



Design for a cluster randomized controlled trial to evaluate the effects of the CATCH Healthy Smiles school-based oral health promotion intervention among elementary school children

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ARTICLE INFO

Keywords:

Caries prevention
School-based intervention program
Elementary school children
Program design
Health promotion
Oral health related quality of life

ABSTRACT

Background: The top two oral diseases (tooth decay and gum disease) are preventable, yet dental caries is the most common childhood disease with 68% of children entering kindergarten having tooth decay. CATCH Healthy Smiles is a coordinated school health program to prevent cavities for students in kindergarten, 1st, and 2nd grade, and is based on the framework of Coordinated Approach to Child Health (CATCH), an evidence-based coordinated school health program. CATCH has undergone several cluster-randomized controlled trials (CRCT) demonstrating sustainable long-term effectiveness in incorporating the factors surrounding children, in improving eating and physical activity behaviors, and reductions in obesity prevalence among low-income, ethnically diverse children. The aim of this paper is to describe the design of the CATCH Healthy Smiles CRCT to determine the effectiveness of an oral health school-based behavioral intervention in reducing incidence of dental caries among children.

Methods: In this CRCT, 30 schools serving low-income, ethnically-diverse children in greater Houston area are recruited and randomized into intervention and comparison groups. From which, 1020 kindergarten children (n = 510 children from 15 schools for each group) will be recruited and followed through 2nd grade. The intervention consists of four components (classroom curriculum, toothbrushing routine, family outreach, and schoolwide coordinated activities) will be implemented for three years in the intervention schools, whereas the control schools will be offered free trainings and materials to implement a sun safety curriculum in the meantime. Outcome evaluation will be conducted at four time points throughout the study period, each consists of three components: dental assessment, child anthropometric measures, and parent survey. The dental assessment will use International Caries Detection and Assessment System (ICDAS) to measure the primary outcome of this study: incidence of dental caries in primary teeth as measured at the tooth surface level (dfs). The parent self-report survey measures secondary outcomes of this study, such as oral health related behavioral and psychosocial factors. A modified crude caries increment (mCCI) will be used to calculate the primary outcome of the CATCH Healthy Smiles CRCT, and a two-tailed test of the null hypothesis will be conducted to evaluate the intervention effect, while considering between- and within-cluster variances through computing the weighted-average of the mCCI ratios by cluster.

Conclusion: If found to be effective, a platform for scalability, sustainability and dissemination of CATCH already exists, and opens a new line of research in school oral health.

Clinical trials identifier: At ClinicalTrials.gov - NCT04632667.

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1. Introduction

Dental caries is a chronic disease, identified as an epidemic among American youth, particularly affecting families and children living in poverty. Over 51 million hours of school are missed every year because of dental-related problems [1,2]. Data from the 2011–2012 National Health and Nutrition Examination Survey (NHANES) indicate that approximately 56% of American children aged 6–8 years have dental caries and low-income children are particularly affected [3]. Childhood is the ideal age to develop and promote oral health enhancing behaviors (e.g. brushing, flossing, regular dental checkups, and healthy eating) and to inhibit oral health compromising behaviors (e.g. frequent consumption of sugary snacks and drinks) [1,4]. Public schools are an ideal place to reach nearly 23.9 million young children [5] in K-5 grades in the U.S. through school-based interventions, which have been shown to be an effective way to improve disadvantaged children’s health behaviors [6]. Moreover, a recent review identified a gap in the literature and the need to rigorously test theory-derived, school-based behavioral oral health interventions that include environmental components, such as supervised toothbrushing routines [7].

The Texas Education Code, Section 38.014 regulated elementary school to implement coordinated health program on oral disease

prevention [8]. Section 38.0144 is also rooted in the Center for Disease Control and Prevention (CDC) Whole School, Whole Community, Whole Child Model [5], and is in alignment with National Health Education Standards [9] and Association for Supervision and Curriculum Development standards [5]. Rooted in the CDC Whole School, Whole Community, Whole Child Model [5] and grounded in Social Cognitive Theory [10,11], Coordinated Approach to Child Health (CATCH) was developed by UTHealth researchers and follows the CDC coordinated school health 10-component model for diet and physical activity behaviors [5] and is CATCH is approved by the Texas Education Agency as a coordinated school health program. Moreover, CATCH is widely disseminated nationwide through a non-profit CATCH Global Foundation with existing digital platforms for easy access of training and program materials. Using the evidence-based CATCH framework [12–15], the CATCH Healthy Smiles program was developed as an oral health promotion intervention to address the high caries rate in American children [16]. CATCH Healthy Smiles integrated oral health education into the existing CATCH K-2 framework to develop a seamless school-based oral health program for children, and helps students and their families develop the oral health care knowledge, skills, and habits that are needed to prevent decay [16].

This paper describes the study design of a cluster-randomized

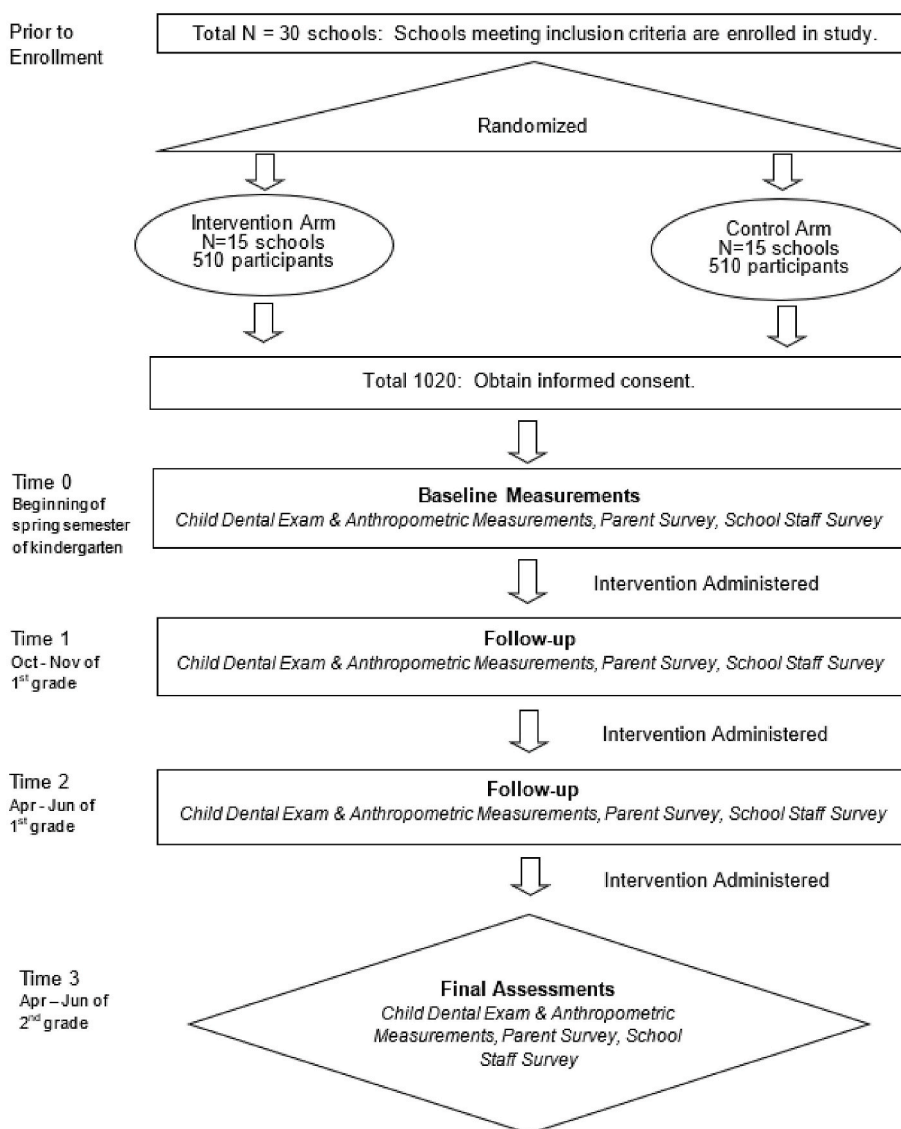


Fig. 1. Schematic of study design.

controlled trial (CRCT) to determine the efficacy of CATCH Healthy Smiles in reducing incidence of dental caries among children from low-income populations in the U.S.

2. Methods: participants, interventions, and outcomes

This study is a Phase III, parallel group, two-arm, single-center, CRCT with a 1:1 allocation ratio to determine the efficacy of CATCH Healthy Smiles in reducing the incidence of dental caries. See Fig. 1

2.1. Study setting and eligibility criteria

2.1.1. School and teacher inclusion criteria

The study setting is schools eligible meeting the following criteria: 1) located in the Greater Houston, TX metropolitan area, 2) >75% of the children enrolled in the free/reduced school lunch program, 3) plan to or have enrolled children in kindergarten in the 2021–2022 or 2022–2023 school year, 4) agree to implement the assigned intervention program, and 5) agree to participate in and assist with the measurements. All teachers and staff employed at the schools teaching the participating cohort of students are eligible to implement the intervention components. Teacher inclusion criteria for study participation include: 1) teaching students that are enrolled in the study (e.g., kindergarten teacher in year one), 2) ability to speak and read English, and 3) provide signed and dated informed consent.

2.1.2. Parent-child dyad inclusion criteria

To be eligible to participate in this study, a parent-child dyad must meet the following criteria: 1) provide signed and dated parent/guardian informed consent, 2) willing to have the same household adult complete all the surveys for the study, 3) willing to comply with all study procedures, 4) ability of the parent/guardian to speak and read in English or Spanish at a 4th grade level, 5) child enrolled in the participating school in Kindergarten grade in the 2021–2022 or 2022–2023 school year with no existing family plans to move to a different school during the study period, and 6) child ability to participate in the regular activities at school.

2.1.3. Child exclusion criteria

An individual child who meets either of the following criteria will be excluded from participation in this study: 1) any condition/disorder that may make it difficult to conduct an accurate visual examination for caries (e.g. severe fluorosis, enamel hypoplasia, special dental setting needs, severe cleft palate), or 2) any condition or situation that may interfere with the child's receipt of the curriculum components (e.g. a child consistently engaged with other therapies, instruction, or activities during the toothbrushing routine). Both exclusion criteria will be listed on the consent forms for parents/guardians to help identify the need for exclusion. Dental examiners may also identify an exclusion criterion (e.g. severe fluorosis) during the dental assessment.

2.2. Intervention and control conditions

2.2.1. Intervention condition

Developed using the intervention mapping method [17] and grounded in the Social Cognitive Theory constructs [10,11], CATCH Healthy Smiles is the oral health promotion intervention for our study. CATCH uses a train-the-trainer model whereby the teachers and school staff are trained in implementing program components. This allows for sustainability beyond the study period and capacity building within the school systems for oral health promotion and nutrition education [12, 14,18,19]. Moreover, we developed the duration of CATCH Healthy Smiles program based on prior CATCH-based studies that have resulted in positive health outcomes and behavior change for children [12,14,18, 19]. CATCH Healthy Smiles curriculum was pilot tested in elementary schools in Houston, TX in the 2016–2017 school year, and was found to

be feasible and well-received by teachers and school children [16].

Fig. 2 outlines the CATCH Healthy Smiles intervention logic model, which targets training, skill building, problem solving, communication, and practice that will affect **children's, teachers', and parents'**: (1) **knowledge and awareness**, (2) **expectations**, (3) **self-efficacy**, (4) **subjective norms**, (5) **social support**, (6) **change in behavior**, and (7) **outcomes related** to oral hygiene. Such outcomes include engaging in regular dental care, proper toothbrushing/flossing technique and frequency, healthy eating, drinking and snacking behaviors, and how it relates to oral health. These messages are operationalized via multiple components including the toothbrushing activities, coordination kit, classroom curriculum, Physical Education (PE) activities, cafeteria signage, and parent outreach activities (see Appendices A and B).

Intervention implementation: The intervention will be delivered in-person by classroom teachers, PE teachers, and the selected site coordinator (also known as the CATCH Healthy Smiles Leader). All school staff implementing CATCH Healthy Smiles can access program sessions, materials, and resources on the CATCH Global Foundation's online platform (<http://catchinfo.org/>). Program components necessary to ensure intervention fidelity are described in Table 1. Trained intervention specialists, or study staff, will provide technical assistance and support to the school teams and monitor intervention fidelity.

Classroom implementation and family outreach: The classroom teachers in kindergarten through 2nd grade will deliver each of the five, 25-min classroom sessions within a semester and send home the coordinating parent/guardian materials after each session. Additionally, teachers will administer one extension activity per month for the school year.

Toothbrushing routine implementation: CATCH Healthy Smiles Leader will lead the students in a weekly (kindergarten) or twice-a-week (1st and 2nd grades) tooth brushing routine for the duration of the school year. Students will brush their teeth for 2 min with supervision from the CATCH Healthy Smiles Leader and classroom teachers.

Schoolwide implementation: The CATCH Healthy Smiles Leader will support and ensure implementation of school-wide level through: oral health morning announcements made once monthly, themed bulletin boards posted and changed bi-monthly, one supplemental activity per month for a total of at least 5 months administered by PE teachers, and posters and cafeteria labels that will remain posted throughout the school years.

Strategies for monitoring and improving adherence: Field observations will be completed during school visits by trained study staff. Classroom teachers and CATCH Healthy Smiles Leaders at each school will also complete a short survey tracking their implementation progress (see Table 1).

2.2.2. Control condition

To ensure comparability of the intervention and control schools, all control schools will be offered free trainings and materials to implement the Ray and the Sunbeatables®: A Sun Safety Curriculum - an evidence-based curriculum that educates children, parents, and teachers about sun protection and promotes sun safety behaviors in an effort to reduce children's lifetime risk of developing skin cancer (see <https://sunbeatables.org/>). While we will track training of this program, we will not be tracking the progress of sun safety program implementation at the control schools.

2.3. Outcomes

The primary and secondary outcomes for the CRCT are described here. All other study measures are detailed in section 4.1 below.

2.3.1. Primary outcome

Child incidence of dental caries is the primary outcome for the study as measured by dental caries incidence at the tooth surface level in the primary teeth (dfs). All dental assessments will be conducted by trained

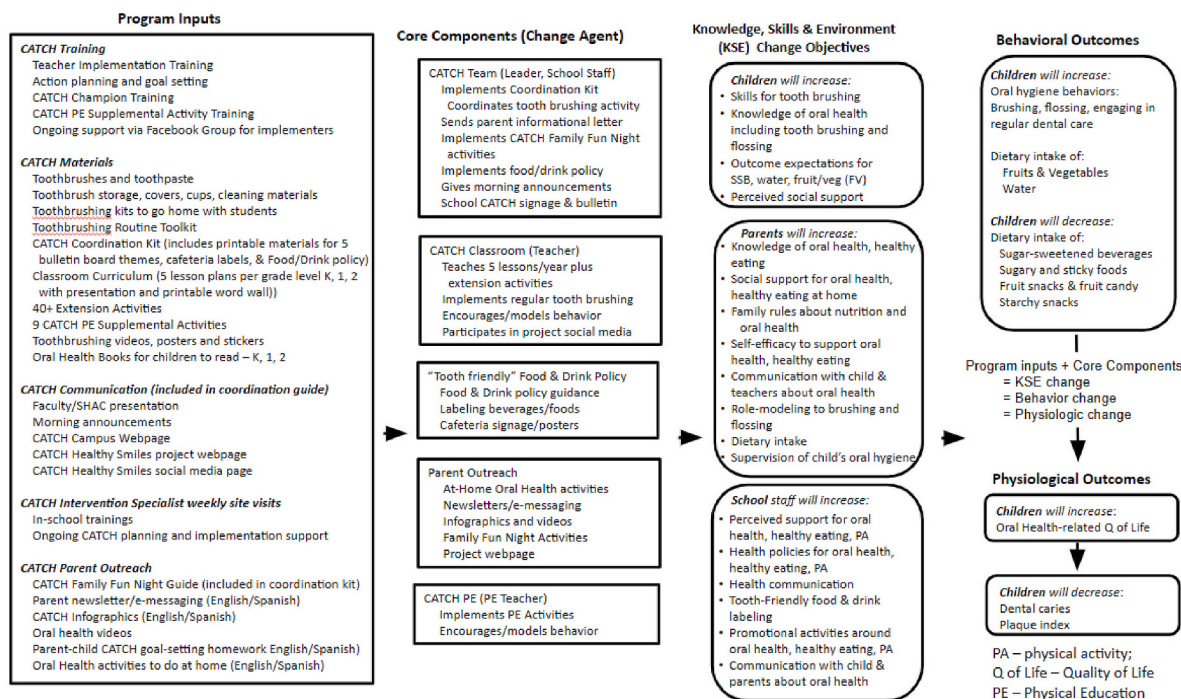


Fig. 2. CATCH Healthy Smiles intervention logic model.

dentists and recorded by trained dental assistants using the International Caries Detection and Assessment System (ICDAS) [20].

2.3.2. Secondary outcomes

The study will also assess the impact of CATCH Healthy Smiles on the incidence of dental caries in the primary teeth at the tooth level (dft), and permanent teeth at the tooth and tooth surface level (DFT and DFS respectively). This represents the number of teeth and tooth surfaces that became decayed or were treated for dental caries (by filling or extraction) after baseline among three follow-up measurements.

Behavioral, psychosocial, and environmental outcomes. The secondary aims for this study are to determine the impact of CATCH Healthy Smiles on changes in child behavioral, psychosocial, and environmental factors, including: (a) toothbrushing, flossing, and dental care frequency; (b) dietary intake, e.g., increased intake of fruits and vegetables and decreased intake of sugary cariogenic foods; (c) oral health-related quality of life; and (d) school nutrition environment. At baseline (T0) and the three follow-up assessments (T1-T3), parent surveys will be used to collect children's behavioral and psychosocial secondary outcomes. *Parents* will report on child's frequency of brushing, flossing, and dental visits, oral health-related quality of life, dietary intake, and their own knowledge of oral health, dietary intake, social support for oral health, self-efficacy to support child's oral health, communication with child and school about oral health, role modeling of oral health behaviors, family rules related to oral health, and supervision of child's toothbrushing. *School staff* will report on secondary outcomes related to the school environment, including support from school leadership for oral health-related activities, school policies, communication with students and parents, promotional activities and the labeling of cafeteria food and drink as tooth-friendly.

2.4. Participant timeline

Enrollment of parent/child dyads will occur during the second semester of the child's kindergarten year. Parent/child dyads will be measured at four time points: baseline (T0, at the start of the second semester of child's kindergarten school year prior to starting the intervention), end of kindergarten school year, end of 1st grade school year,

and end of 2nd grade school year (See Table 2).

2.5. Sample size

The primary outcome of interest is incidence of dental caries as measured at the primary tooth surface level (dfs) using ICDAS. We will dichotomize this incidence as 0 vs ≥ 1 dfs/DFS due to the sparsity of numbers greater than 1 and for a more conservative estimate of the power. Since the outcomes are dichotomized, the tooth and surface level outcomes will be equivalent and thus the sample size estimates are the same. Assuming a constant intraclass correlation coefficient ($\rho = ICC$) for all k schools (clusters) to be included, the variance of the sample proportion of the primary outcome is given by $V(\bar{Y}) = \left(\frac{\pi_1(1-\pi_1) + \pi_2(1-\pi_2)}{km} \right) \times [1 + (m-1)\rho]$ where \bar{Y} is the sample proportion of students gaining at least one caries lesion in the dentine in a tooth surface, m is the number of students in each school and ρ is the ICC. Using the ICC and the variance of the differences in the intervention group estimates from the pilot data, the team calculated the estimated number of students and elementary schools needed for varying effect sizes and for $1 - \beta = 80\%$ power with type I error rate of 0.05 (2-sided)

using the following formula: $n = \frac{(z_{\alpha/2} + z_{\beta})^2 (\pi_1(1-\pi_1) + \pi_2(1-\pi_2))(1+(m-1)\rho)}{[(\pi_1 - \pi_2)^2]}$, with

π_1 and π_2 denoting the mean proportion in the intervention and control groups at the last follow-up, respectively. This sample size is conservative given that the analytic plan will also take into account the outcome measure at baseline and thus should have increased power. Based on our pilot study [16], the team estimated that kindergarteners have a dft prevalence of $14/26 = 54\%$ and 2nd graders have a prevalence of $36/48 = 73\%$. Therefore, the team assumed an absolute increase of 19% in the control group. Assuming a test for two proportions in a cluster-randomized design with 80% power, alpha = 0.05, a within-school intraclass correlation coefficient of 0.03, the study would need 13 schools per arm, 35 kids per school to detect a 12% difference in the outcome (61% in the intervention group and 73% in the control group [21]. We will be able to detect an absolute increase of 13% in the intervention arm compared to the 19% increase in the control arm (6% difference in the outcome [22]. Therefore, the effect size is expected to

Table 1
CATCH Healthy Smiles components, fidelity monitoring, and signals triggering inadequate fidelity.

CATCH Healthy Smiles Components	Program Components Schools Should be Doing	Inadequate Fidelity is triggered	Monitored by ...
Classroom Level - Classroom Sessions	<ul style="list-style-type: none"> All 5 sessions taught once/week for 5 weeks in the fall Semester in grades kindergarten, 1st and 2nd. Students understand 75% or more of the lesson content Students engage in 75% or more of the lesson discussion and activities 	<p>Criteria to signal inadequate fidelity:</p> <ul style="list-style-type: none"> Less than all 5 sessions taught in grades kindergarten, 1st and 2nd. Teacher reported a less than 50% score of students' understanding of the class materials. Teacher reported a less than 50% score of students' engagements in the lesson. <p>Actions to address it:</p> <ul style="list-style-type: none"> The intervention specialist reaches out to the teachers/CATCH Healthy Smiles Leaders and provide technical assistance^a. 	<ul style="list-style-type: none"> Surveys at the end of each lesson to be completed by teacher Direct Observation by intervention specialists using the CATCH field checklist.
Toothbrushing Routine	<p><u>In kindergarten</u>: 1 day/week starting the same week that Session 1 is taught continuing once weekly until the end of the school year</p> <p><u>In 1st and 2nd grades</u>: 2 days/week throughout the school year</p>	<p>Criteria to signal inadequate fidelity:</p> <ul style="list-style-type: none"> <u>In Kindergarten</u>: less than 2 days/month starting with Session 1 <u>In 1st and 2nd grades</u>: less than 4 days/month for the entire school year Teacher reported a less than 50% score of students' engagements in the toothbrushing activity. <p>Actions to address it:</p> <ul style="list-style-type: none"> the intervention specialist reaches out to the teachers and provide technical assistance alert principal/CATCH Healthy Smiles Leaders to provide technical assistance^a. 	<ul style="list-style-type: none"> Weekly electronic surveys to be completed by teacher Direct Observation by intervention specialists using the CATCH field checklist.
Parent Outreach	1 set of materials (info sheet, at-home activity, video links) sent home after each classroom session (5 sets total)	<p>Criteria to signal inadequate fidelity:</p> <ul style="list-style-type: none"> (teacher) Less than all 5 sets of materials (info sheet, at-home activity, video links) sent to parents OR materials are sent out of order OR materials are combined. (parent) Less than all 5 sets of materials (info sheet, at-home activity, video links) received and reviewed. <p>Actions to address it:</p> <ul style="list-style-type: none"> the intervention specialist reaches out to the teachers and provide technical assistance^a. 	<ul style="list-style-type: none"> Electronic surveys at the end of each PowerPoint to be completed by teacher Brief electronic surveys to parents
Extension Activities	<ul style="list-style-type: none"> 2 extension activities per month after the 5 sessions are taught each school year Students engage in 75% or more of the lesson discussion and activities 	<p>Criteria to signal inadequate fidelity:</p> <ul style="list-style-type: none"> 1 extension activity every other month after the 5 sessions are taught each school year. Teacher reported a less than 50% score of students' engagements in the extension activity. <p>Actions to address it:</p> <ul style="list-style-type: none"> the intervention specialist reaches out to the teachers and provide technical assistance^a. alert the CATCH Healthy Smiles Leaders to provide technical assistance^a. 	<ul style="list-style-type: none"> Weekly electronic surveys to be completed by teacher Direct Observation by intervention specialist using the CATCH field checklist.
School-Wide PE Supplemental Activities	1 PE Activity per month starting in January (out of 9 activities total)	<p>Criteria to signal inadequate fidelity:</p> <ul style="list-style-type: none"> 2 PE activities out of 4 months per semester were not completed. PE teacher/coach reported a less than 50% score of students' engagements in the PE supplemental activity. <p>Actions to address it:</p> <ul style="list-style-type: none"> the Intervention Specialist reaches out to the PE teacher and provide technical assistance^a. 	<ul style="list-style-type: none"> End of month surveys to be completed by PE teacher/coach Direct Observation by intervention specialist using the CATCH field checklist.
Morning Announcements	<p>1 Announcement per month starting in September rotating through the themes</p> <ul style="list-style-type: none"> Sept: Brushing Announcement Oct: Flossing Announcement Nov: The Dentist Announcement Dec: Tooth-Friendly Foods & Drinks Announcement Jan: Brushing Announcement Feb: Flossing Announcement Mar: The Dentist Announcement Apr: Tooth-Friendly Foods & Drinks Announcement May: Brushing Announcement 	<p>Criteria to signal inadequate fidelity:</p> <ul style="list-style-type: none"> 2 out of 4 were not completed in the fall semester. 2 out of 4 were not completed in the spring semester. <p>Actions to address it:</p> <ul style="list-style-type: none"> the intervention specialist reaches out to the CATCH Healthy Smiles Leaders and provide technical assistance^a. 	End of month surveys to be completed by CATCH Healthy Smiles Leaders
Bulletin Boards	<p>1 bulletin board posted on a bi-monthly basis</p> <ul style="list-style-type: none"> Theme 1: September Theme 2: November Theme 3: January Theme 4: March Theme 5: May 	<p>Criteria to signal inadequate fidelity:</p> <ul style="list-style-type: none"> No oral-health related materials posted on the bulletin board observed during direct observation. <p>Actions to address it:</p> <ul style="list-style-type: none"> the intervention specialist reaches out to the CATCH Healthy Smiles Leaders and provide technical assistance^a. 	<ul style="list-style-type: none"> Direct Observation by intervention specialist using the CATCH field checklist. End of month surveys to be completed by CATCH Healthy Smiles Leaders
Posters		Criteria to signal inadequate fidelity:	

(continued on next page)

Table 1 (continued)

CATCH Healthy Smiles Components	Program Components Schools Should be Doing	Inadequate Fidelity is triggered	Monitored by ...
	<p>6 Posters hung starting in September and rotating spots periodically</p> <ul style="list-style-type: none"> ● September: Hang Brushing Directions poster in participating classrooms and choose high traffic for the rest of the posters like the bathrooms, hallways and cafeteria ● October-May: Periodically rotate the positions of the posters to keep it fresh 	<ul style="list-style-type: none"> ● No oral-health related posters hung posted observed during direct observation. <p>Actions to address it:</p> <ul style="list-style-type: none"> ● the intervention specialist reaches out to the CATCH Healthy Smiles Leaders and provide technical assistance^a. 	<ul style="list-style-type: none"> ● Direct Observation by intervention specialist using the CATCH field checklist. ● End of month surveys to be completed by CATCH Healthy Smiles Leaders
Cafeteria Labels	Cafeteria Labels placed on the food line 2x/week indicating crunchy fruits and vegetables as tooth-friendly starting in September	<p>Criteria to signal inadequate fidelity:</p> <ul style="list-style-type: none"> ● No cafeteria labels placed 2months out of 4 in the fall semester. ● No cafeteria labels placed 2months out of 4 in the spring semester. <p>Actions to address it:</p> <ul style="list-style-type: none"> ● the intervention specialist reaches out to the CATCH Healthy Smiles Leaders and provide technical assistance^a. 	<ul style="list-style-type: none"> ● Direct Observation by intervention specialist using the CATCH field checklist. ● End of month surveys to be completed by CATCH Healthy Smiles Leaders
Family Fun Nights	Activity implemented at 1 after-school event per semester (e.g. Back-to-School Night, Literacy Night, Sports, etc.) The schools are also encouraged to create an oral health-themed after school event and incorporate a selection of the activities.	None	End of month surveys to be completed by CATCH Healthy Smiles Leaders

^a Providing technical assistance includes (but not limited to): identifying barriers, troubleshoot and identify potential solutions, creating action plans, etc.

be between 6 and 12% difference between the groups. Assuming that there will be a 15% attrition rate over the study period, we planned to enroll 41 children per school. The total estimated sample size will thus be $13 \times 2 \times 41 = 1066$ children (from 26 schools). The 15% attrition rate is based on our experience with prior school-based studies conducted in similar populations [23–27]. During the initial wave of recruitment, we recruited an average of 34 students per school instead of the 41. We therefore conducted a sample size re-estimation using the 34 students instead of 41 and will increase the number of schools accordingly to 30 (15 per arm). This will lead to $15 \times 2 \times 34 = 1020$ children from 30 schools.

2.6. Recruitment

2.6.1. Recruitment of schools

Because the unit of analysis will be the school in this CRCT, recruitment starts with enrolling schools from the list of eligible schools in the Greater Houston area. First, approval for conducting the study will be obtained from the district. Then, individual schools will be approached and invited to participate.

2.6.2. Recruitment of parent/child dyads and school staff

A letter of invitation will be sent home to parents/guardians via their children to invite them to participate, and study staff will give presentations to kindergarten, first, and second grade teaching staff and parents/guardians at parent nights inviting them to participate in the research study. School staff will also be recruited in a similar manner.

3. Methods: assignment of interventions

3.1. Allocation and blinding

3.1.1. Allocation

Sequence generation. In this CRCT, schools will be enrolled into the study in academic year waves and matched into pairs based on the number of kindergarten students (weight = 1), percentage Hispanic/Latino students (weight = 1), percentage African American students (weight = 1), percentage of free/reduced lunch (weight = 0.8), and number of kindergarten classes (weight = 0.5) using optimal

multivariate matching. One school in each matched pair will be randomly assigned to the intervention and the other to the control group.

Allocation concealment mechanism. Once the cohort of schools participating in the study is finalized for the academic year, randomization will be conducted, and the schools will be notified of which arm they have been allocated to.

Implementation. Study biostatisticians will generate the allocation sequence, and schools will be matched into pairs. Parent-child dyads and staff will then be recruited from schools, and the study team will enroll participants.

3.1.2. Blinding

Only data collection staff will be blinded to the intervention assignment.

4. Methods: data collection

4.1. Data collection and quality control

Dental assessments and child anthropometric measures will be conducted by dentists and trained study staff at the schools during regular school hours at baseline and three follow-up measures. Parent and school staff surveys will be administered as a hard copy or electronically via email and/or mobile phone.

4.1.1. Dental assessment

All dental examiners will be trained and calibrated in the ICDAS dental examination protocol for examining children in elementary schools. The study team will determine inter-examiner agreement in assessing carious lesions at surface levels by re-examining all teeth surfaces in a random sample of 10% of the sample and will calculate the kappa-coefficient for inter and intra-examiner agreement. If there is a kappa score lower than $k = 0.8$ on either, dentists will discuss and resolve the doubts and differences. Dental examiners will be recalibrated annually.

4.1.2. Child anthropometrics

Child height and weight measurements will be conducted at school

Table 2
Schedule of study measures and timepoints for CATCH Healthy Smiles, a school-based CRCT.

Procedures	School Allocation	Participant Enrollment	T0 - Baseline Measurement ^a (2nd Semester Kindergarten)	Year 1 ^a Intervention implementation (2nd Semester Kindergarten)	T1 - Follow-up Measurement (Oct - Dec of 1st Grade)	Year 2 Intervention implementation (1st Grade School Year)	T2 - Follow-up Measurement (Apr-Jun of 1st Grade)	Year 3 Intervention implementation (2nd Grade School Year)	T3 - Follow-up Measurement (Apr-Jun of 2nd Grade)
School Allocation	X								
Signed Consent Form	I	X	X						
Verify Participant Eligibility Criteria		X	X						
Intervention Implementation				X		X		X	
Dental Assessment Child's			X		X		X		X
Anthropometric Measurement			X		X		X		X
Parent Survey			X		X		X		X
Teacher Survey			X		X		X		X
Assessment of Adverse Events					(X)		(X)		(X)
Monitor Intentionality Fidelity				X		X		X	

^a Initially, T0 - Baseline measurement was planned for 1st semester of kindergarten year and Year 1 Intervention Implementation was planned for kindergarten school year. Timeline shown reflects adjustments made due to the COVID-19 pandemic.

by trained project staff, and these will be used to compute Body Mass Index (BMI), which will be used to estimate child BMI z-scores and weight status [28] and could be a potential covariate in the analysis of our secondary dietary outcomes. Quality control measures for intra-rater reliability will be taken on at least 10% of the students chosen randomly. Data collectors will be recalibrated annually.

4.1.3. Survey instruments

Parent survey. Parents will self-report behavioral and psychosocial constructs on themselves and their children. Children constructs include toothbrushing and flossing frequency [29], dental visit frequency and reason [29], oral health-related quality of life [30], dietary intake, and nighttime eating after brushing [31]. Parent constructs include knowledge of children's oral hygiene (6-items [32]), social support for healthy eating [33], self-efficacy to care for child's teeth [34], communication about healthy eating with child and school [27], toothbrushing and flossing frequency [31], supervision and engagement in child's oral hygiene (12 items [35]) family rules about oral health, and perception of child's oral health [29]. All constructs will be measured in each parent survey. Additionally, at baseline, parent surveys will ascertain: child and parent age, race/ethnicity, gender, socioeconomic status, education, nativity, language spoken at home, food insecurity, and family size. All surveys (100%) will be assessed by study staff for completion and ambiguous responses. Study staff will contact study participants to obtain responses to unanswered questions or ambiguous responses.

School staff surveys. School staff will receive surveys to measure the secondary outcomes related to the school environment, school policies related to oral health (food or toothbrushing), school's oral health-related communication with students and parents, labeling of cafeteria food and drink as tooth-friendly, and promotional activities and events to support oral health.

4.1.4. Process measures

Process evaluation information will be collected throughout the school year during the implementation periods in intervention schools to help monitor fidelity and gather feedback. Process evaluation measures consist of session- and activity-specific feedback from school staff, and direct observations. For school staff feedback, those who assist with intervention implementation (e.g. principals, classroom teachers, PE coaches) will be asked to provide feedback on an electronically administered survey. For direct observation, trained study intervention specialists will visit the intervention schools to conduct field observations using the direct observation form on session- and activity-implementation and school environment.

4.2. Participant retention

To facilitate retention with high levels of family involvement, this program aims to be fun for children, engaging for parents/guardians, and culturally sensitive.

5. Methods: data management, statistical methods, and monitoring

5.1. Data management

The Data Coordinating Center (DCC) will be maintained at UTHealth by study investigators.

5.2. Statistical methods

The primary analyses will use the intent to treat cohort, where each child is analyzed according to the school's randomization assignment regardless of whether the child leaves the school or is not evaluated at the follow-up dental examinations. A secondary analysis will be conducted on the per-protocol cohort using the children that have at least

one completed follow-up dental examination.

5.2.1. Analysis of primary outcome

The primary outcome of the trial is incidence of dental caries in primary teeth as measured at the tooth surface level (dfs) using ICDAS. The decayed, missing, and filled tooth surfaces (dmfs for primary dentition/DMFS for permanent dentition) and decayed, missing, and filled teeth (dmft for primary dentition/DMFT for permanent dentition) will be assessed and captured at each dental examination visit using ICDAS, although the dfs/DFS and dft/DFT scores will be used for the analysis. The categorization of a lesion at each tooth/surface (the “d/D” component) will be based on a caries cutpoint of >2 . The threshold is chosen based on clinical rationale and good inter- and intra-observer agreement during ICDAS training. This corresponds to either a caries lesion(s) or presence of both caries lesion(s) and a restoration. If a tooth/surface has a score below the threshold, it will be considered sound. The “f/F” component corresponds to a permanent or temporary filling or when a filling is defective but not decayed. The dmft for primary teeth will be used to create the primary outcome and DMFT for permanent teeth will be used for the secondary outcome.

The primary outcome for the CATCH Healthy Smiles trial will use a modified crude caries increment (mCCI), similar to how is described in Broadbent and Thomson (2005) [36]. This will be based on the dft/DFT assessments, not considering a missing tooth as an event since assessors cannot determine the reason for a missing tooth with a visual examination only, and the team expects missing teeth to naturally exfoliate due to the age range of the children assessed. Using ICDAS, a positive lesion is defined as a decay code of 3–6 and activity code 2. A filled surface will use codes 3–9; codes 1–2 will not be considered filled. Each surface will be compared longitudinally from baseline in Kindergarten (t_0) through the last follow-up during 2nd grade (t_1, t_2, t_3). The formula for the $mCCI_i = \frac{\sum_{j=1}^n (\text{events where surface sound}_{(i_0)} \text{ but DMF}_{(i_j)})}{n}$ for an incident event at any follow-up at times $j \in \{1, 2, 3\}$ and for student i . Only primary teeth that are non-missing will be used in this calculation and tracked for an incident event when they transition to being filled or have an active lesion at any follow-up time. If the primary tooth goes missing during the follow-up, we will impute the mCCI using the worst filled or lesion code during the follow-up prior to it having gone missing. For example, if a primary surface is sound at baseline, then has an active lesion at the first follow-up and then goes missing by the last follow-up, the surface will be considered as having had an incident event for the primary outcome and be counted in the numerator of the mCCI.

With the dichotomization, this is equivalent to the tooth level (dft), but can differ if treating the outcome as the mCCI ratio (continuous variable). The numerator in the mCCI can range from 0 to 88 (five surfaces for posterior teeth and four surfaces on the anterior teeth) and is the count of the primary teeth surfaces with an incident event during any of the follow-up time points. The teeth not counted are unerupted teeth, congenitally missing teeth or supernumerary teeth, and teeth removed for reasons other than dental caries prior to the baseline visit. For dft, there are a total of 20 teeth.

For the evaluation of intervention efficacy, we will conduct a two-tailed test of the null hypothesis that the average dfs is equivalent among children in the schools randomized to the intervention compared to those in the control group, adjusted for the average baseline scores. They will use a two-stage approach where they first estimate summary outcome measures by cluster and then fit a linear regression on the cluster-level summary measures [37]. The sample size calculation considered a dichotomous dft/DFT as the outcome to be conservative. For the primary analysis, they will aggregate the continuous score by cluster since the number of clusters ($n = 26$) is not considered to be very large and this approach has been shown to conserve power and maintain type-1 error [22]. Additionally, the precision of the treatment effect estimates will be the same whether the study uses a cohort or cross-sectional design [38].

The weighted-average of the mCCI ratios will be computed by cluster, with the weights set to the inverse of the estimated theoretical variance of the cluster means: $w_i = \frac{1}{\sigma_b^2 + \frac{\sigma_w^2}{m_i}}$, where σ_b^2 and σ_w^2 are the between- and within-cluster variances and m_i is the number of students in cluster i [39].

5.3. Data monitoring

In addition to the PI’s responsibility for oversight, study oversight will be under the direction of a Data and Safety Monitoring Board (DSMB). The DSMB will operate under the rules of an NIDCR-approved charter that will be approved at the organizational meeting of the DSMB. No formal rules will be used to halt the study. However, the DSMB could make a recommendation to stop the study due to logistical or safety issues. Subsequent review of serious, unexpected, and related adverse events (AEs) by the Medical Monitor, DSMB, IRB, or relevant local regulatory authorities may also result in suspension of further study intervention or assessment. Audits independent from investigators and the sponsor will be conducted every six months.

6. Ethics and dissemination

6.1. Research ethics

The study is approved by the institutional review board Committee for the Protection of Human Subjects at the University of Texas Health Science Center at Houston (HSC-SPH-19-0838). Any amendment to the protocol will require review and approval by the IRB before the changes are implemented.

Informed consent will be obtained from all participating parents and school staff. Consent forms will be distributed by the schools and returned to study staff who will confirm eligibility. While *all* teachers and children in the participating grades at the intervention schools will receive the program components respectively, only those consenting will be measured. Child assent will be obtained at each measurement. Any student who feels uncomfortable during assessment will be allowed to opt out.

To safeguard confidentiality, the data from the dental assessment will be recorded using a HIPAA compliant capture system for clinical data. When surveys are received from the field, pages that contain participant names will be physically removed from the data and placed in separate locked file cabinets at UTHealth School of Public Health in Houston. Additional physical security features include: (a) locked access doors, (b) remotely monitored security alarms, and (c) fire detection and suppression system. Physical access to these storage areas are limited to authorized personnel. All electronic data will be stored in Redcap. Moreover, the PHI data will be entered into a separate data location apart from the survey and assessment data.

7. Discussion

This paper presents the study design for a CRCT evaluating the impact of the CATCH Healthy Smiles, a school-based oral health intervention, on reducing incidence of dental caries in low-income elementary school children in Texas. Preventing dental caries among children is a global public health priority and is proven to be preventable with lifestyle adjustments such as adequate oral hygiene, healthy nutrition, and access to care. However, the youth oral health literature reveals studies that have primarily focused on clinic and community-based interventions, while the evidence for oral health promotion in school-based settings is limited [40]. Systematic reviews of the literature have identified schools as an effective venue to successfully implement and evaluate health promotion programs to improve diet and physical activity among children [6]. Specifically, the CATCH program has demonstrated consistent significant improvements in utilizing

coordinated approach in promoting health behaviors among elementary school children from diverse populations, including dietary habits, time spent in physical activity, and reduced prevalence of obesity [12–15, 19]. Evidence suggests that long-term implementation of school-based health promotion strategies can lead to sustained behavioral change [12,41].

Furthermore, in Texas, all public schools are required to implement a coordinated health program. In 2013, an unfunded oral-health education mandate was passed in Texas [8]. Per the Texas Education Code, Section 38.0144:⁸ “Each program must provide for coordinating: (1) health education, including oral health education; (2) physical education and physical activity; (3) nutrition services; and (4) parental involvement.” Developed by UTHealth researchers and is licensed and disseminated by the CATCH Global Foundation 501c3, CATCH is a well-recognized program in Texas, and has been approved by the Texas State Board of Education. By integrating oral health education seamlessly into an existing, well-recognized CATCH K-2 framework, our study will add significantly to the body of literature on school-based oral health promotion interventions, and if successful, a platform for widespread dissemination exists.

Another important consideration is that this study is being conducted in schools that serve children from low-income and ethnically diverse families, who are more likely to experience dental caries [42]. Thus, if found to be effective, CATCH Healthy Smiles could reduce oral health disparities.

This study protocol has strengths as well as limitations. Strengths of this study include the rigorous CRCT study design, the attention control, and the objective, clinical measure of the outcomes, i.e., decayed, missing, and filled tooth surfaces and teeth. Limitations may include generalizability of the study results: since the study is only eligible for

schools with over 75% of students qualified for free and reduced-price lunch program, the findings of the study may not be applicable to all elementary schools in the U.S.

Funding

This study was funded by the National Institutes of Health/National Institute for Dental and Craniofacial Research (NIDCR) [Grant Number: 4UH3DE029213 - 02].

Study investigators no have financial or competing interests.

Protocol version

February 9th, 2022.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

Acknowledgements

The authors would like to acknowledge the UTHealth Michael and Susan Dell Center for Healthy Living, CATCH Global Foundation, and Harris County Public Health for their support on the project.

Appendices.

APPENDIX A

CATCH Healthy Smiles: Program components, implementation, and monitoring

Program Components	Program Components to be Implemented*	Monitored by ...
Classroom Sessions	All 5 sessions taught once/week for 5 weeks in grades kindergarten, 1st and 2nd.	<ul style="list-style-type: none"> Surveys at the end of each lesson to be completed by teacher Direct Observation by intervention specialists using the CATCH field checklist.
Toothbrushing Routine	<p><u>In kindergarten:</u> 1 day/week starting the same week that Session 1 is taught continuing once weekly until the end of the school year</p> <p><u>In 1st grade:</u> 1–2 days/week throughout the school year</p> <p><u>In 2nd grade:</u> 2 days/week throughout the school year</p>	<ul style="list-style-type: none"> Weekly surveys to be completed by CATCH Healthy Smiles Leaders Direct Observation by intervention specialists using the CATCH field checklist.
Parent Outreach	1 set of materials (info sheet, at-home activity, video links) sent home after each classroom session (5 sets total)	<ul style="list-style-type: none"> Weekly surveys to be completed by teacher Brief electronic surveys to parents
Extension Activities	1 extension activity per month after the 5 sessions are taught each school year	<ul style="list-style-type: none"> Weekly electronic surveys to be completed by teacher Direct Observation by intervention specialist using the CATCH field checklist.
PE Supplemental Activities	1 PE Activity per month starting in January (out of 9 activities total)	<ul style="list-style-type: none"> Monthly surveys to be completed by PE teacher/coach Direct Observation by intervention specialist using the CATCH field checklist.
Morning Announcements Bulletin Boards	1 Announcement per month starting in September rotating through the themes	Monthly surveys to be completed by CATCH Healthy Smiles Leaders
Posters	1 bulletin board posted on a bi-monthly basis	<ul style="list-style-type: none"> Direct Observation by intervention specialist using the CATCH field checklist. Monthly surveys to be completed by CATCH Healthy Smiles Leaders
Posters	6 Posters hung starting in September and rotating spots periodically	<ul style="list-style-type: none"> Direct Observation by intervention specialist using the CATCH field checklist. Monthly surveys to be completed by CATCH Healthy Smiles Leaders
Cafeteria Labels	Cafeteria Labels placed on the food line 2x/week indicating crunchy fruits and vegetables as tooth-friendly starting in September	<ul style="list-style-type: none"> Direct Observation by intervention specialist using the CATCH field checklist. Monthly surveys to be completed by CATCH Healthy Smiles Leaders
Family Fun Nights	Activity implemented at 1 after-school event per semester (e.g. Back-to-School Night, Literacy Night, Sports, etc.) The schools are also encouraged to create an oral health-themed after school event and incorporate a selection of the activities.	Monthly surveys to be completed by CATCH Healthy Smiles Leaders

* all program components are implemented by trained school staff including but not limited to, classroom teachers, PE teachers, principals, assistant principals, cafeteria staff, and school nurse.

APPENDIX B

CATCH Healthy Smiles Classroom Sessions and Student Learning Objectives

Session	Student Learning Objectives
Session 1: Healthy Smiles for Life	Students will be able to: <ul style="list-style-type: none"> · Explain teeth are important because they help us chew, talk, and smile · Explain you have to brush your teeth at least twice a day for 2 min with help from a guardian to keep teeth clean · Identify swishing with water as a way to remove stuck-on food between brushings
Session 2: Brushing	Students will be able to: <ul style="list-style-type: none"> · Explain that you have to brush your teeth at least twice a day for 2 min with help from an adult to keep your teeth clean · Describe what happens to teeth when they are not kept clean · Identify swishing with water as a way to remove stuck-on food between brushings · Describe common brushing problems and discover solutions · Create personal oral health care goals
Session 3: Flossing	Students will be able to: <ul style="list-style-type: none"> · Explain that you have to floss once a day to clean between teeth · Describe how to floss teeth · Describe what happens to teeth that are not flossed · Identify swishing with water as a way to remove stuck-on food between brushings and flossing
Session 4: The Dentist	Students will be able to: <ul style="list-style-type: none"> · Describe the dentist as a doctor who cares for your teeth · Describe the events that take place during a dental check-up · Recognize the importance of regular dental visits · Distinguish between factual and false statements about caring for teeth · Create personal oral health care goals
Session 5: Tooth-Friendly Foods & Drinks	Students will be able to: <ul style="list-style-type: none"> · Distinguish between drinks/foods that are tooth-friendly and drinks/foods that are not · Identify water as the best tooth-friendly drink · Identify swishing with water as a way to remove stuck-on food between brushings · Describe crunchy fruits and vegetables as the best tooth-friendly choices · Explain that choosing tooth-friendly drinks and foods helps to keep your smile healthy · Set a class wide goal to keep healthy smiles

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