

## Preventing caries in preschoolers: Successful initiation of an innovative community-based clinical trial in Navajo Nation Head Start ☆

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### ABSTRACT

Navajo Nation children have the greatest prevalence of early childhood caries in the United States. This protocol describes an innovative combination of community-based participatory research and clinical trial methods to rigorously test a lay native Community Oral Health Specialists-delivered oral health *intervention*, with the goal of reducing the progression of disease and improving family knowledge and behaviors.

**Methods/Design:** This cluster-randomized trial designed by researchers at the Center for Native Oral Health Research at the University of Colorado in conjunction with members of the Navajo Nation community compares outcomes between the manualized 2-year oral health fluoride varnish-oral health promotion intervention and usual care in the community (*child-caregiver* dyads from 26 Head Start classrooms in each study arm; total of 1016 dyads). Outcome assessment includes annual dental screening and an annual caregiver survey of knowledge, attitudes and behaviors; collection of cost data will support cost-benefit analyses.

**Discussion:** The study protocol meets all standards required of randomized clinical trials. Aligned with principles of community-based participatory research, extended interaction between members of the Navajo community and researchers preceded study initiation, and collaboration between project staff and a wide variety of community members informed the study design and implementation. We believe that the benefits of adding CBPR methods to those of randomized clinical studies outweigh the barriers and constraints, especially in studies of health disparities

**Abbreviations:** AI/AN, American Indian/Alaska Native; BRFQ, Basic Research Factors Questionnaire; CBPR, community-based participatory research; CNOHR, Center for Native Oral Health Research; COHS, Community Oral Health Specialist; DCC, data coordinating center; dmft, decayed, missing and filled teeth; ECC, early childhood caries; FV, fluoride varnish; HS, Head Start; HSC, Head Start Center; IHS, Indian Health Service; NIDCR, National Institute of Dental and Craniofacial Research; NN, Navajo Nation; NNHRRB, Navajo Nation Human Research Review Board; OHP, oral health promotion.

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and in challenging settings. When done well, this innovative mix of methods will increase the likelihood of valid results that communities can use.

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## 1. Introduction

Early Childhood Caries (ECC) is defined as dental caries (commonly known as dental decay) in the primary teeth of children aged 6 years or younger [1]. Although ECC is largely preventable, it is the most prevalent chronic infectious disease in children in the United States [2], and the level of disease seen in American Indian/Alaska Native (AI/AN) children is by far the highest, suggesting disparate risk and the need for effective, culturally accepted interventions [3–5]. The most recent Indian Health Service (IHS) report cites caries rates of 68.4% for AI/AN preschool children (45.8% with untreated dental decay) and a mean decayed and filled teeth (dft) measure 3 times greater than for their non-Native counterparts [3]. In the Navajo population, dental decay among preschool children is especially severe; a recent survey reported a mean prevalence of 6.5 decayed, missing, and filled teeth (dmft) for 2–5 year olds [3], the highest in Indian Country.

Simple clinical procedures such as the application of fluoride varnish (FV) and oral health promotion (OHP) activities have shown promise in the prevention of ECC [6,7]. Among clinical interventions to prevent caries in children, the use of fluoride demonstrates the strongest evidence base and most predictable success [8,9]. FV, a professionally available topical agent, has been employed in the prevention of caries since 1964. The unique and favorable clinical characteristics of FV have prompted the publication of clinical practice recommendations from the American Dental Association and the American Academy of Pediatric Dentistry [10] that support off-label use of FV as the preferred technique for cost-effective caries prevention in children under the age of six [11,12]. The goals of OHP programs for children and caregivers are to increase knowledge, encourage positive attitudes toward oral health care, and improve parental behaviors related to ECC and contributing factors such as regular dental visits, feeding and nutrition, and oral hygiene practices [6]. With the possible exception of interventions focused on nutrition education [13], the few well-designed dental health education intervention studies have not found strong evidence that interventions relying on OHP alone result in long term behavior change with significant reductions in caries incidence [6,14–16].

Although OHP alone may not produce desired behavior change, relatively simple intervention approaches that combine FV with OHP activities for children and parents in a community-based setting appear to offer effective and efficient ECC prevention [6]. Dental providers are not always available, especially in geographically isolated communities. In other areas of health care, trained paraprofessionals from the community (including Community Health Representatives in AI/AN communities [17]) have effectively delivered services, because members of a community are better able to communicate with patients and understand the barriers to care [18,19].

This paper describes the protocol for a study to assess the effectiveness of a combined OHP–FV intervention for children

enrolled in the Navajo Nation (NN) Head Start (HS) program and their parents/caregivers (“caregivers” henceforth), delivered by lay AI Community Oral Health Specialists (COHSs). The primary outcome measure is reduction in caries increase for children receiving the intervention, compared with children in similar HS Centers receiving usual care only. We are unaware of any other pediatric OHP–FV clinical research trials conducted on NN.

## 2. Rationale

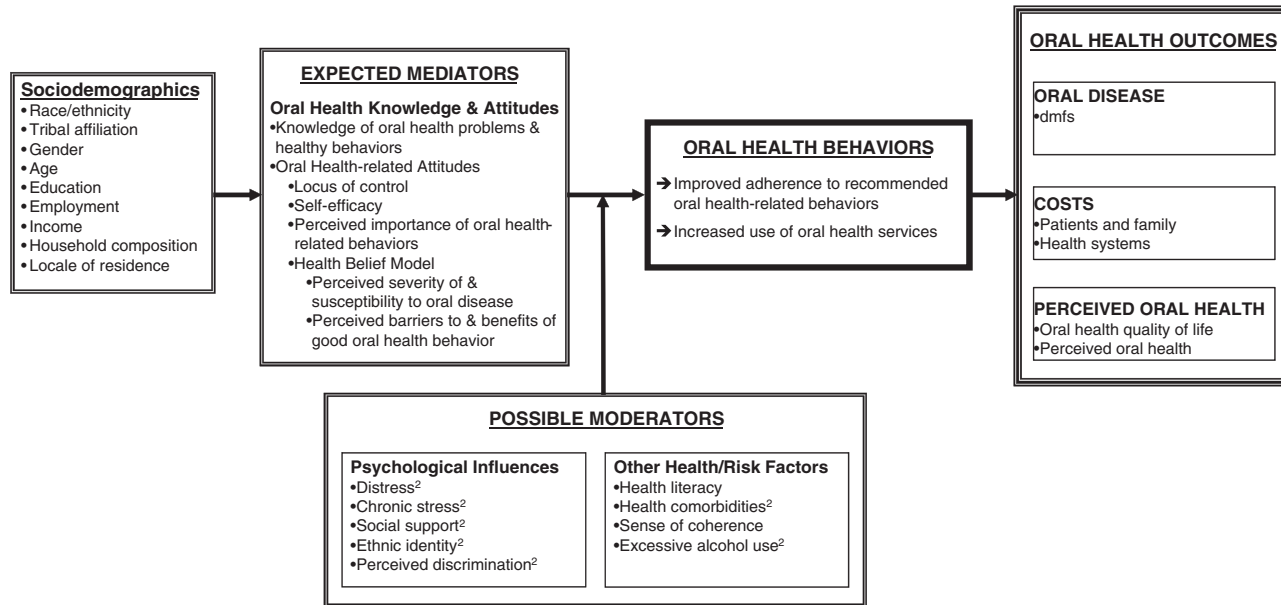
### 2.1. Combined research strategies

The protocol for this study combines community-based participatory research (CBPR) and clinical trial methods. Community ownership contributes to effective, culturally sensitive health interventions [20,21]. CBPR collaboratively engages community and academic partners in a manner “that equitably involves all partners in the research process and recognizes the unique strengths that each brings” [22]. Advantages include the ability to test an intervention in real-world samples that reflect the community population of interest and place greater importance on sensitivities of the community, but the quasi-experimental design of most such studies excludes an unbiased comparison group. Clinical trials generally remove the selection bias by drawing participants from a carefully selected sample (i.e., excluding individuals with potentially confounding characteristics) and randomly assigning them to study arms but may have other restrictive criteria that can impede community participation in and understanding of the design and implementation of a low-risk research study.

Few clinical trials to date have incorporated CBPR methods. De Las Nueces et al. [20] conducted a review of recent peer-reviewed literature (2003–2010) and found only 19 articles that reported such studies. None of the studies took place in AI/AN settings or addressed oral health (one examined parent/child relationships; 10 explored weight, nutrition, physical activity, smoking, and/or blood pressure). Reported CBPR methods generally, but variably, included community involvement in identifying the problem, recruitment, intervention development and delivery, data collection, or a community advisory group. Fewer reported community involvement in interpreting analytic results or disseminating findings. Ten of the studies used a cluster randomization similar to that used in the study reported here.

Investigators in the Center for Native Oral Health Research (CNOHR) and the Centers for American Indian and Alaska Native Health designed this protocol, building on a strong foundation with the community beginning long before study initiation. They shared (and continue to share) the community’s commitment to better health for their children and developed an intervention acceptable to the community while also employing scientifically valid clinical trial methods.

**Conceptual Framework for the Clinical Research Trial**



**Fig. 1.** Conceptual framework.

## 2.2. Conceptual framework

Fig. 1 provides a schematic of the conceptual model for this study, adapted from the MacArthur Foundation Research Network in Socioeconomic Status (SES) and Health model of pathways from SES to health [23] to incorporate factors that have special relevance in AI/AN communities. From this model, we expect the intervention to affect not only the primary outcome of caries but also several secondary outcomes, including cost of oral health care. We also anticipate that factors such as knowledge, attitudes, and behaviors will moderate or mediate responses to the intervention and that stress and social support may influence how individuals respond to the intervention.

The primary hypothesis of this study is that an intensive 2-year intervention in which specially trained COHSs offer fluoride varnish (FV) four times per school year to AI children aged 3–5 years at their enrollment in HS classrooms and multiple oral health promotion (OHP) activities to those children and their caregivers (Group 1; 26 classrooms) vs. the delivery of usual oral health care made available in the community (Group

2; 26 classrooms) will: 1) reduce the decayed, missing, and filled primary tooth surfaces (dmfs) increase over two years in the Group 1 children when compared to the Group 2 children, and 2) result in improved caregiver dental knowledge, attitudes, and behaviors.

## 2.3. Specific aims

The study has the following primary specific aims:

1. To develop, with input from tribal/community members, a manualized intervention for an ECC prevention program to be delivered by specially trained community lay health workers (COHS)
2. To implement and evaluate the delivery of a combined FV–OHP program in Navajo Head Start classrooms, comparing intervention and usual care groups
3. To assess effectiveness by comparing decayed, missing, and filled primary tooth surfaces (dmfs) over time between the two groups.

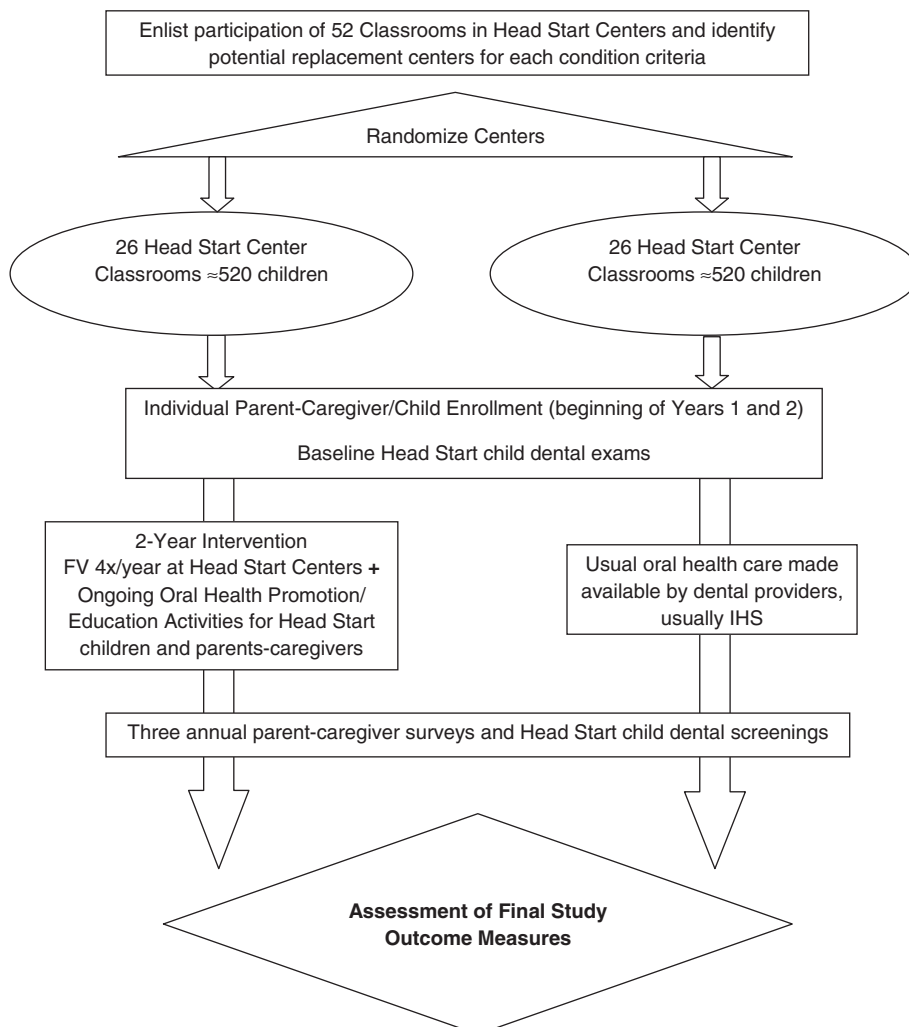


Fig. 2. Schematic of study design.

In addition, the study has the following secondary objectives:

1. To assess specific caries patterns (the site and location of decay provide an indication of the underlying cause of decay, e.g., impacted food vs. baby-bottle tooth decay)
2. To investigate moderators/mediators of the intervention conditions
3. To investigate participant utilization of medical and dental services for oral health problems and compare oral health care costs between the two groups.

### 3. Methods

#### 3.1. Study design

This study is a cluster-randomized trial (Fig. 2) designed by researchers at CNOHR in conjunction with members of the NN community to compare outcomes between an oral health intervention delivered by trained COHS and usual care in the community. CNOHR is one of three Early Childhood Caries Collaborating Centers funded by the National Institute of Dental and Craniofacial Research (NIDCR) to focus on oral health disparities and the only one that addresses specific needs of the AI/AN population.

#### 3.2. Setting

The NN is home to more than 170,000 Navajo (also called Diné). Encompassing over 27,000 square miles, the reservation is the largest in the US and covers more area than the 10 smallest states in the country. Administratively, 110 chapters provide structure for the tribal government, and 5 agencies comprise the organizational units for service delivery. Researchers advised by AI community members decided to focus on the potentially high-yield strategy of collaborating with Navajo Nation Head Start, which has a broad reach in AI/AN communities.

#### 3.3. Acquisition of Navajo Nation tribal and local community support and research approval

Prior to funding, representatives of the tribe (Navajo Nation Head Start directors, health coordinators, family service workers, tribal chapter leaders, child health and dental professionals, and others who provided important consultation and support) provided input to the planning of this research project, beginning with a meeting with the researchers.

Once the proposal was funded, the Principal Investigator and the Navajo community liaison (a NN tribal member) spent approximately 18 months introducing and explaining the study to community members and tribal leaders throughout the NN. Then study investigators conducted the formal processes of obtaining the necessary tribal and local approvals including a full review by the Navajo Nation Human Research Review Board (NNHRRB).

From the various NN-wide contacts, several individuals were selected to serve as members of the Community Advisory Board. They reviewed all intervention activities and materials and provide ongoing community oversight, advice, and encouragement.

#### 3.4. Acquisition of institutional approval

In addition to review and approval by the NNHRRB, the study was reviewed and approved by the Colorado Multiple Institutional Review Board and the funding agency, the NIDCR.

#### 3.5. Selection of control group

A strength of clinical trials is the ability to compare results between randomly selected groups who do and do not receive an intervention. In Native communities, potential participants may view the random assignment as unfair, especially if the study offers nothing of concrete benefit to the reference (control) group. Because all NN children have FV available to them through IHS services, researchers decided on (and the community accepted) “usual care in the community” as the control condition. “Usual” rather than “standard” better describes care available in this real-world community setting in which oral health services (both IHS and private providers) and access to them vary a great deal.

#### 3.6. Study participants and enrollment

Eligible participants include children aged 3–5 years at the time of their enrollment into HS and a caregiver for each child enrolled in the study. Children were AI or children of other races/ethnic groups enrolled in the HS classes on the reservation. Children younger than 3 years of age at the time of HS enrollment, children without a consenting legal guardian, and adults unable to understand English well enough to consent or to complete the computerized survey in English were excluded. In addition, in intervention classrooms, children were excluded if they presented with an allergy to any components of the FV or if they were home-based rather than enrolled in the HS classroom. All other children and their caregivers were actively recruited to join the study.

Enrollment occurred in all study classrooms at the beginning of each of the two intervention years (Cohort 1 and Cohort 2). Cohort 2 recruitment and enrollment focused on eligible children and caregivers either new to the HS program or initially uninterested in participating. When possible, Cohort 1's adult participants were re-consented in order to allow communication using text messaging, which was not included in the original consent form and for which NNHRRB required the additional consent. These activities also served to maintain contact with families whose children had “aged out” or were no longer enrolled at that particular HS. Cohort 1 participants in the intervention arm of the study whose children remained in HS for the two years had the opportunity to receive the full 2-year “dose” of the intervention; Cohort 2 participants and those Cohort 1 participants whose children left HS (usually to enter elementary school) received only one year of intervention exposure.

Field staff visited each study HS classroom to introduce the study, while also collecting data about non-study dental health activities that occur regularly in the classroom and information about FV provided in the classroom from other sources as well as information about the levels of fluoridation in community water; they repeated the visits at the beginning and end of each intervention year. HS teachers and staff sent study information flyers to all families and actively promoted recruitment through their everyday contacts with the families.

In an 8-week period, offering two separate enrollment opportunities, 3-member trained research enrollment teams (field staff and/or COHS) assigned to specific geographic areas completed the consent and enrollment process. Consent differed by age: participating adults, whether parents or other primary caregivers, consented for themselves if aged 18 or older; parents aged 15–17 although able to provide consent for their children needed the consent of their parents for their own participation. The enrollment process included observing and recording the child's caries experience and having caregivers complete a computer-based survey that is described in the “Outcome measures” section.

### 3.7. Intervention

“Manualized” intervention. The investigators developed a manual that describes the intervention in detail sufficient for reproduction, assurance of fidelity, and ultimately dissemination if proven effective.

#### 3.7.1. Development and COHS training

Oral health and behavioral science experts developed the FV–OHP intervention and prepared training and intervention manuals. Study personnel recruited, hired, and trained eight tribal community members as COHS to deliver the intervention. All of them had at least bachelor's level education or equivalent experience. Training included an initial week of orientation to the project: instruction in oral disease and health, introduction to relevant behavioral and educational foundations, preparation for enrollment, and acquisition of required research training and credentials. The university study personnel (including a pediatrician, a registered dental hygienist, a biochemist, and a behavioral scientist) then provided a second week of hands-on intervention and FV application training in the field, with an additional intervention training session just before initiating the program in the field and subsequent periodic refresher sessions. Each COHS had responsibility for 3–4 classrooms and worked closely with the HS teachers in their classrooms to coordinate events and communicate with families.

The field staff dental hygienist trained the COHS to understand the function and application of FV and provided hands-on experience. The 3M ESPE VANISH™ is a 5% sodium fluoride white varnish distributed in 0.5 ml sealed unit dose packages, with dosage stickers to measure the quantity dispensed per

application. Each COHS documented every application (with up to three follow-up opportunities in each classroom within the specified “treatment” window to capture children who might be absent) and contacted the caregivers within a specified interval after each application to check for any unanticipated reactions. The dental hygienist conducted periodic unannounced quality assurance assessments throughout the year.

#### 3.7.2. Intervention activities

The intervention included both the application of FV for the children and OHP activities for children and caregivers. Four times each school year, the COHS applied FV to teeth of those intervention arm's children in the HS classroom during repeated visits (see Table 1). Children or their caregivers could refuse the FV, but none did, although occasionally a child resisted the application. Participants in the usual care arm were not prevented from receiving FV from other sources as part of usual care but did not receive FV or any “dose” of the OHP activities from study personnel.

All families received toothbrushes and toothpaste for all family members at enrollment; intervention children and participating caregivers received additional supplies throughout the study period. The commercially available toothpaste contained 0.243% sodium fluoride, the standard for both adult and child toothpastes in the United States.

The COHS also provided OHP activities to children five times per year and to caregivers four times per year. OHP activities began with a kick-off event for caregivers and children that introduced the project. The kick-off provided an opportunity for caregivers to experience daily classroom oral health activities, see how fluoride varnish is applied, and become acquainted with future activities, while engaging the children in age appropriate classroom oral health activities (e.g., exploring their faces and mouths and demonstrating to their caregivers how they brush their teeth at HS).

The remaining three parent events, which occurred at various times and locations to maximize attendance, included 1) an overview of the importance of primary teeth, prevention of tooth decay, consequences of tooth decay, and caregivers' roles in prevention; 2) two small-group OHP activities; 3) a simple goal-setting activity; and 4) a fruit basket raffle for enrolled caregivers who attended. The remaining four child events incorporated brief, highly interactive activities into a HS classroom session. Topics included teeth, tooth brushing, nutrition (avoidance of sticky foods), visiting the dentist, and fluoride.

**Table 1**

Yearly intervention timeline.

	November	December	January	February	March	April	May
Kick-off event	X	MU					
Parent event 2		X	MU				
Parent event 3			X	MU			
Parent event 4							
Child event 2		X	MU			X	MU
Child event 3			X	MU			
Child event 4				X			
Child event 5					MU		
Fluoride varnish 1		X	MU		X	MU	
Fluoride varnish 2			X	MU			
Fluoride varnish 3				X	MU		
Fluoride varnish 4					X	MU	

Note. MU = make-up sessions.

**Table 2**

Explanation of measures in the basic research facts questionnaire.

Measure <sup>a</sup>	Description	Range <sup>b</sup>
<i>Oral Health Locus of Control</i> 3 Subscales	Locus of Control (LOC) measure captures a person's attitudes about who or what has control over their child's oral health outcomes (i.e., the parent themselves, other people, or chance).	1–5 1 = strongly disagree 5 = strongly agree
Internal Locus of Control (3)	Each subscale represents the average score for all items within the subscale and represents the extent to which participants believes control for their child's oral health outcomes lies with the parent (internal LOC), the dentist (powerful other LOC), or is up to chance (chance LOC).	
External Locus of Control – Powerful Others (3)		
External Locus of Control – Chance (3)		
<i>Health Belief Model</i> 4 Subscales	The Health Belief Model is one of the major models intended to explain health behavior. The model predicts that behavior is a function of the subscales.	1–5 1 = strongly disagree 5 = strongly agree
Perceived Susceptibility (3)	Perceived susceptibility – How susceptible does a parent feel his/her child is to poor oral health outcomes?	
Perceived Seriousness (3)	Perceived severity – How severe does the parent think developing caries would be?	
Perceived Barriers (5)	Perceived barriers – Does the parent perceive many barriers to following recommended oral health behavior?	
Perceived Benefits (5)	Perceived benefits – Does the parent perceive many benefits to following recommended oral health behavior?	
Self-Efficacy (14)	Self-efficacy represents a person's confidence that he/she can successfully engage in a specific health behavior. The overall self-efficacy score represents how sure participants are that they can engage in recommended behavior to take care of their children's teeth.	1–5 1 = Not sure at all 5 = extremely sure
Importance (14)	The overall importance score represents how important it is to participants that they engage in specific oral health behaviors (the same behaviors as mentioned above, for self-efficacy).	1–5 1 = not at all important 5 = extremely important
<i>Sense of Coherence</i> 3 Subscales, and overall score	Sense of Coherence (SOC) is a construct intended to assess the degree to which participants feel the world makes sense and has meaning.	1–7 Higher numbers indicate stronger coherence
Comprehensibility (5)		
Meaningfulness (4)		
Manageability (4)		
Overall Sense of Coherence (13)		
Distress (6)	The overall distress score represents the amount of distress participants have experienced in the last 30 days.	1–5 1 = none of the time 5 = all the time
<i>Chronic Stress</i> 5 Subscales	Chronic Stress captured ongoing stress related to personal expectations, hassles associated with the local community, and community dysfunction.	1–4 1 = strongly disagree 4 = strongly agree
Expectations (3)		
Location Hassles (5)		
Community Family Dysfunction (2)		
Community Risky Behaviors (5)		
Community Economic Distress (2)		
Perceived Discrimination (9)	The perceived discrimination measure represents the amount of discrimination participants feel they are subject to, on account of being American Indian.	1–4 1 = never 4 = often
Oral Health Behavior (9)	The overall behavior score represents the percentage of oral health behavior items that were answered with an "adherent" response. Adherent means the participant is following the recommended oral health behavior.	0–100%
Oral Health Knowledge (14)	The overall knowledge score represents the percentage of oral health knowledge items answered correctly.	0–100%
Alcohol Use (3)	A shortened version of the Alcohol Use Disorders Identification Test (AUDIT). Because the shortened version includes only the three consumption items, it is referred to as the AUDIT-C. The alcohol score provides an indication of the degree to which a participant drinks excessively.	0–12 Large numbers represent greater alcohol use
Social Support (4)	The Social Support score represents the average score for items within the Instrumental Social Support section of the Oral Health Survey. This overall score indicates the degree to which participants believe they have others available to help them when needed.	0–1 0 = no available support 1 = support available
Financial Stability (4)	The Financial Stability score is a measure of the degree to which participants feel they have adequate access to the basic things people need, such as food and clothing.	0–1 0 = financially unstable 1 = financially stable

Note:

<sup>a</sup> In the first column, numbers in parentheses represent the number of items in the scale/subscale.<sup>b</sup> "Range" indicates the range of the computed scale/subscale.

Fidelity. The dental hygienist monitored each COHS' initial fluoride applications in the classroom at the beginning of each intervention school year until the COHS achieved and maintained protocol-specified standards and a second time during later period of the HS school year. Trained quality monitors observed all parent OHP events and one student activity (in addition to the kick-off event) in each classroom each year, and they recorded and if possible corrected any deviations from the intervention protocol on the spot. Weekly meetings of study and field staff provided opportunities for discussion, and study staff provided refresher training as needed.

### 3.8. Outcome measures

Timing. Baseline data (dental screening of children and caregiver surveys) were, and continue to be, collected at baseline (at the beginning of the study for Cohort 1, at the beginning of the second study year for Cohort 2) and annually throughout the study (i.e., 4 iterations for Cohort 1, 3 iterations for Cohort 2, including baseline).

Dental caries. The study's primary outcome measure is the number of decayed, missing and filled tooth surfaces (dmfs) of the child and its change over time. Study-trained and calibrated licensed dental hygienists blinded to the study condition conducted visual screenings of the enrolled children's mouths at baseline and will do so annually through the duration of the study (total of four screenings for Cohort 1 and three for Cohort 2). Trained study personnel also blinded to the study condition record the observations, using an electronic dental research record designated as CARIN (CARIES Research Instrument) specifically designed for documentation of the dmfs measure.

The dental hygienists conduct the screenings using a head lamp (Surgitel) and lighted mouth mirror (Defend MirrorLite Illuminated Mouth Mirror brand and type). They brush the teeth to remove debris, dry them with gauze, and then systematically evaluate them for the presence of decayed and filled surfaces. Caries detection and measurement criteria as described by Pitts [24,25] are used to visually evaluate and score lesions [26].

If the hygienist observes a "dental emergency" (e.g., a dental abscess) in a study child during a screening in the HS classroom, she or he refers the child to the HS teacher, who has HS procedures in place for managing medical emergencies. If the screening occurs elsewhere (e.g., in a Chapter House during follow-up data collection for families whose children no longer attend HS), then the hygienist advises the parent to seek dental care for the child.

Prior to study initiation and annually during the study, examiners were and will continue to be calibrated to a "gold standard" dentist to ensure that the study examiners can collect data consistently during the study. The calibration consists of conducting multiple dental examinations of the same children by different examiners to measure the degree of agreement among examiners. Each examiner was required to achieve a standard Kappa score of at least 0.7.

Table 2 (Caregiver Knowledge, Attitudes and Behaviors) summarizes the computerized 190-question Basic Research Factors Questionnaire (BRFQ) developed by the Early Childhood Caries Collaborating Centers to assess dental knowledge, attitudes, and behaviors in all center studies in both Native and non-Native child-family populations. The instrument was pilot tested in the field. Although the length of the

questionnaire may appear burdensome, fewer than ten caregivers failed to complete it at baseline. Bilingual study personnel were available to assist as needed (rarely) with the questions themselves or with the computers, and only two individuals could not be consented because of language.

Questions also ask about potential moderators and mediators, including caregiver sociodemographics; locus of control; self-efficacy; perceived susceptibility, seriousness, barriers, and benefits from the Health Belief model; importance of oral health/disease; distress; stress; perceived discrimination; and sense of coherence. These data allow assessment of change over time, support an evaluation of the effectiveness of the OHP component of the intervention, and provide information about possible mediators and moderators of effects of the intervention.

### 3.9. Cost data

The IHS will provide dental care utilization data, and study personnel collected information about costs of the intervention using a sampling method that gathers data from research and field staff for one "typical" week each quarter, separating intervention costs from those strictly related to research. The study health economist will use these data to compare costs of dental health care plus costs of the intervention in the intervention arm with costs of dental care in the usual care arm.

## 4. Sample size, statistical power, randomization and analysis

### 4.1. Sample size and statistical power

The study sample size was based on dmfs data from the 1999 IHS oral health survey [5]. The following parameters were used to calculate sample size: 1) expected mean dmfs of 23 without any intervention, with a standard deviation of 24; 2) percent reductions in projected increase of dmfs of 10% in the usual care group and 40% in the intervention group; 3) an average cluster size (HS class) of 20 children; 4) an intraclass correlation for the dmfs measure of 0.045; 5) a statistical power of 80%; 6) a retention rate of 70%; and 7) a two-sided *t*-test at the  $\alpha = 0.05$  level. The methods of Donner et al. [27] were used to calculate sample size. Retention rates in clinical trials are typically  $\geq 80\%$ , but a lower retention rate of 70% was used for this trial because of the known mobility of the study population. Calculations determined a target sample size of 1,040 children in 52 HS classrooms.

### 4.2. Randomization

The unit of randomization for this study is the HS Center (HSC), which may contain one or multiple classrooms. The HSCs were stratified by agency and by one vs. multiple classrooms. Within these strata, the HSCs were randomized into the intervention or the usual-care groups using a random number generator. Randomization placed an equal number (26) of HS classrooms into each treatment arm. At the time of enrollment, there were approximately 82 HS Centers with approximately 100 classrooms. A small number of HSCs (fewer than 5) were excluded from the study due to their remoteness and the potential for extreme travel difficulties.



### 4.3. Analysis

The primary analysis will assess the differences between the intervention group and the usual care group in the dmfs measures at baseline and at the beginning of the following 3 school years. Linear mixed models will be used in longitudinal analyses to account for children clustered within HS classrooms and the potential for a variable number of observations over time within each child. Secondary analyses will examine the heterogeneity of treatment effect using the data from the BRFQ.

For the cost analyses, the study economist will directly compare the net costs incurred in the two treatment arms, including direct dental and medical costs, other direct costs (e.g., travel costs), and indirect non-dental or medical costs (e.g., costs associated with patient time for a dental or medical visit).

### 4.4. Data management and oversight

The clinical trials being conducted by the Early Childhood Caries Collaborating Centers share a central data coordinating center (DCC) at the University of California San Francisco. The DCC is using the OnCore® Enterprise Research clinical trials data management system [28] which is a web-based data entry and management system. Because of the remoteness of the NN and the unreliability of Internet connection, the CNOHR investigators have implemented a distributed data entry system using laptop computers for the entry of the dental screening and survey data, and paper forms for enrollment, intervention, quality assurance, and adverse events data. These data are then transmitted from the NN Field Office to the university, where they undergo examination for completeness before being transmitted to UCSF. Data that identify participants remain in the Field Office and at the university. The NIDCR and DCC staffs coordinate the review of the progress of all of the clinical trials with one central Data Safety Monitoring Board.

The study databases residing at the university and the DCC do not contain any data that could identify participants. The study databases reside behind the university firewalls, with limited password-protected access. Study ID numbers contained in the study databases are used to link individual participant data with their identifying information.

## 5. Discussion

This study is designed to test the effectiveness of a community-based oral health promotion and preventive service delivery model for a reservation population, not to test the efficacy of the FV or OHP components. We believe that this study has many strengths. The design of the study combines the rigor of a cluster randomized clinical trial with the contextual benefits of CBPR. Structurally, the design of the study meets all of the relevant CONSORT criteria for clinical trials [29]. The literature has not as clearly defined desired components for CBPR, but the protocol described here includes critical community elements identified by Israel et al. [22] – partnership development and maintenance, community assessment, problem definition, research methodology including recruitment and retention, and data collection – and ultimately the potential for sustainability of the program. Additionally, the study includes an intervention that has been “manualized” for ready translation to other

settings; a clinically important primary outcome variable; the BRFQ dataset that potentially will enable us to explain the treatment effect and to study the heterogeneity of the treatment effect; a large sample size and inclusion of a large proportion of HS centers in the NN; and a cost analysis that could help with arguing for the sustainability of the program.

The study also has a few limitations, primarily related to challenges associated with the study setting and the conduct of research in a geographically large and isolated real-world community. It is perhaps more cost effective to select a setting like HS rather than approaching families on an individual basis, but there are some downsides. Funding for HS can be precarious and may force schools to close early, which in turn can affect researchers' ability to implement an intervention and conduct research. In addition, the NN comprises an extremely large geographic area that requires traveling long distances, sometime in bad weather and on bad roads.

We believe that this innovative combination of methods serves as an exemplar for studies of the sort reported by De Las Nueces et al. [20]. We would be remiss, however, if we did not make clear the challenges and constraints inherent to this approach. Clinical trials require tremendous specification of detail, adherence to externally defined protocol criteria, and rigorous data management and safety oversight by a variety of agencies and boards. Critical concerns about participant safety in treatment trials increase the complexity of protocol design, program implementation, and data collection and may be difficult and frustrating for community partners to understand, especially when interventions such as this one carry so little risk or potential for harm. CBPR brings its own complications. Building partnerships, collaborations, and trust takes a great deal of time, for which grantors often have not provided support. That was not the case here, thanks to NIDCR's focus on disparities research, and the funding climate for community-based research is slowly improving. Only when community members and academic partners have built that relationship can they finalize and implement study design, protocol, and procedures. The extent of community involvement varies considerably, but good research requires it. Researchers conducting studies in community settings have to adapt to field conditions. No matter how well the intervention is designed and monitored for fidelity, there will be variation.

Overall, we believe that the benefits of adding CBPR methods to those of randomized clinical studies outweigh the barriers and constraints, especially in studies of health disparities and in challenging settings. When done well, this innovative mix of methods will increase the likelihood of valid results that communities can use. Our hope is that, in the final analysis, this intervention will prove to be effective, the health care savings from reducing early childhood caries will be greater than the cost of the intervention, and the program will be sustainable in the future to reduce the dental health disparities in American Indian children.

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## References

- [1] American Academy of Pediatric Dentistry. Definition of early childhood caries. *Pediatr Dent* 2006;28:13.
- [2] Centers for Disease Control and Prevention. Children's Oral Health: Overview. [http://www.cdc.gov/OralHealth/children\\_adults/child.htm](http://www.cdc.gov/OralHealth/children_adults/child.htm). [Updated 09/10/2013].
- [3] Phipps KR, Ricks TL, Manz MC, Blahut P. Prevalence and severity of dental caries among American Indian and Alaska Native preschool children. *J Public Health Dent* 2012;72:208–15.
- [4] United States Department of Health and Human Services Centers for Disease Control. Dental caries in American Indian and Alaskan native children. *MMWR Morb Mortal Wkly Rep* 1985;34(26):400–1.
- [5] United States Department of Health and Human Services Indian Health Service. The 1999 oral health survey of American Indian and Alaska Native dental patients. Rockville, MD: Indian Health Service, Division of Dental Services; 2002 106.
- [6] Satur JG, Gussy MG, Morgan MV, Calache H, Wright C. Review of the evidence for oral health promotion effectiveness. *Health Educ J* 2010;69(3):257–66.
- [7] Weintraub JA, Ramos-Gomez F, Jue B, Shain S, Hoover CI, Featherstone JD, et al. Fluoride varnish efficacy in preventing early childhood caries. *J Dent Res* 2006;85(2):172–6.
- [8] Azarpazhooh A, Main PA. Fluoride varnish in the prevention of dental caries in children and adolescents: a systematic review. *Today's FDA* 2008;20(7):21–5 [27].
- [9] Lawrence HP, Binguis D, Douglas J, McKeown L, Switzer B, Figueiredo R, et al. A 2-year community-randomized controlled trial of fluoride varnish to prevent early childhood caries in Aboriginal children. *Community Dent Oral Epidemiol* 2008;36(6):503–16.
- [10] Weyant RJ, Tracy SL, Anselmo TT, Beltrán-Aguilar ED, Donly KJ, Frese WA, et al. Topical fluoride for caries prevention: executive summary of the updated clinical recommendations and supporting systematic review. *J Am Dent Assoc* 2013;144(11):1279–91.
- [11] American Academy of Pediatric Dentistry. Policy on oral health care programs for infants, children, and adolescents. *Pediatr Dent* 2006; 27(7):16.
- [12] American Dental Association Council on Scientific Affairs. Evidence-based clinical recommendations: professionally applied topical fluoride. *J Am Dent Assoc* 2006;137(8):1151–9.
- [13] Feldens CA, Giugliani ERJ, Duncan BB, MdL Drachler, Vítolo MR. Long-term effectiveness of a nutritional program in reducing early childhood caries: a randomized trial. *Community Dent Oral Epidemiol* 2010;38(4): 324–32.
- [14] Albino JEN, Orlando VA. Promising directions for caries prevention with American Indian and Alaska Native children. *Int Dent J* 2010; 60:216–22.
- [15] Rong WS, Bian JY, Wang WJ, De Wang J. Effectiveness of an oral health education and caries prevention program in kindergartens in China. *Community Dent Oral Epidemiol* 2003;31(6):412–6.
- [16] Watt RG. From victim blaming to upstream action: tackling the social determinants of oral health inequalities. *Community Dent Oral Epidemiol* 2007;35(1):1–11.
- [17] Satterfield D, Burd C, Valdez L, Hosey G, Shield JE. The “in-between people”: participation of community health representatives in diabetes prevention and care in American Indian and Alaska Native communities. *Health Promot Pract* 2002;3(2):166–75.
- [18] Lawrence HP. Oral health interventions among Indigenous populations in Canada. *Int Dent J* 2010;60(Suppl. 3):229–34.
- [19] Owens JS, Richerson L, Murphy CE, Jagelewski A, Rossi L. The parent perspective: informing the cultural sensitivity of parenting programs in rural communities. *Child Youth Care Forum* 2007;36:179–94.
- [20] De Las Nueces D, Hacker K, DiGirolamo A, Hicks LS. A systematic review of community-based participatory research to enhance clinical trials in racial and ethnic minority groups. *Health Serv Res* 2012; 47:1363–86.
- [21] Viswanathan M, Ammerman A, Eng E, Garlehner G, Lohr KN, Griffith D, et al. Community-based participatory research: assessing the evidence. Rockville, MD: Agency for Healthcare Research and Quality; 2004 [AHRQ publication 04-E022-2].
- [22] Israel BA, Schulz AJ, Parker EA, Becker AB. Review of community-based research: assessing partnership approaches to improve public health. *Annu Rev Public Health* 1998;19:173–202.
- [23] Adler NE. Overview of health disparities. In: Thomson GE, Mitchell F, Williams MB, editors. Examining the health disparities research plan of the National Institutes of Health, unfinished business. Washington, D.C.: The National Academy Press; 2006. p. 121–74.
- [24] Pitts NB. Modern concepts of caries measurement. *J Dent Res* 2004; 83(Special Issue C):C43–7.
- [25] Pitts NB. Clinical diagnosis of dental caries: a European perspective. *J Dent Educ* 2001;65(10):972–8.
- [26] Casamassimo PS, Thikkurissy S, Edelstein BL, Maiorini E. Beyond the dmft: the human and economic cost of early childhood caries. *J Am Dent Assoc* 2009;140(6):650–7.
- [27] Donner A, Birkett N, Buck C. Randomization by cluster sample size requirements and analysis. *Am J Epidemiol* 1981;114(6):906–14.
- [28] OnCore Enterprise Research. <http://forteresearch.com/enterprise-research-oncore>.
- [29] CONSORT. Transparent Reporting of Trials. <http://www.consort-statement.org>; 2012.