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Family Access to a Dentist Study (FADS): A Multi-Center Randomized Controlled Trial

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Abstract

Introduction—Many low-income parent/caregivers do not understand the importance of cavity-free primary (baby) teeth and the chronic nature of dental caries (tooth decay). As a consequence, dental preventive and treatment utilization is low even when children are screened in schools and referred for care. This study aims to test a referral letter and Dental Information Guide (DIG) designed using the Common-Sense Model of Self-Regulation (CSM) framework to improve caregivers' illness perception of dental caries and increase utilization of care by children with restorative dental needs.

Methods—A multi-site randomized controlled trial with caregivers of Kindergarten to 4th grade children in urban Ohio and rural Washington State will compare five arms: (1) CSM referral letter alone; (2) CSM referral letter + DIG; (3) reduced CSM referral letter alone; (4) reduced CSM referral letter + DIG; (5) standard (control) referral. At baseline, children will be screened at school to determine restorative dental needs. If in need of treatment, caregivers will be randomized to study arms and an intervention packet will be sent home. The primary outcome will be dental care based on a change in oral health status by clinical examination 7 months post-

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screening (ICDAS sealant codes 1 and 2; restoration codes 3–8; extraction). Enrollment commenced summer 2015 with results in summer 2016.

Conclusion—This study uses the CSM framework to develop and test behavioral interventions to increase dental utilization among low-income caregivers. If effective this simple intervention has broad applicability in clinical and community-based settings.

Keywords

Dental care; Referral; Children; Caregiver; Illness perception

1. Introduction

Dental caries (tooth decay, cavities) is the leading chronic childhood disease in the United States and throughout the world [1, 2]. Ten million U.S. preschool and school-age children have untreated caries and profound disparities exist by race, socio-economic status, and geographic region [3]. Untreated cavities can lead to serious infections and pain, interference with eating/speaking, overuse of emergency departments, lost school time [4], and poorer oral health-related quality of life [5–8]. Untreated primary teeth are a strong predictor of future caries indicating the chronicity of the disease [9–12]. In the U.S., despite coverage through Medicaid, the state administered national health program, median dental utilization of low-income children is only 33–37% among the states [13, 14].

School screening has been endorsed by the World Health Organization to identify children in need of dental treatment [15]. Twelve U.S. states mandate school screening, but they do not require tracking and evaluation of children who receive referrals [16]. Recently, Nelson et al. (2012) [17] found only 19% received follow-up care after school screening, referral, and parental reminders. Studies in the U.K. have also failed to demonstrate the effectiveness of dental screening [18, 19]. Oral health education and/or motivational interviewing based on other health behavior theories have been most often used as behavioral interventions to improve dental access, but their effectiveness have been inconclusive [20, 21] and these interventions have had limited success in eliminating or reducing dental disparities in young children [22–28].

Most low-income parents/caregivers see tooth decay as acute, to be responded to only when there is pain or visible cavities [29]. One potentially useful but untested approach is the Common-Sense Model of Self-Regulation (CSM) [30, 31]. The CSM is a framework wherein individuals create a mental illness representation (or perception) based on the abstract and concrete sources of information available to them. Six key domains guide the cognitive illness representation: *Identity, cause, consequence, timeline, cure or controllability, and illness coherence*. The CSM being a “parallel-processing” model [32] requires an *emotional domain* [33] since individuals use past illness experience, cognitive, and emotional representation to self-manage their illness. In this manner the CSM is unique from other health behavior theories [34]. Illness perception has been demonstrated empirically in several medical and psychological illnesses to predict health outcomes [35–48], and in development of behavioral interventions to change perception and improve health outcomes [49–51].

This randomized controlled trial assesses the application of the CSM framework to develop behavioral interventions to improve dental access. The Family Access to a Dentist (FADS) trial employs a new CSM theory-driven referral letter and a dental information guide (DIG) to address 3 core caregiver issues – (a) importance of caries-free primary teeth for protection of permanent teeth (b) viewing dental caries as a chronic disease rather than acute; and (c) navigation of resources for dental care access. The new referral letter and DIG aims to move caregivers from an inaccurate to an accurate perception of dental caries for them to self-manage their children's cavities and seek timely care.

2. Methods

2.1. Trial Design

The FADS trial is a Phase III multi-site, double-blind, parallel-arm, community-based randomized controlled trial with five arms. The trial has been registered with [Clinicatrials.gov](https://www.clinicaltrials.gov) (NCT02395120) and is currently in the recruitment phase.

The Institutional Review Board of University Hospitals Case Medical Center, Cleveland (designated IRB) approved all study procedures with University of Washington being the reliant IRB. This protocol follows the SPIRIT [52] and CONSORT (Consolidated Standards of Reporting Trials) statements [53] and relevant extensions [54].

2.2. Research Objectives and Hypothesis

The purpose of the study is to evaluate the effectiveness of a new referral approach to increase receipt of dental care among inner-city urban African American, and rural Hispanic and White elementary school children who are screened at school and have restorative dental treatment needs. The primary aim is to evaluate the effectiveness of new interventions (CSM-based referral letter alone, CSM referral letter + Dental Information Guide: DIG) versus a standard (control) referral letter given to parents/caregivers for increasing receipt of dental care among their K-4th grade children with restorative dental needs. Additionally, we will also explore a reduced CSM referral letter with and without the DIG compared to standard letter. We hypothesized that the CSM-based interventions will increase receipt of dental care compared to the standard referral letter.

The secondary aim is to assess changes in parent/caregiver illness representation/perception and behavioral intention between enrollment (beginning of school year), and follow-up (two-week and end of school year) to understand the underlying mechanisms of the new vs. standard referral letter that result in receipt of dental care. We hypothesized the CSM-based interventions will increase receipt of dental care through the primary mediating effect of changes in caregiver illness representation/perception and thus influencing behavioral intention (mediators assessed using the Illness Perception Questionnaire – Revised for Dental (IPQ-RD) and other study measures) after controlling for child and caregiver socio-demographics.

2.3. Participant recruitment, enrollment, and retention

The study sites are in Ohio and Washington State comprising of 10 schools and three school districts. Children and their parents/caregivers will be participants of this study. The recruitment for both sites will follow a 2-stage process: (1) all caregivers of K-4 children enrolled in the respective study schools will be invited to have their children participate in the dental screening; (2) consented children will be screened and those who fulfill the inclusion criteria will be enrolled into the study. Previously successful recruitment strategies will be followed [17]. The venues for recruitment will be parent-teacher meetings, open house, curriculum nights, health fairs, and at prearranged convenient times during school drop-off /pick-up of the child. Teacher support will be gained for their assistance in sending introductory flyers and consent forms home to increase recruitment. Outreach workers will be hired from the local community to assist with recruitment at the schools. Candidates will be parent-teacher liaisons who are knowledgeable about the schools and caregivers, and who will foster trust among caregivers.

According to the two-stage process for enrollment, the *initial inclusion criteria* of parent/caregiver-child dyads are: provide signed and dated consent form (also assent form for children 7 and older); willing to comply with all study procedures and be available for the duration of the study; male or female child in grades K-4; and child in good general health as evidenced by parent report (including children with special health care needs). The *initial exclusion criteria* are: illiterate, caregiver age < 18years. In the second stage of enrollment, *additional inclusion criteria* for continuation and participation in the RCT is based on the beginning of the school year dental screening where primary caregivers will be randomized if their child has primary (canines and molars) or any permanent tooth with an International Caries Detection and Assessment System (ICDAS) active lesion score of 2 or greater (localized enamel changes to extensive cavity). At this stage, further *exclusion criteria* for non-eligibility to participate in the RCT include: Caregivers whose children have no cavities (ICDAS lesion score of < 2). These caregivers will receive the standard letter indicating the results of the screening; and caregivers of children screened who have cavities with urgent needs (1 tooth with ICDAS lesion code of 5/6 with a fistula or cellulitis). Here, the school district procedures will be followed so the child can receive emergency care. The study has a 6 week recruitment time frame starting mid-week of August 2015.

Since the protocol requires completion of questionnaires at three time points by the caregivers, several strategies will be used to retain the participants. At recruitment, necessary contact information (address, home and work telephone number, cell phone number, telephone number and contact information for close family members and friends) will be obtained. Outreach staff will review and update contact information prior to sending any materials home to the participant. Incentives will be given to the caregivers in the form of gift certificates at the time of recruitment (\$5), 2-week follow-up (\$5), and at exit exam (\$10) for the completion of study questionnaires.

2.4. Interventions

Theoretical framework and conceptual model—The experimental intervention of the new referral letter was based on the five cognitive constructs of the Common Sense Model

of Self-Regulation (CSM) [30, 31]. While this framework has not been used in dentistry, the CSM has been used to develop interventions for diabetes [55, 56], asthma [56], attendance for cardiac rehab [51], and primary care [57]. A CSM theory-based letter has been successfully shown to improve cardiac rehabilitation attendance [51, 58]. The CSM proposes that in response to a health threat, people form a cognitive and emotional representation (perception) of their illness which guides their coping and action planning, followed by an appraisal of the coping strategy. Five key cognitive constructs guiding the illness representation or perception are: *Identity*, the patient/caregiver labeling of disease and its symptoms; *Cause*, the individual's perception of the underlying cause of their illness; *Consequence*, the belief about the impact of the illness physically and socially; *Timeline*, the personal beliefs about the illness being acute, chronic, or cyclical in nature; and *Cure or controllability*, the belief whether the illness can be cured or kept under control by the individual or others. The importance of these concepts is that they are readily alterable, as opposed to many other factors in the system. The Illness Perception Questionnaire Revised (IPQ_R) [33, 59] has been used to identify these five dimensions of illness representation, together with illness coherence and emotional representation. Our research team has developed a validated and reliable Illness Perception Questionnaire-Revised for Dental (IPQ-RD) specifically addressing caregiver's perception of their child's dental caries. The psychometric properties of the IPQ-RD indicated excellent model fit (RMSEA = 0.078) and internal consistency (Cronbach's alpha >0.74).

The theory-based new referral letter includes a cognitive and resource component. For the cognitive component, the intervention letter addresses 2 core issues (baby teeth's impact on adult teeth and the disease's chronic nature). The text of the new intervention letter (Table 1), from the identity construct to timeline construct is a chain of reasoning aimed at giving information and helping caregivers understand children's dental disease. The last line (timeline construct) reinforces the two core issues (baby teeth's impact on adult teeth and the disease's chronic nature). Because the final timeline text is fundamental to improving caregiver's perception regarding chronic nature of caries we also proposed to explore the impact of a reduced new referral letter (with the timeline text removed) on our primary outcome. For the resources component, the new letter and Dental Information Guide (DIG) will address the need for adequate knowledge of resources.

Figure 1 illustrates the pathway through which the referral approaches (new letter alone, new letter plus DIG, reduced new letter alone, reduced new letter plus reduced DIG) are intended to result in action by the caregiver. The child's receipt of care will be mediated by changes in caregiver's illness representation/perception and behavioral intention, which will result from the interventions. The first mediator, caregiver's illness perception is comprised of the cognitive representation (identity, cause, consequences, controllability, and timeline sub-constructs). The second mediator is caregiver's behavioral intention [60], i.e. their motivation or intention for taking their child to the dentist. Intention to initiate an action is also the first step in action planning. The moderating variables in the model are caregiver's literacy, self-efficacy, dental fear, perceived stress, and dental insurance status.

Additionally, to test other causal explanations for the effect of the intervention letters on receipt of dental care, measures from the health belief model (HBM: caregiver beliefs and

attitudes, self-efficacy) and theory of planned behavior (TPB: subjective norms) theories will also be considered as mediators in this conceptual model. Additional mediational analysis will be conducted to explore alternative causal explanations.

Specifics of the Behavioral Intervention

Theory-based new referral letter only (Arm 1): The intervention is the CSM theory-based referral letter. The text of the letter addresses the cognitive dimensions of the CSM (identity, cause, timeline, consequences and control).

New referral letter + DIG (Arm 2): The intervention is the same letter as in arm 1 + the dental information guide (DIG) to reinforce/change illness perception, knowledge about dental caries, and resources to seek care. The dental information guide will be presented as a brochure with illustrations which provides myths and facts about dental caries, making appointments and Medicaid access, transportation and dentist availability resources. The DIG was pilot-tested and modified based on content experts, caregivers and community leaders input. While the general information on dental caries is similar for both sites, other resource information on how to seek care and a list of dentists is adapted to the specific site.

Reduced new referral letter alone (Arm 3): The intervention is a reduced (removing text corresponding to “timeline”) CSM theory-based referral letter. The letter includes the remaining cognitive dimensions of the CSM (identity, cause, consequences and control). While the last line (timeline construct) reinforces the core issues (baby teeth’s impact on adult teeth and the disease’s chronic nature), the text and constructs leading up to the last line are equally important. The final message is fundamental to the intervention letter and this version will allow an estimate of the effect of the “timeline” text itself.

Reduced new referral letter + DIG (Arm 4): The intervention is the same reduced letter as in arm 3 + a reduced dental information guide (Reduced DIG) to reinforce/change illness perception, knowledge about dental caries, and resources to seek care. As with the reduced letter, text and illustrations related to the “timeline” construct have been removed in the reduced DIG. This version will allow for an estimate of the effect of the “timeline” text and illustrations.

Modified Standard (Control) letter (Arm 5): The control is a modified standard letter (based on November 2007 guidelines for Oral Health Screening in Ohio Schools). This letter is consistent with others used across the country and will be used in both the Ohio and Washington sites.

For all arms of the study presented above, the intervention letters were tested for readability and clarity with caregivers of K-4 children. The Spanish translation of the letters was done by a native Mexican Spanish speaker and back translated by a second individual to ensure comparability. Both English and Spanish versions were written at a 6th grade level or lower. School District records include information on the primary language spoken at home.

Administration of Intervention—For all arms of the study the letters will be sent home with the child on the day of the screening and mailed to the caregiver’s address within 24

hours. The address will be obtained during recruitment and verified prior to sending the letter home.

Participant Compliance with Intervention—Procedures will be in place to ensure that the referral letters (and DIG for arms 2 and 4) are received, read, and understood. These include: 1) a numeric code (ex. 1089) at the bottom of all referral letters; 2) a trained Outreach worker (OW) will call the caregiver within 48 hours of the dental screening to confirm receipt of the referral letter. A total of 5 attempts will be made at various times during the day and evening to reach the parent/caregiver. At this call, the OW in addition to verifying the letter was received will also ask the caregiver to read the code at the bottom of the letter; 3) to ensure that caregivers read and understood the referral letter, a self-addressed stamped postcard will be enclosed with the referral letter. There will be two questions on the postcard: (a) I have read and understood the letter (yes/no); (b) I understand that my child's dental screening in the school was not a complete dental exam (yes/no). Caregivers will be able to answer question “(b)” if they read the letter because this sentence occurs in both the standard and CSM referral letters. Outreach workers will remind caregivers to answer the questions and return the postcard.

2.5. Data collection

Participants from both sites will complete all questionnaires on the same schedule (Table 2) regardless of the intervention arm.

Outcome—The primary outcome will be receipt of dental care based on a change in child's oral health status determined by clinical examination between baseline (beginning of school year) and follow-up at study exit (end of school year). This is defined as ICDAS sealant codes 1 and 2, and restoration codes 3–8 or extraction of 1 tooth previously identified with an active ICDAS lesion code of 2 at baseline. Every attempt will be made to complete ICDAS screening and follow-up to avoid missing data. Caregivers will be notified prior to the exams and urged to send the children to school. If children are absent 1 more attempt will be made to complete the dental exams on a different day.

Exams will be conducted in a portable dental chair in the schools by a dental examiner trained/calibrated in the International Caries Detection and Assessment System (ICDAS). A total of six examiners (three for each site) have been trained by a gold standard examiner in the ICDAS protocol in a 4 day training and calibration session July 20–23, 2015 prior to the start of recruitment. Excellent reliability was found between (wKappa = 0.77 to 0.95) and within examiners (wKappa = 0.78 to 1.0). Examiners will not utilize dental radiographs. All examiners will be blinded to the treatment arms of the study. At follow-up, the examiner will also not have access to the results of the first examination to avoid detection bias.

Mediator Measures—The first mediator will be change in the overall Illness Perception Questionnaire-Revised for Dental (IPQ-RD) and the cognitive (identity, consequences, timeline, cause, cure/controllability) subscale scores [33, 59, 61, 62]. The second mediator will be a change in behavioral intention [60, 63, 64]. Behavioral intention will be assessed using the caregiver questionnaire and is measured by the summative score of 2 items (e.g.,

“I want to take my child to the dentist“, and “I plan to take my child to the dentist” on a 5-point scale [63]. The use of these measures will allow us to better understand the mechanisms of action of the intervention based on our conceptual model (Figure 1). A decrease in IPQ-RD scores (i.e. lower score) indicates better illness representation/perception, while increase in behavioral intention scores indicate a higher intention to take the child to dentist for follow-up care.

The change in IPQ-RD and behavioral intention scores will be calculated between baseline and the 2-week and exit follow-ups. To assess the reliability of the IPQ-RD presumably after visits to the dentist (between 2 and 4 weeks), a sub-sample of 60 caregivers (20 each in arms 1, 2, and 4) will be randomly selected to respond to the IPQ-RD after 4 weeks. The IPQ-RD subscales have Cronbach’s alpha > 0.7 and good discriminant validity between the constructs for both English and Spanish versions. The reading level of the questionnaires is approximately 6th grade assessed by the Flesch-Kincaid Grade Level readability statistics and requires approximately 5 to 10 minutes time to complete.

All parents/caregivers will complete a paper copy of the questionnaires. If there are any unanswered questions, outreach workers will call caregivers to clarify whether or not questions were inadvertently missed.

Other moderator and confounding measures—The caregiver questionnaire will also assess moderators and confounding variables indicated in the study’s conceptual model (Figure 1). Moderators include questions regarding caregiver’s literacy [65], self-efficacy [66], dental anxiety and fear [67], perceived stress [68], caregiver dental history and child’s dental access (NHANES IV). Confounders include child’s age, race, previous dental visit, and caregiver socio-demographics (age, race, education, occupation, marital status). Education and occupation will be used to calculate socio-economic status (SES) using Hollingshead index [69]. Additionally, at the two-week and exit follow-ups caregivers will be asked debrief questions pertaining to their child’s receipt of dental care. This information will be used to qualitatively describe whether the child received care, whether treatment was completed and if not, if a follow-up appointment was made, and what helped/hindered the caregiver take/not take the child to the dentist.

2.6. Fidelity checks

The outreach and study staff, who will facilitate the receipt of intervention letters and access to the study questionnaires, attended a 3-day in-person training on the conduct of the study protocol and logistics. In-class training incorporated the topics of human subject protection, Good Clinical Practice (GCP), and the study protocol. The outreach staff will follow a standard script while talking or making calls to caregivers, and have been trained to follow the script. Fidelity of the outreach staff telephone contacts with caregivers will be assessed throughout the study to ensure that they have not provided additional information to the children’s caregivers that might influence the outcome. The first 10 calls placed by the outreach staff will be audio recorded using digital media and reviewed by the project coordinators at both sites to ensure fidelity of the calls and accuracy of data recording. Outreach staff will be provided with feedback on their performance and conduct including

but not limited to these specific areas; adherence to telephone script, adherence to protocol and good clinical practice. Outreach staff with a telephone contact with less than acceptable quality will receive a private training session focused on problematic areas.

2.7. Sample size and Power estimates

The primary outcome analysis is to compare dental care receipt among the five study arms, overall and separately for each study site (Cleveland & Washington). All changes will be recorded on a tooth level and then dichotomized at the caregiver level as having received or not received dental care for their child/children. The sample size was calculated with the following assumptions: 19% dental care receipt rate for standard letter [17], 37% rate for new letter alone (based on Medicaid utilization among children: [14]), 57% rate for new letter + DIG (based on 57% who reported that they took their child to the dentist or had an appointment after receiving the new letter + DIG in a prior R34 study within two months). Then, using a two-sided test for equal proportions (namely, a Z test with pooled variance), a sample size of 306 subjects per site will provide 80% power to detect rate differences of 19% versus 37% (Standard vs New) or 37% versus 57% (New vs New + DIG) for each site, and 98% power for each of these comparisons using the combined sample.

There are three main treatment comparisons to assess the overall CSM referral letter and DIG: CSM referral letter alone versus standard letter (Arm 1 vs Arm 5), CSM referral letter plus DIG versus standard letter (Arm 2 vs Arm 5), and CSM referral letter alone versus CSM referral letter plus DIG (Arm 1 vs Arm 2). The issue of multiple testing, both multiple comparisons and multiple sites, was addressed using a gatekeeper approach. By specifying a sequence of tests, this approach will allow for the use of a nominal 0.05 alpha level for each test while maintaining a 0.05 family-wise alpha level for the six tests (three at each study site). An additional exploratory comparison will be conducted to assess the effect of the targeted component (e.g., the 'timeline' text): CSM referral letter with and without DIG versus reduced CSM referral letter with and without DIG (Arm 1, 2 vs Arm 3, 4). As siblings (with the same caregiver) may be included in the study, a conservative approach will be to consider the required sample sizes as referring to the number of caregivers. Somewhat greater power will be expected if within-caregiver correlation is less than 1.

For the Ohio and Washington sites, an estimated total of 330 caregivers/per site will be randomized to the five groups for a total sample size of 660 after accounting for any drop-outs at randomization and still maintain the required 80% power for the trial. The two reduced letter arms will have a lower sample (12 caregivers/arm/site) randomized to this condition, while the other three main arms will have a higher sample (102 caregivers/arm/site).

With regard to the secondary outcome, the overall IPQ-RD score, the expected sample size of 660 will provide for each site 80% power to detect an 10 point decrease in the mean score (e.g., from an expected mean of 127 for the standard letter to 117 for the new letter) assuming a common standard deviation of 27 (estimated from previous data). A decrease in IPQ-RD scores indicates better illness representation of caregiver. Since the IPQ-RD has never been utilized previously, a popular rule of thumb [70] was used which considers the above standardized effect size of 0.37 (10/27) as a medium, and thus plausible, effect size.

2.8. Randomization and Blinding

Caregivers will be recruited at the beginning of the school year and complete baseline forms (consent form, Illness Perception Questionnaire-Revised for Dental (IPQ-RD) questionnaire, and caregiver questionnaire) prior to dental screening and randomization. Children in K-4 whose parents have consented will receive a dental screening exam in early October 2015. At the same time following screening exams eligible caregivers of children with restorative referrals will be randomized. Caregivers will be randomly assigned to one of the five study arms in a 17:17:2:2:17 ratio; randomization of caregivers will be stratified by their child's grade level and school. The caregivers with multiple children will receive the same treatment based upon the grade level and school of one of their first eligible child. Permuted blocks will be used to ensure approximately the targeted treatment proportions within strata. Only the biostatistician and the data manager will be aware of the blocking scheme and the actual assignments

2.9. Planned Analysis

Analysis of Primary Outcome (Dental Care Receipt)—The analysis of the dental care outcome will use a generalized estimating equations (GEE) approach [71] with a logit link and an exchangeable working correlation structure to account for correlations among multiple children for a given caregiver. The model will include indicators for the interventions, the stratification variables (school and grade) and baseline socio-demographic variables (child's age, race, and caregiver SES, education, and marital status). If interactions with intervention are found, separate models for subsets of interventions will be fit. Separate models will be fit for each site as well as overall (controlling for site).

A model-based standardization approach [72] will be used to estimate relative risks among the interventions. A bootstrap approach will be used to obtain a 95% confidence interval for each relative risk. Significance will be determined using a gatekeeper approach to hypothesis testing [73]. First, a test for a difference in dental care receipt rates for Standard vs New CSM letter + DIG at the 0.05 nominal alpha level will be performed. If and only if this test is significant, then will proceed to test (at the 0.05 nominal alpha level) Standard vs. New letter, New vs New + DIG (both), and the reduced letter comparisons.

Analysis of Secondary Outcomes (Questionnaire data)—Summary statistics (including means and standard errors) for questionnaire responses for both the IPQ-RD and behavioral intention items within the caregiver questionnaire will be calculated by site and intervention group. This will be done for the overall questionnaire (IPQ-RD and behavioral intention), for each of the five IPQ-RD constructs, and the two behavioral intention questions. Analyses will be done by site and overall (controlling for site). For each construct (or overall) a linear regression model will be used with the mean response as the (summary measure) outcome, and intervention, stratification and demographic variables as covariates. In the event of missing questionnaire responses determined to be missing completely at random (MCAR) [74], the summary measure will be computed based on available data and weights will be incorporate in the regression model to account for differential missingness. If the MCAR assumption is found to be violated, a multiple imputation approach will be used.

In addition, the mechanisms through which interventions impact dental care receipt will be investigated. Specifically, a mediation formula approach [75] will assess the proportion of intervention effects occurring through alternative paths, for example, the three-link path: through caregiver illness representation and behavioral intention. As a supplementary analysis, we will use measurements such as self-efficacy to test the Health Belief Model as an alternative explanation for the effectiveness of the experimental intervention. The relative contribution of the multiple hypothesized mediators will also be examined by including them together in a multiple mediator model.

3. Discussion

To our knowledge, the FADS trial is the *first* to develop and test oral health behavioral interventions based on the Common-Sense Model of Self-Regulation (CSM) framework [30, 31]. Our trial is innovative because it: 1) Employs a theory-based referral letter that aims to restructure the caregiver illness representation of tooth decay; 2) Uses the CSM which is a systems framework with constant feedback [76] that is useful for self-management and appraisal of illness threat. Previous behavioral interventions with oral health education and motivational interviewing have been inconclusive. (5, 6) Traditionally, oral health education has provided disjointed factual knowledge. The CSM, by incorporating the individual's cognitive and emotional representation can help connect the oral health facts with a chain of reasoning to better understand the dental caries process; 3) Tests the mechanism of the new referral letters using the Illness Perception Questionnaire for dental (IPQ-RD) that was developed specifically for caregivers of children with dental caries; 4) Addresses the three core parent/caregiver issues (importance of baby teeth, chronicity of dental caries, resources) in a completely new theoretical paradigm. Although a letter and Dental Information Guide (DIG) may be considered as simple interventions, their basis is in theory with an explicit causal mechanism of action which fit the U.K. M.R.C. guidelines of a complex intervention [77]. Such a grounded approach has shown to be effective in increasing cardiac rehabilitation rates [51]. On a practical level, the referral letter also informs the parent/caregiver the results of their children's dental screening exam.

School screenings have not been successful in stimulating dental attendance for children who need care ([17–19]. Therefore, the theory-based letter and Dental Information Guide that is used in this trial may be instrumental in increasing effectiveness of school screening now mandated in 12 states and conducted voluntarily in many others. It also addresses limitations in school-based programs [78]. This is the first significant improvement in school-based oral health care in years. This approach is potentially cost-effective, easily transportable, and sustainable because it uses fewer resources. The approach can be adapted to federally qualified health centers (FQHCs) and clinics serving low-income families, where caregiver follow-through is problematic.

There may be potential limitations as with all studies. *First*, it is possible that the sample size may not be achievable if the enrollment of K-4th grade children is lower in the proposed schools than in previous years or if there is decreased caries rates among these children. We are unable to control for these unforeseeable changes in these schools. *Second*, it is also likely that caregivers may not read the letter and DIG carefully. But, having a numeric code

in the referral letters that the caregiver reads to the outreach staff, and also replying to two questions in the postcard to be returned may be simple strategies to monitor compliance. Our study can be helpful in finding out if this strategy does work to monitor compliance. Further, the referral letter also gives the results of the screening exam that most caregivers would want to know regarding their child's dental status. Also, for those caregivers randomized to the arms that also receives the DIG, they have been designed to be visually illustrative and appealing to a low-income population. We expect adherence to the intervention to be high due to our efforts to address the letter and DIG's literacy level and to be visually interesting. Our pilot-testing of these interventions showed that caregivers were engaged and informed by the letter and DIG.

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Abbreviations

CSM	Common-Sense Model of Self-Regulation
ICDAS	International Caries Detection and Assessment System
IPQ-RD	Illness Perception Questionnaire Revised for Dental
DIG	Dental Information Guide

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Figure 1.
Conceptual model describing the pathway mechanisms of the proposed new interventions in the FADS trial

Table 1

New intervention letter text and associated Common-Sense Model of Self-Regulation (CSM) constructs

Intervention letter text	CSM construct
Cavities are the #1 childhood health problem . Children may have cavities even if they do not have pain . Cavities should be treated when found.	Identity
Cavities can be serious in baby teeth. Cavities can affect children's learning and how they look and feel about themselves .	Consequences
Other health problems may not be under your control. But, you can prevent cavities by taking your child to the dentist at least once a year . Your child will benefit from this greatly.	Controllability
Cavities do not just happen. Bacteria cause cavities . A dentist can clear up the bacteria.	Causes
If cavities are not treated, the bacteria in baby teeth can affect adult teeth .	Timeline

Table 2

Summary of study measures and timeline in the FADS trial

Variable Type	Measure	Timeline ¹
Intervention Study Arms	<ul style="list-style-type: none"> • CSM referral letter alone • CSM referral letter + DIG • Reduced CSM referral letter alone • Reduced CSM referral letter + DIG • Modified Standard letter 	At randomization
Primary Outcome	Dental exams <ul style="list-style-type: none"> • Child's receipt of dental care 	Beginning and end of school year
Secondary Outcomes (Mediators)	IPQ-RD <ul style="list-style-type: none"> • Caregiver illness perception Caregiver Questionnaire <ul style="list-style-type: none"> • Behavioral intention 	Baseline, Two-week, and Exit
Moderators	Caregiver Questionnaire <ul style="list-style-type: none"> • Caregiver literacy • Caregiver self-efficacy ² • Caregiver dental fear • Caregiver perceived stress • Subjective norm ² • Dental insurance status Site (urban/rural)	Baseline
Confounders	Child's age, race, dental visit Caregiver socio-demographics (age, race, SES, education, marital status)	Baseline

¹ **Baseline:** prior to screening dental exam; **At randomization:** after baseline dental screening exam; **Two-weeks:** Two weeks after randomization; **Exit:** two weeks before end of school year dental exam

² Caregiver self-efficacy and subjective norms will also be considered as potential **mediators** in the additional mediational analyses, and will be measured at the **Exit** in addition to **Baseline**.