contents; instructions for filling them out will be given

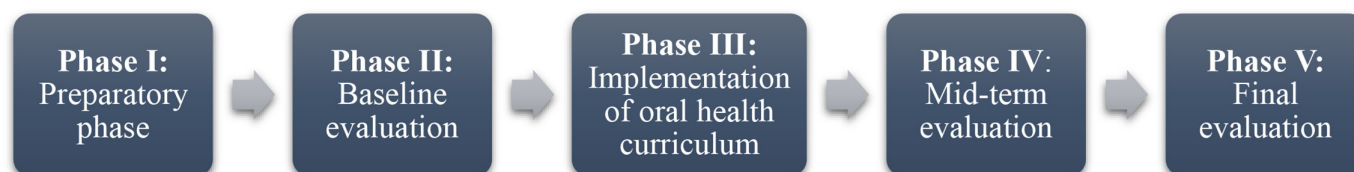


Figure 2 Phases of the study.

Age (years)	Oral Health Topics	Educational Aids	Health Instructor	Settings
13-15	Healthy teeth, primary and permanent dentition, tooth brushing, and parts of teeth, decay chemistry, fluorides, flossing, dental appointments, tobacco habits, trauma management, and nutrition.	Curriculum divided into modules with age-appropriate instructions for the students. Lesson plans with instructor instructions, hands-on demonstrations, hand-outs, or master copies for each child will be included in each module.	Dental health professional and school teacher.	Classroom

Figure 3 Layout of oral health curriculum intervention (educational intervention trial).

and the responses will be recorded. They will be given 15–20 min to complete the questionnaire. Special instructions would be given not to ask or consult a colleague while answering the questionnaire. An extra visit will be made to survey the absentees who missed the initial one. The dental surgeons will carry out the standardised American Dental Association type of clinical oral examination of the children using mouth mirrors and explorers under standard aseptic conditions in broad daylight.²⁶ An oral health check-up card would be given to the study participants for their parents' information, suggesting the need for dental care. As a benefit of participating in the study, children will be given a referral card from the dental hospital for any further check-ups or treatment.

Phase III: Implementation of the oral health curriculum

During this phase, schoolteachers will be trained and oriented to the curriculum.

Training of schoolteachers

A teacher's orientation programme will be conducted, where the teachers will be familiar with the curriculum by giving detailed explanations of different conditions involving oral health expected in the schoolchildren as per the curriculum. A session of oral health education for the teachers will also be conducted as a benefit for enrolling to the project.

During this training, the teachers will explain the importance of oral health, its relationship with general health and how they can integrate oral health instructions in their daily practice. They will be advised on their role in preventing orodental problems of schoolchildren. Any doubts regarding the implementation of the curriculum and subject-related queries will be cleared through the open discussion sessions. A list of teachers who volunteer to participate in the study will be obtained at the end of the orientation programme.

Delivering oral health curriculum

A schoolteacher will be identified as the coordinator and communication point for implementing the curriculum, appointed by the school principal. Scheduling of lesson plans will be done by consulting the principal and schoolteachers. There will be one session every 4 months, and each session will be reinforced in the next session. For the last session, reinforcement will be given during the final

questionnaire administration. The principal investigator (PI) (dentist) will impart the oral health curriculum for group A. For group B, schoolteachers of respective grades who volunteered to participate in the study will impart the lessons.

Visits to schools

- *Frequent, timely visits by the dental practitioner:* for each school, a 2-year intervention of the oral health curriculum will be conducted in six sessions with a 4-month interval between sessions. So, the dental practitioner will have a total of six visits to each school to impart the oral health curriculum to schoolchildren (group A). Additional visits will be made to survey those who were unable to attend the first. For each session, the children will have the opportunity to listen, have a discussion and ask the dentist/teacher questions. Students are also expected to gain skills through hands-on class demonstrations. There will be a total of four modules divided into 11 lessons to be given in six sessions.

Phase IV: mid-term evaluation

After 1 year of the implementation phase, a mid-term evaluation in the form of a KAB survey using the same questionnaire that was administered during the baseline assessment among all students will be conducted. An extra visit to account for absentees will also be performed.

Phase V: final evaluation

After 2 years of the implementation phase, the same children will be re-evaluated. The final clinical examination and KAB questionnaire recording will be performed in the same manner as the baseline evaluation. An extra visit to account for absentees will also be performed.

Patient and public involvement

We conducted a community outreach programme called Amrita Smitham in different schools in Kerala, India, where we gave oral health education to the schoolchildren, their parents and the teachers. We have identified that there is a need for oral health awareness among school-going children, leading to the encouragement of a novel structured educational activity through the development and implementation of an oral health curriculum. The principal, parents and schoolteachers will all

play an essential role in implementing the oral health curriculum.

Study outcomes

The study outcomes and outcome assessments are summarised below.

Outcome measures

Primary outcome

1. Dental caries increment
 - a. DMFT Index.

Secondary outcomes

1. KAB in relation to oral health.
2. Oral Hygiene Index-Simplified (OHI-S).
 - a. Change in index scores (DMFT, OHI-S) and difference in KAB regarding oral hygiene post-intervention.
 - b. Comparing index scores (DMFT, OHI-S) and KAB scores between the dental professional and school-teacher.

Outcome assessment

Oral examination

The DMFT (aggregate of DMFT in the permanent dentition) Indices will be recorded to assess dental caries as per WHO survey methods,²⁶ and OHI-S will be taken for assessment of oral hygiene status.

KAB questionnaire

To assess KAB regarding oral health, questionnaires will be developed for the schoolchildren based on the oral health curriculum. The questionnaire will contain closed-ended questions assessing sociodemographic characteristics along with children's knowledge of oral health, attitude regarding importance of oral health and oral hygiene behaviours adopted by them. The questionnaire will be in English language as students could follow this language.

Data collection

Data will be collected at three time points: baseline, 1 year (mid-term) and 2 years (final). The data collection tool will be a KAB questionnaire along with clinical oral examinations, including recording dental indices DMFT and OHI-S. The participant timeline is given in [figure 4](#).

Data management

The PI will be conducting all aspects of data collection and management. All participants will be given a unique study Participation Identification Number (PIN). Data will be entered under this identification number onto the laptop of the PI that will be controlled with a unique username and password. Once data entry is complete, the database will be locked prior to any trial analysis. Following consent, identifiable (consented participants only) data linked to the PIN will be held locally at the research office in a locked filing cabinet. After completion of the study, the identification, screening and enrolment logs will be

securely archived at the research office for 5 years, unless otherwise advised by the university.

Randomisation and blinding

Randomisation will be at school level (urban and rural), with each school being considered as a cluster. Blocked randomisation will be undertaken by geographical area, using a lottery method. The study coordinator and local in-charge of the respective school at each geographical site will be informed of their allocation to group A or group B.

Due to the nature of the intervention (education), blinding is not possible for this trial. We did not take this into account for the risk of bias judgements because appropriate blinding of study participants or study staff is not achievable. It is very difficult to follow blinding in educational intervention trials, especially in a school setting.

Statistical analysis plan

The observed data will be coded, tabulated and analysed using SPSS software for Windows (Verison 23). Descriptive statistics will be reported as mean±SD for continuous variables or else a median and IQR will be reported and frequency and percentage for categorical variables. KAB scores will be added and computed separately. Repeated measures analysis of variance (ANOVA) will be used to test the statistical significance of the change in KAB for oral health curriculum across time periods in each group or a McNemar's test can be used or a Cochran's Q for each interval of time. Comparison of overall KAB scores between the dentist and teacher in the intervention group will be analysed using independent t-test and with the control group will be assessed using one-way ANOVA test or a Friedman's test. In case of statistical significance, a Bonferroni multiple comparison test will be applied. Mean DMFT and OHI-S will be assessed for all groups, and comparisons will be done using one-way ANOVA test followed by post-hoc test. For oral hygiene behaviours, comparison will be done using X² test. A p value of less than 0.05 will be considered statistically significant.

Planned start and end dates

Trial start date: 1 April 2023; trial end date: 1 April 2025.

Expected outcomes

- ▶ In 2 years, we expect:
 - New dental caries increments not more than 10% due to improved knowledge in dental caries management.
 - Increased dental service utilisation and increased availing of preventive dental services.
 - Improved oral hygiene behaviour with good oral hygiene index scores due to increased knowledge of oral hygiene habits
 - Improvement in KAB regarding oral hygiene post-intervention.

	STUDY PERIOD			
	Enrolment	Start of intervention (baseline)	1 year (+/- one week)	End of intervention
TIMEPOINT	t ₀	t ₁ 0 months (+/- one week)	t ₂ 1 year (+/- one week)	t ₃ 2 years (+/- one week)
ENROLMENT:				
Eligibility screen	x			
Informed consent	x			
INTERVENTION: All participants in the intervention group will receive the intervention which consists of Dental professional (Group A) and school teachers (Group B)				
DATA COLLECTION				
Knowledge, attitude and behavior questionnaire		x	x	x
Clinical oral examination		x	x	x
DMFT		x	x	x
OHI-S		x	x	x

Figure 4 Participant timeline. DMFT, Decayed, Missing and Filled Teeth Index; OHI-S, Oral Hygiene Index-Simplified.

Trial management

The trial will be overseen by a Trial Management Group (TMG) comprising of the research heads, dean and clinical research unit head. The conduct of the trial will be advised by a Programme Steering Committee of clinical trials, which provides expert oversight of the trial, making decisions as to the future continuation (or otherwise) of the trial by monitoring recruitment, approving proposals by the TMG concerning any change to the design of the trial, as well as receiving letters of feedback from the schoolteachers.

CONCLUSION

There is no oral health component in the Indian school health curriculum, and there are currently no structured oral health initiatives for schoolchildren. As a result, the Indian health education system urgently needs a curriculum for oral health that is well planned and scheduled. An oral health curriculum can provide children with the knowledge that allows them to make judicious choices

about how they live their lives and preserve their health. The way forward for oral health promotion in children is the gradual and increasing incorporation of fundamental awareness on oral health in the form of a curriculum—the HPS concept. Interventions in the classroom can raise children’s awareness of their oral health cost effectively. If found to be effective in positively changing children’s behaviour, an oral health curriculum may be added to the school curriculum in the future.

Ethics and dissemination

► *Informed consent and assent:* as the participants are all minors, written informed consent will be obtained from the parents of the study participants. The children will give assent to confirm their willingness to participate in the study. A participant information sheet (PIS) explaining the need for the study, information on trial interventions, procedures and protocols to be followed during the study, side effects and risks, if any, benefits, confidentiality statement, right to withdraw the statement and contact details of the

investigators will be provided to the parents. The PIS will be prepared based on the informed consent form template for clinical studies prescribed by the WHO.

- ▶ **Ethical approval:** ethical approval was obtained from the Institutional Ethics Committee of Amrita Institute of Medical Sciences and Research Centre (dated: 19 July 2022, no: IEC-AIMS-2022-ASD-179). The trial was registered prospectively with the Clinical Trial Registry of India (registration number: CTRI/2022/09/045410). The study will be carried out following the trial protocol, the Declaration of Helsinki, Good Clinical Practice and local guidelines (Indian Council of Medical Research).

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Acknowledgements This research study acknowledges the support of the Indian Council of Medical Research (ICMR), New Delhi, India. The Amrita Institute of Medical Sciences and the ICMR will both receive a project report at the end of the study.

Contributors HD and CJ have made a substantial contribution to the conception, study design and revision of the manuscript. VR, VKaruveetil, VKumar and PB were involved in the design and revision of the paper. BV and DJ were involved in the drafting and revision of the protocol critically for important intellectual content. All authors have read and approved the final version of the manuscript.

Funding This work was supported by the Indian Council of Medical Research (ICMR) under the fellowship 'Nurturing Clinical Scientists' (NCS) scheme award (grant number: HRD/Head-NCS-2019 dated 30 December 2021), to HD as a part of the salary grant for PhD for a period of 3 years (fellowship stipend: 1 lakh/month INR; research contingency: 1 lakh/annum INR; total grant: 39 lakhs INR).

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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