JHSPH Institutional Review Board

RESEARCH PLAN

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Study Title: Preventing Early Childhood Obesity, Part 1: Family Spirit Nurture, 3-9 Months
IRB No.: 7476
PI Version Number/Date: V8, 05-30-2018

1. Aims of the Study:

This study aims to assess the impact of a brief home-visiting module, called "Family Spirit Nurture" (FSN), on American Indian (AI) parent feeding practices associated with increased risk for early childhood obesity, with a primary focus on delaying introduction of infants' Sugar Sweetened Beverage (SSB) (including soda, energy drinks, juice with added sugar and other drinks with added sugar) intake while teaching mothers complementary feeding and responsive parenting practices. We will also assess how water insecurity may moderate parents' feeding of SSBs to young children. Finally, we will explore whether maternal knowledge of oral health practices and/or reduction of infants' SSB intake influences early indicators of infant's oral health (i.e., infants' oral microbiome and plaque formation). Our evaluation will employ a randomized controlled design, in which the control condition receives a beneficial home-safety educational model and assistance in safety proofing their homes for small children. Assessments in both groups will occur at baseline (between 0-14weeks postpartum) and 4 months, 6 months, 7 months, 8 months, 9 months and 12 months postpartum.

Primary Aims:

***Aim 1*:** To determine the effectiveness of the brief (6 lessons) FSN home-visiting parent feeding practice module on reducing SSB initiation and frequency among infants between 3 and 12 months of age. ***Hypothesis 1*:** Infants whose mothers receive FSN vs. controls will be less likely to introduce SSBs between 3 and 12 months of age.

Aim 2: To determine the effectiveness of FSN to promote optimal complementary feeding and responsive parenting practices. ***Hypothesis 2*:** Mothers who receive FSN vs. controls will be more likely to practice recommended complementary feeding and responsive parenting practices between 3 and 12 months of age.

Aim 3: To determine the impact of water insecurity on SSB consumption among infants between 3 and 6 months of age. ***Hypothesis 2:*** Parents who report water insecurity vs. those who do not will be more likely to give infants SSBs between 3 and 6 months of age.

Secondary Aims:

Secondary Aim 1: To explore if provision of water to families reduces SSB intake among mothers and infants ages 6 to 9 months of age.

Secondary Aim 2: To explore if infants in the FSN intervention have better oral health outcomes than control infants up to 12 months postpartum.

2. Background and Rationale:

Epidemiology of American Indian Childhood Obesity

Childhood obesity has more than doubled among children in the past 30 years[12]. In the first part of the 2010s, 8.9% of 2-5 year olds in the United States were overweight or obese and 2% were extremely obese[3]. Reservation-based American Indian (AI) children suffer the highest rates of early childhood obesity and related lifetime consequences of any racial or ethnic group in the US [4]. Among AIs, disparities in overweight begin at birth. A greater percentage of AI women give birth to large-for gestational age (LGA) babies than women of all other races/ethnicities[5]. In 2012, 12.5% of AI infants and 23.8% of toddlers were obese compared with 10.2% of infants and 16.0% of toddlers of other races/ethnicities. AI obesity rates continue to rise with age: in 2012, 41.2% of AI preschoolers were obese compared to 30.2% of all other races/ethnicities[6]. Early life obesity translates to formidable chronic disease—especially cardiovascular disease (CVD) and diabetes[7-9]. CVD, once rare among AIs, now exceeds rates in other US populations and is more often fatal[10]. Further, diabetes has emerged as a public health issue among AI youth. In 2009, diabetes rates among AI youth ages 10-19 were 2.6 times higher than the US all races/ethnicities rate and 7.0 times higher than the non-Hispanic White youth rate[11]

The Role of SSBs, Feeding Practices and Water Insecurity in Childhood Obesity

The rise in obesity can be attributed to many factors including early life feeding behaviors and environment. Sugar Sweetened Beverages (SSBs), play a key role in early childhood obesity[12] [13]. Children introduced to SSBs before 6 months of age are 92% more likely to be obese at age 6. Those who consume >3 SSBs per week at 10-12 months of age have twice the obesity rate as children who consume no SSBs[14]. Overweight/obese 2-to-5-year-old AI children consume 51% more SSBs than their normal-weight AI counterparts [15, 16]. Prior studies conducted by the research team on Navajo Nation indicate high infant SSB consumption within the participating Navajo research community: at 6 months postpartum, 46% of Navajo mothers reported they had fed their infants SSBs; and 87% by 12 months (unpublished data).

In addition to reducing children's SSB consumption, optimal complementary and responsive feeding confers additional obesity protection in early life. Studies indicate early introduction of complementary foods (< 6 months of age) increases infants' risk of obesity[17, 1819]. Similarly, non-responsive feeding styles—characterized by excessive control (e.g. force or restriction), indulgence, or non-involvement—are associated with low child self-regulation of intake[20, 21].(CITE) Benefits of responsive feeding include: children's increased attention to internal signals of hunger and satiety and reduced risk of rapid weight gain and pediatric obesity [22-24 25]

The environment, primarily access to clean, safe and acceptable drinking water may contribute further to the consumption of SSBs and obesity among children. Studies among adolescents and adults have shown that when there is a lack of potable water, individuals consume more SSBs [2627 2829].However, the relationship between SSB intake and water security among infants and young children is not well studied. Recent estimates suggest that up to 40% of Navajo families lack access to clean, safe drinking water[30]. This study will explore the relationship between household water security and SSB introduction in infants living on the Navajo Nation.

The Role of SSBs in Oral Health

Consumption of SSBs also contributes to poor oral health. Tooth decay is the most prevalent dental disease of childhood and 62% of American Indian children 2-5 years have tooth decay, which is four times higher than US white children [31] Eighty-six percent of Navajo children 2-5 years of age have tooth decay experience according to the 2010 IHS Oral Health Survey, which is the highest among all IHS Areas. A recent oral health promotion study among Navajo 3-year olds attending Head Start revealed that that 90% of children had caries at baseline with an average of 18.2 tooth surfaces identified as decayed, missing (due to caries) or filled (dmf). By five years of age, 98% had decay experience and an average of 37.5 dmf tooth surfaces[32, 33]. At least 60% of Navajo 3-year olds enrolled in the Head Start study had decay present on the maxillary (upper) incisors, which are among the first teeth to erupt and experience significant exposure to cariogenic liquids such as SSBs taken from a bottle or sippy cup [33]

Severe decay has serious and long-lasting health consequences such as higher healthcare costs, pain, infection, delayed speech development in children, lower self-esteem, poorer performance in school, and poorer oral health outcomes in adults. Tooth decay is caused when oral bacteria metabolize carbohydrates and release acid onto the tooth surface as a byproduct. More frequent exposure to dietary carbohydrates (e.g., sugars) leads to excessive release of acid onto the tooth surface and selects for oral bacteria that thrive in an acidic environment and are the key contributors to acid production [34]. AI children have several biological risk factors that place them at higher risk of developing caries due to early intake of SSB including earlier tooth eruption and a greater number of teeth present at SSB initiation[35]. Education-based interventions such as FSN that focus on improved infant feeding practices to minimize consumption of SSBs have effectively reduced caries prevalence in other populations. These reductions are presumably mediated by changes in the oral microbiome [36]. Data collection from this trial will inform future intervention development and studies of oral health outcomes among AI children.

Participating Community

The Shiprock community, where this program will be implemented, is located in northwestern New Mexico and part of the Northern Agency of the Navajo Nation. The Northern Agency extends into Arizona, New Mexico and Utah and is home to ~30,000 tribal members. There are approximately 175,000 people living on the Navajo Nation and 33% of all tribal members are under the age of 18. The average household size on the Navajo Nation is 3.5 persons. Married couple families make up 39% of households and 26% of households are headed by single mothers. 14.7% of households on the Navajo Nation are multi-generational and the median household income for the Navajo Nation is $27,389. Poverty rates on the Navajo Nation (38%) are more than twice the poverty rate in Arizona (15%). Almost half (44%) of children <18 years are living in poverty.

3. Study Design

A. Provide an overview of your study design and methods.

Overview of Study Design

We will conduct a pilot randomized 1:1 controlled trial with 136 mother-infant dyads randomized to either intervention or control. Participants will be pre-screened for water insecurity and distributed equally across the two study arms using stratified block randomization. The intervention group (n=68) will receive the FSN home-visiting module, consisting of six 45-minute

lessons delivered biweekly by trained local AI Family Health Coaches (FHCs), from 3 to 6 months postpartum. The lessons focus on elimination or reduction of Sugar Sweetened Beverages (SSBs) among infants while teaching mothers complementary feeding and responsive parenting practices. The control group (n=68) will receive three home-based lessons with home safety information (injury prevention is a priority identified by Navajo leadership that does not interfere with study questions). All families will receive delivery of drinking water from 6 to 9 months postpartum. Through this staggered design, we will evaluate the impact of the FSN on infant feeding practices associated with increased risk for early childhood obesity, with a primary focus on delaying introduction of infant's SSB intake. We will also be able to evaluate the impact of the availability of potable water on SSB intake, with or without family education. In addition, participants will have the opportunity to provide additional consent for a nested oral health study to evaluate the impact of the FSN curriculum and water provision on infant oral health indicators.

Methods:

Study implementation will include four phases (Figure 1):

Phase 1 (Referral, Recruitment, Consent, Baseline Assessment and Randomization): Potentially eligible mothers will be referred to our study staff, who will screen for eligibility, consent/assent mothers, conduct baseline assessment, and assign randomization status. Randomization will be assigned after the completion of the baseline assessment, including scoring of the participant's water insecurity status. Two randomization lists (one for water secure mothers and one for water insecure mothers) will be created prior to study initiation using STATA 14 statistical software[37].

Part 2 (Home-Based Education Intervention): Local FHCs, trained and employed by Johns Hopkins, will deliver either the intervention (6-session FSN) or the control condition (3- Home-Safety Lessons) between 3 to 6 months postpartum.

Part 3 (Water Delivery): All participants will have drinking water delivered to their home from 6 to 9 months postpartum. FHCs will deliver water either weekly or less often, depending on needs of family. The amount of water delivered will be based on number of adults and children residing in home during this period of the study.

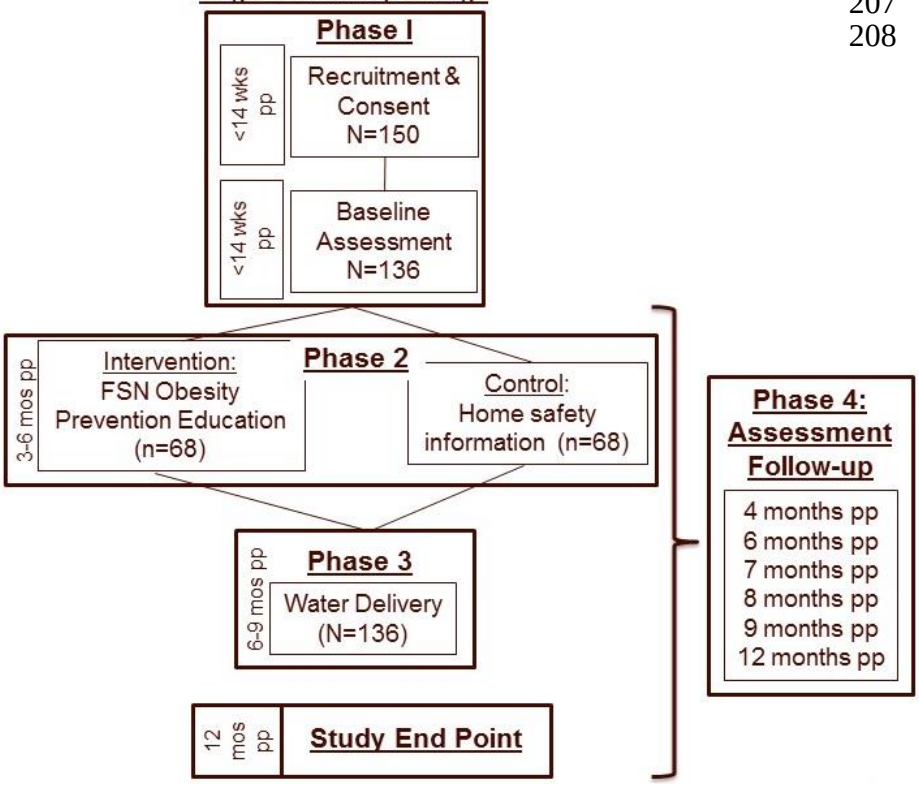
Part 4 (Assessment): Our assessment post-baseline consists of a mixed-methods assessment, including maternal self-reports and maternal FHC-administered interviews collected using REDCap at 4, 6, 7, 8, 9 and 12 months postpartum and maternal and infant medical chart reviews. If consent is given for the nested oral health study, the additional assessments will include a maternal self-report measure, collection and microbiologic testing of infant plaque and saliva, an infant oral examination, tooth eruption evaluations and infant medical and dental chart reviews.

B. Provide sample size and a clear justification as to how you arrived at your projected sample size.

We aim to consent 150 mothers of infants 0-14 weeks of age, with the goal of 136 mothers completing a baseline assessment and being randomized to either intervention or control. Sample size and statistical power estimates were based on the primary hypothesis that the FSN intervention will decrease the introduction and frequency of SSBs among infants between 3 and 12 months of age. The primary outcome we used for determining sample size was "percent ever introduced SSBs at the endpoint of the study (12 months postpartum)". A sample size of 136 mother-infant dyads, or 68 per study arm, will be needed to detect a 24% between group

difference (FSN vs. control), taking into account an estimated 10% attrition at 12 months postpartum (based on the previous Family Spirit trial, with 80% power and significance level of 5% [38]. The sample size is also powered to detect meaningful between-group differences in: a) mean maternal knowledge scores; b) percent introduced complementary foods at 6 months of age; and c) mean scores on responsive feeding scale (see Table 2). Sample sizes and power were calculated using Stata 14's power command.[37]

Figure 1: Study Design



4. Participants:

The study will engage self-identified AI mothers of an infant between 0 and 14 weeks postpartum living in the Northern Navajo Medical Center catchment area. Approximately 80,000 AIs seek care at Northern Navajo Medical Center, with approximately 650 births per year (unpublished data from Navajo Medical Center)

Inclusion Criteria:

1. American Indian ethnicity
2. Female
3. 13 years of age or older
4. Mother to a baby between the ages of 0 and 14 weeks
5. Living within 50 miles of the Northern Navajo Medical Center

Exclusion Criteria:

1. Inability to participate in full intervention or evaluation (e.g., planned move, residential treatment, etc.)

2. Unwilling to be randomized

Potential participants will be screened for satisfaction of these eligibility requirements as they are recruited into the study (see Recruitment Section below).

5. Study Procedures:

A. *Recruitment Process:*

1. *Describe how you will identify, approach, and inform potential participants about your study. Include details about who will perform these activities and what their qualifications are.*

Subjects will be recruited from OB/GYN and pediatric clinics, WIC programs, and word of mouth. Allied clinical and service staff at the recruitment (for example, doctors, nurses, WIC providers) will talk with the mother about the study. If she is interested in learning more about the study, providers will complete a **provider referral form** and send it to the study team. Potential participants may also complete the **self-referral form** and drop it in the locked drop-box in the clinic waiting room. In addition, study staff may be present in the waiting room to provide potential participants with more information about the study. Providers in relevant health and human service settings (OB/GYN clinics, pediatric clinics, WIC programs) will receive regular in-services and reminders from our study staff on the study protocol; participant eligibility criteria and study progress. Staff will also put a flag in the charts of potentially eligible participants to help providers remember to discuss the study with the patient.

We will also use the local media to recruit interested participants. We will publish a print add in the local newspaper, complete radio public services announcements and post flyers in places frequently used by potential participants (grocery stores, clinics, WIC offices). All promotional materials will be approved JHSPH IRB.

If we have recruitment challenges, we may also use community gatherings, such as health and jobs fairs, which are often attended by Johns Hopkins field staff. The Johns Hopkins Shiprock field site run a variety of studies and service projects in the tribal communities selected for this study.

In addition, we have requested a waiver of HIPAA Authorization to be used for recruitment of study participants. In order for the study staff to identify potentially eligible women during the recruitment process, we need to identify women that fit the study's eligibility criteria. The waiver will allow the study staff to obtain demographic information from potential participants' electronic health records and clinic visit sign-in and appointment logs at the participating health clinic. Study staff will only access the records described in the research application and the waiver of HIPAA Authorization. We have determined during the first few months of study implementation that recruitment via provider referrals and self-referrals misses a good number of potentially eligible participants who could benefit from the study. Access to electronic medical records and appointment logs will enable study staff to directly contact potentially eligible participants to see if they may be interested in the study.

Once a referral is made (either by a community provider or self-referral), a trained study staff member will contact the potential participant and use a script to explain details of the study, verify the individual's interest in participating, and make sure they meet all eligibility criteria. If interested, the study staff member will collect information utilizing the initial contact form, set up an appointment to meet with her (and her guardian is she is 13-17 years of age) to explain the study in further detail and carry out an informed assent/consent process.

All recruitment activities will be completed by trained Johns Hopkins employees. All study staff will be trained in human subject's research and will be required to complete the CITI ethics and HIPAA modules prior to any interaction with participants or study data. Certificates of training in human subject's research are kept on file at the Center for American Indian Health's office in Baltimore.

2. Address any privacy issues associated with recruitment. If recruitment itself may put potential participants at risk (if study topic is sensitive, or study population may be stigmatized), explain how you will minimize these risks.

B. *Consent Process:*

1. Describe the following details about obtaining informed consent from study participants. If a screening process precedes study enrollment, also describe the consent for screening.

Study staff will obtain informed written consent from all minor and adult participants.

The informed consent process will be administered in a confidential location convenient to the participant (e.g., clinic room, project office, participant's home).

During the consent process, program staff will explain the study to participants, including study procedures, risks and benefits associated with participating in the study and the rights and responsibilities of study participants. Staff will encourage participants to ask questions and will also ask the participant to explain the study in their own words to ensure that they understand the purpose of the study, their participation, and the risks and benefits. Study staff will allow the participant an appropriate amount of time to consider whether they want to participate and to ask questions. If the participant appears reluctant or uninterested, staff will encourage them to ask questions and will answer all questions thoroughly. If the participant is not interested, staff will thank them for considering the study and leave. If the participant is clearly knowledgeable and interested in participating in the study, staff will have the participant sign and date the consent form. After that, the staff member will sign and date the consent form. The participant will be given a copy of the consent form and the original will be kept in the participant's confidential record in a locked study cabinet. If the participant is a minor, she will sign the assent form and program staff will contact the youth's parent for signing of the parental consent form. No participants will complete an assessment until the consent form (and assent form, where applicable) has been completed by both the participant (and the participant's guardian, where applicable) and staff member.

After signing consent for the study, mothers will be offered participation in a nested oral health study that includes: a maternal questionnaire on oral health knowledge, attitudes and behaviors; collection of infant saliva and plaque samples for microbiologic analysis; an infant oral examination to identify tooth decay; infant tooth eruption evaluations to identify the presence of

baby teeth; and, review of the infant's medical and dental charts to collect oral health risk factors and examination findings. Program staff will explain the additional assessments associated with the nested study to participants, including study procedures, risks and benefits associated with participating in these assessments and the rights and responsibilities of study participants during the consenting process. Study staff will explain that not taking part in the assessments associated with this nested study will not impact their participation in the other parts of the study. If they would like to participate in the oral health nested study, they will sign an additional section on the consent form to indicate this.

The research will take place in the United States in the Northern Navajo Agency (within 50 miles of Shiprock, NM) on the Navajo Nation, located in New Mexico. The consent process will be completed in English.

Country	Consent Document(s) (adult consent, parental permission, youth assent, etc.)	Languages
United States of America	• Adult Consent • Youth Assent • Parental Permission	English

C. *Study Implementation:*

1. Describe the procedures that participants will undergo. If complex, insert a table below to help the reviewer navigate.

Intervention:

Intervention activities will consist of the delivery the FSN home-visiting module between 3 to 6 months post-partum. FSN was developed through an iterative process between Johns Hopkins University and communities in the Navajo Nation. This participatory approach included leadership from our Community Advisory Board (CAB) for cultural and contextual guidance and continuous engagement of Navajo stakeholders. The format of the intervention is consistent with past Family Spirit, a maternal and child health home visiting program developed by the research team and rigorously tested in a previous study (IRB # H.22.05.06.14.A1). The FSN curriculum draws on lessons learned from Family Spirit and targets early childhood feeding behaviors and practices. Trained FHC will teach lessons to mothers and other caregivers the mother invites to participate using tabletop flipcharts in participants' homes or private locations of their choosing. Lessons are highly visual and interactive, and will incorporate cultural teachings related to infant feeding and nutrition that support aims. This study will assess the impact of 6 of the FSN lessons delivered to mothers at developmentally critical time to establish optimal infant feeding practices (3-6 months postpartum), including: 1) Delayed introduction of SSBs: Health Coaches will provide support, education and skills to help mothers reduce or avoid SSB feeding between 3-6 months of life. Based on American Academy of Pediatric guidelines, they will teach that breast milk, formula and water are the best beverage choices in the first year of life [39].; 2) Complementary Feeding: The AAP recommends introducing complementary/solid foods around 6 months of age. Health Coaches will provide support, education and skills to ensure proper timing, methods and choices related to introduction of solids; and 3) Responsive feeding: Embedded in the emotional context between caregivers and children that occurs during meals, responsive feeding styles are characterized by positive

caregiver guidance and recognition of the child's cues of hunger and satiety[21]. Health Coaches will provide support, education and skills to help parents learn to recognize their infant's cues of hunger and satiety and respond in developmentally sensitive, emotionally supportive, and non-intrusive ways.

Control Program: Mothers randomized to the control group will receive 3 educational lessons on home safety and child safety proofing. These meaningful topics were selected so as not to dilute measurement on key FSN outcomes and to provide benefit to all study participants. Lessons will be delivered monthly (at 3, 4 and 5 months postpartum) in the same format as the FSN lessons, by trained FHCs in the home of the participant or in a private place of their choosing.

Water Delivery: Drinking water will be delivered to the household of each participant (both in the intervention and control groups) from 6 to 9 months postpartum. The amount of water will be determined by the number of children and adults living in the household at the time of water delivery. The first delivery of water will occur at the time of the 6-month evaluation and the last delivery will occur at the time of the 9-month evaluation. Water will be delivered as often as weekly. Those families who do not need weekly water delivery (based on their preference and their usage of the first delivery of water) will receive water less frequently.

Data Collection: (Table 2 and Table 3)

Data collection will include interviews, self-report assessment, observations and medical chart reviews. If the participant consents to the nested oral health study, data collection will also include an additional self-report assessment, collection and testing of infant oral specimens, infant tooth eruption evaluation, infant oral examination and review of medical and dental charts.

Completed by Health Coach:

Session Summary Form:

Completed by the Family Health Coach at each session, this form will include information about the visit date, time, participants involved, lesson covered or other activity completed during the visit, activities completed and necessary referrals. No time burden for participants.

Interviews:

Trained study staff members will ask participants questions, probe participants and record participants' answers via REDCap.

Maternal Demographics: Assessment developed by the study team, will include information about maternal age, living situation (including number in household) and socioeconomic status. The Maternal Demographics assessment will be completed at baseline, 4, 6, 9 and 12 months postpartum.

Modified Infant Beverage Intake Questionnaire: Mothers will be asked questions from an adapted version of the Pre-School-Aged Beverage Intake Questionnaire (BEVQ-15), shown to be reliable and valid among children ages 3 to 5 years of age [40]. Additional feeding questions developed by the study team based on previous studies conducted by the co-investigators are also asked. The 61-item adapted assessment will be used to assess beverage intake among infants and includes questions about the frequency of infant's beverage intake in the past month including breastmilk and formula, feeding practices, introduction of complementary feeding, and introduction of SSBs among infants. The assessment will be completed at baseline, 4, 6, 7, 8, 9 and 12 months postpartum.

Maternal Beverage Intake Questionnaire: Mothers will be asked questions from an adapted version of the Beverage Intake Questionnaire (BEVQ-15) a 15-item assessments including questions about their beverage intake in the past month. The assessment has been shown to be reliable at assessing beverage intake among adults[41]. We have adapted the assessment to

ensure cultural and contextual match with participants. The assessment will be utilized to assess beverage intake among mothers and will be completed at baseline, 4, 6, 7, 8, 9 and 12 months postpartum.

Self-Report:

All participants will complete a self-report via REDCap assessment. The self-report includes the following questionnaires:

Household water security: Participants will complete the 20-item household water security and accessibility assessment at baseline, 4, 6, 7, 8, 9 and 12 months postpartum. The assessment was developed in partnership with Navajo stakeholders and includes questions utilized in previous studies and from the World Bank's Living Standards Measurement Study [43]. It will be utilized to identify household water security status of enrolled mothers.

Infant and Toddler Responsive Feeding Scales: Completed by the mother at baseline, 4, 6, 9 and 12 months postpartum, this 24-item questionnaire asks mothers to indicate how often they engage in specific feeding behaviors to assess maternal feeding styles. The assessment has been used and validated in culturally diverse settings[44]

Maternal Nutrition and Feeding Practices Knowledge: A 14-item assessment created by the study team to assess maternal knowledge through a series of curriculum based knowledge questions. Mothers will complete the assessment at baseline, 4, 6, 9 and 12 months postpartum.

Perception of Eating: Adapted from the perceptions of eating questionnaire utilized with WIC mothers, the 4-item assessment will be completed by the mother at baseline, 4, 6, 9 and 12 months postpartum and assesses mother's perception of their infant's weight.[42]

Perceived Stress Scale: Completed by mothers, the 4-item questionnaire will assess maternal stress. The assessment will be completed by mothers at baseline, 4, 6, 9 and 12 months postpartum.[42]

CES-D: Utilized to assess depression among mothers, the 20 item questionnaire has been utilized to assess depression with Navajo mothers. The questionnaire asks participants to rate how often over the past week they experienced symptoms associated with depression, such as restless sleep, poor appetite, and feeling lonely. Response options range from 0 to 3 for each item (0 = Rarely or None of the Time, 1 = Some or Little of the Time, 2 = Moderately or Much of the time, 3 = Most or Almost All the Time). Scores range from 0 to 60, with high scores indicating greater depressive symptoms. A CES-D score of 16 or greater indicate individuals at risk for clinical depression. The assessment is both valid and reliable and will be completed by mothers at baseline 4, 6, 9 and 12 postpartum.

Infant Temperament: The 6-item questionnaire will be completed by mothers at baseline, 4, 6, 9 and 12 postpartum to assess their perception of infant's temperament. The assessment has been utilized with WIC mothers.[42]

Safety Questionnaire: A 13-item questionnaire developed by the study team will assess maternal knowledge, attitudes and behaviors associated with household safety. Mothers will complete the assessment at baseline, 4, 6, 9 and 12 months postpartum. Results from this assessment will be utilized to inform community members and stakeholders of the benefit of the study on those who are randomized to the control condition.

Brief Infant-Toddler Social and Emotional Assessment (BITSEA): The 42-item assessment a screener for social-emotional/behavioral problems and delays in competence. The assessment will be completed at 12 months.[45]

Satisfaction Questionnaire: The satisfaction questionnaire will assess participant's program satisfaction. Developed by the research team, the assessment will be completed at 12 months.

Observations

Home Safety Observation: A 27 item household safety developed by the study team will capture key aspects of child safety in the home. The home safety checklist will be completed by study staff at baseline and 12 months postpartum. Results from this assessment will be discussed with study participants and strategies for improving home safety will be discussed with participants.

Medical Chart Reviews

Growth and Birth Statistics -Infant- Medical chart reviews will be conducted by Family Health Coaches at 12 months postpartum. The medical chart review will collect information about the child's gestational age, gender, birth weight and length as well as the child's weight and length over their first year of life. The reviews will be conducted by trained study staff.

Medical Chart Review – Mother- Medical chart reviews will be conducted by Family Health Coaches at 12 months postpartum. The medical chart review will collect information about the number of children the mother has had, diabetes status before and during birth as well as weight and height before pregnancy, during pregnancy and during the first year of their child's life.

NESTED ORAL HEALTH STUDY ASSESSMENTS

Only participants who consent to the nested oral health study will participate in the following assessments.

Self Report:

Oral Health Questionnaire: A 40-item questionnaire developed and validated by the Oral Health Disparities Research Centers study team will assess maternal knowledge, attitudes and behaviors associated with their child's oral health. Mothers will complete the assessment at baseline, 6, 9 and 12 months postpartum.

Chart Review:

Medical Chart Review-Infant: Medical chart reviews will be conducted for the nested oral health study by trained study clinicians at 12 and 24 months postpartum to document oral health risk factors and findings from the pediatrician's oral exam.

Dental Chart Review- Infant: Dental chart reviews will be conducted by research study clinicians at 12 and 24 months postpartum to document utilization of dental services and completion of dental procedures (e.g. fluoride varnish application).

Infant Specimen Collection, Tooth Eruption Evaluation and Oral Examination:

Infant Saliva and Plaque Collection: Specimens will be collected from infants at baseline, 6, 9 and 12 months post-partum and subjected to laboratory-based microbiologic analysis.
Infant Tooth Eruption Evaluation: The infant tooth eruption evaluations will be completed at baseline, 6, 9 and 12 months post-partum to document the presence and eruption pattern of teeth.
Infant Oral Examination: Trained research study dental personnel hired by Johns Hopkins (e.g., dentist or hygienist) will conduct an oral examination of the infant's mouth at 12 months postpartum by to identify tooth decay. If any treatment needs are identified, the infant will be referred to dental care.

Table 2 summarizes selected measures, their timetable, and respondent time burden for the study.

Table 2.										
Instrument	**Time Burden**	**Baseline**	**4 mos**	**6 mos**	**7 mos**	**8 mos**	**9 mos**	**12 mos**	**24 mos**	**All Visits**
Completed by FHC										
Session Summary Form	--------									X
Self-Report Assessments										
Completed as Interviews										
Maternal/Family/Household Demographics	15 min	X	X	X			X	X		
Maternal and Modified Infant BEVQ-15	20 min	X	X	X	X	X	X	X		
Completed by Mothers										
Household Water Insecurity Assessment	5 min	X	X	X	X	X	X	X		
Maternal Nutrition/Feeding Practices Knowledge Test	5 min	X	X	X			X	X		
Infant Responsive Feeding Scales	10 min	X	X	X			X	X		
Perceptions of Eating Scale	5 min	X	X	X			X	X		
PSS	5 min	X	X	X			X	X		
CES-D	5 min	X	X	X			X	X		
Infant Temperament	5 min	X	X	X			X	X		
Brief Infant-Toddler Social and Emotional Assessment	5 min							X		
Safety Questionnaire	5 min	X	X	X			X	X		
Satisfaction Questionnaire	5 min							X		
Observation completed by Family Health Coach										
Home Safety Observation	15 min	X						X		
Infant Medical Chart Review										
BMI Z-Scores	---------							X		
Maternal Medical Chart Review										
Parity, Pregnancy weight gain, BMI	---------							X		
Total Participant Time Burden (min)		**105**	**90**	**90**	**25**	**25**	**90**	**105**	**0**	

Table 3 summarizes selected measures, their timetable, and respondent time burden for the nested oral health study activities.

Table 3.									
Nested Oral Health Study Assessments									
Instrument	**Time Burden**	**Baseline**	**4 mos**	**6 mos**	**7 mos**	**8 mos**	**9 mos**	**12 mos**	**24 mos**
Completed by Mothers									
Maternal Oral Health Questionnaire	10 min	X		X			X	X	
Infant Medical Chart Review									
Oral health risk factors and exam findings	---------							X	X
Infant Dental Chart Review									
Oral exam procedures and findings	----------							X	X
Specimen Collection, Tooth Eruption Evaluation and Oral Examination									
Infant Saliva Collection	2 min	X		X			X	X	
Infant Plaque Collection (when teeth present)	1 min	X		X			X	X	
Infant Tooth Eruption Evaluation	2 min	X		X			X	X	
Infant Oral Examination	10 min							X	
Additional Participant Time Burden (min)		**15**		**15**			**15**	**25**	**0**

The baseline assessment will be completed before 14 weeks postpartum by all mothers who have consented into the study. For mothers who are enrolled when their baby is less than 10 weeks old, the baseline assessment will take place in two sittings. The first sitting will occur after consent is obtained. The maternal demographics and water availability assessments will be administered at this time. The second sitting will occur between 10 and 14 weeks postpartum.

The remainder of the baseline assessment will be administered at this time. For mothers who are enrolled when their baby is between 10 and 14 weeks old, the entire baseline assessment will be completed in one sitting. To schedule this and other assessments, study staff will contact participants first by phone and, if unavailable, through a home visit, to arrange a confidential/private location of their choice for follow-up assessment administration.

Data will be collected and managed using REDCap. A user name and password are required to access the REDCap system. Study staff will launch the assessments on a computer or tablet. Tablets will by synced on a daily basis with REDCap using a secure Wi-Fi connection available at the study site. For the assessments completed via interview, staff will read the question to the participant. Study staff are trained to provide additional information to clarify questions as necessary. After completion of the interview, the study staff member will provide the computer to the participant so that they can complete the remaining assessment via self-report. They will be available if questions should arise. Data collected through REDCap is automatically stored on a Johns Hopkins server secure, HIPAA compliant server. Direct data entry into REDCap eliminates the need for separate data entry and coding. Any data that is collected via hard copy will be entered into REDCap. Data will be downloaded from REDCap as a complete database into de-identified Excel and Stata files that will be stored on JHU's HIPAA compliant, secure server. The data will be retained until the end of the study.

During informed consent, participants will also be asked to sign IHS 810 forms which allow study staff to access their child's medical and dental records at the Northern Navajo Medical Center IHS Hospital. Separate IHS 810 forms will be signed by the mother for each of the following medical chart data reviews: 1) infant growth and birth statistics for the period from the date of study enrollment to one year post enrollment, 2) infant oral health information from the medical charts for the period from the date of study enrollment to two years post enrollment, 3) infant dental/oral health information from dental charts for the period from the date of study enrollment to two years post enrollment Study staff will use separate a medical chart review form to extract information from the participant's child's medical record regarding each of these topics.

Mothers will also be asked to sign an IHS-810 form which allows study staff to access their medical record at the Northern Navajo Medical Center IHS Hospital. Study staff will use the medical chart review form to extract information from the participant's medical record regarding: 1) parity, 2) diabetes status before and during pregnancy, 3) weight before, during and after pregnancy.

The purpose of the infant medical chart and dental chart review is to: 1) determine if the FSN intervention vs. the control condition impacted child z-BMI (for age and gender); 2) obtain information about the oral health risk factors and the findings of the pediatrician's oral exam.

The purpose of the maternal medical chart review is to: 1) determine if the FSN intervention vs. the control condition impacted maternal BMI; and 2) to explore the relationship between maternal diabetes status, maternal weight and child outcomes.

If the participant declines any of the IHS-810 forms, they will still be able to participate in the study.

2. Describe the number and type of study visits and/or contacts between the study team and the participant, how long they will last, and where/how they will take place.

Participants' study involvement will occur over a period of 9 months. The intervention and control condition will be delivered in the home of participants or in a private place of their choosing when participants are 3 to 6 months postpartum. Water will be delivered to the home of the participants from 6 to 9 months postpartum. The final assessments will occur at 12 months postpartum.

Evaluations will be conducted 7 times at: baseline (<14 weeks postpartum), 4, 6, 7, 8, 9, and 12-months postpartum. Each interview, self-report assessment and observation administration will last approximately 25 to 105 minutes. The nested oral health study will last approximately 15 to 25 minutes.

3. Describe the expected duration of the study from the perspective of the individual participant and duration overall.

This intervention will be conducted over a 6-month period; participants in the intervention group will receive 6- 45 minute lessons in their home or a private place of their choosing and participants in the control group will receive 3- 30 minute safety lessons in their home or a private place of their choosing. The baseline assessment will be completed by the participant before 14 weeks postpartum, and evaluations will be completed by the participant at 4, 6, 7, 8, 9 and 12 months postpartum. Participants will have the option to also participate in oral health components at baseline, 6, 9 and 12 months postpartum. Estimated total participation for participants randomized to the FSN intervention, including the full FSN intervention and all evaluation participation, is a maximum of 14 hours and 30 minutes over 10 months. Estimated total participation for participants randomized to the control condition, including the control intervention and all evaluation participation, is a maximum of 11 hours and 30 minutes over 10 months.

3. Provide a brief data analysis plan and a description of variables to be derived.

To assess whether between group comparability was achieved through randomization, demographic and outcome variable distributions at baseline will be compared by group (invention vs. control), using t-tests or chi-square tests as appropriate. For time discrete outcome measures, t-tests or chi-square tests will be used to assess intervention impact on each outcome in unadjusted analyses. Multivariate linear or logistic regression will be used to test the impact of the intervention on each outcome, controlling for baseline demographic characteristics where necessary. For time varying outcomes we will examine the impact of the intervention by analyzing between group differences at each time point using t-tests and multivariate regression analyses. For those outcomes with sufficient power, multi-level mixed-effects models with a random effect at the individual level and appropriate variance structures, and an interaction term for treatmentXchild age will be used to examine change over the intervention period.[46, 47] We will also explore whether water insecurity moderates the impact of the intervention on these outcomes in the multivariate models between 3 and 6 months postpartum. Between 6 and 12 months postpartum, we will explore the impact of the provision of drinking water on SSB intake in both groups. To measure the impact of the control group curriculum, between group differences in home safety knowledge and behavior will be measured at each time point. Missing data will be handled as follows: 1) document reason(s) for missing data to inform model development; 2) assess treatment dropouts to do intent-to-treat analysis; and 3) conduct sensitivity analysis to compare inferences that are based on different plausible reasons for missingness [48]. Navajo and Hopkins investigators will collaborate with

community partners in data interpretation to assure accuracy, cultural acceptance and relevance.

Selected saliva and plaque specimens collected at each time point will undergo next-generation sequencing of the 16S rRNA gene. The resulting sequences will be clustered according to operational taxonomic units (OTU) using a 97% identify cutoff and assigned taxonomy by comparison with fully sequenced bacterial genomes. The relative abundance of bacterial taxa will be compared according to randomization group at each time point using the Kruskal-Wallis test. Kendall's Tau rank coefficient will be used to test for the association between risk factors for tooth decay (e.g., SSB intake) and the relative abundances of selected taxa.

4. Describe whether you are collecting or storing personal identifiers, and if yes, why you need them, and when and how you plan to dispose of them. Signatures on consent forms are considered to be identifiers.

The only personal identifiers that will be collected are:

- participant's name and signature on the study's consent forms and IHS-810 forms
- participant's name, date of birth, and contact information on a referral form and an Initial Contact Form
- recording of participant's name and contact information on Master Roster
- participant's date of birth on the baseline data collection form
- infant's medical and dental record number

A unique ID code will be used to administer and track all data collection forms. All consent forms will be stored until the end of the study, after which they will be destroyed. The Master Roster will be destroyed at the end of the study. Initial Contact Forms will be destroyed at the end of the study.

A Master Roster list will be generated linking participant IDs to study participants' names and primary contact number. The Master Roster will be used only by study staff to manage study logistics and allow for tracking of individual participants as they take part in intervention and evaluation activities. The Master Roster is essential for organization given the nature of the intervention design and staggered design of the home visits. Study staff will only use participant ID numbers on study documents to protect participant confidentiality. This Master Roster will allow study staff members to make the link between individual and ID number. For example, the Master Roster will be used for tracking when participants should receive each of the lessons and evaluations and will help study staff to find participants. The Master Roster will be electronic and password protected. Only specified study staff will have access to the Master Roster.

We will collect the names of study participants and their participant ID on consent forms. All consent forms will be kept in a locked cabinet at the local study site. Study data collection forms will only have participant IDs, never participant names, given the sensitive nature of the questions asked. Date of birth will be collected in addition to participant ID only on the baseline assessment in order to calculate the participant's age.

A unique specimen collection ID will be generated for all specimens collected and can only be linked back to the participant by using participant ID.

5. Answer the following if they are relevant to your study design:

i. If the study has different arms, explain the process for assigning participants (intervention/control, case/control), including the sequence and timing of the assignment.

At the time of enrollment, after a participant has been assigned a participant ID and completed the baseline assessment, their participant ID will be used to randomize individuals to one of two study groups: FSN intervention or control condition.

Randomization will be assigned upon completion of the baseline assessment. Two randomization lists will be created prior to study initiation using STATA 14 statistical software. One list will be used for water secure families and the other for water insecure families to ensure equal distribution across intervention and control groups. After scoring the baseline assessment, a study staff member will assign randomization based on the participant's water security status. The local study coordinator will maintain the list as new participants are randomized.

We will use a 1:1 allocation ratio, which is the most statistically efficient model. We will utilize stratified randomization techniques to ensure a 1:1 allocation of study conditions across household water security status (water secure vs. water insecure). STATA 14 will be used to create the randomized allocation scheme. Participants will be blinded to their randomization status.

ii. *If human biospecimens (blood, urine, saliva, etc.) will be collected, provide details about collection, volume (ml) or number, use, storage, identification, and disposal. Include, if relevant, information about genetic or genomic analyses planned for the biospecimens. Provide JH Biosafety Registration Number for clinical and laboratory based research.*

Saliva and plaque specimens will be collected at 3, 6, 9 and 12 months from each infant for a maximum of 8 specimens collected per infant. About 5ml of saliva will be collected from infants by placing a swab on the floor of the mouth. Plaque will be collected using a cytology brush (CytoSoft). Both specimen types will be inoculated into specimen transport media and stored according to the manufacturer's recommendations until further processing. Specimens will be labeled with a pre-printed barcode and shipped to a collaborating lab overseen by Dr. Nini Tran, DDS, PhD, a pediatric dentist, microbiologist and Assistant Professor at the University of California, Las Angeles (UCLA) School of Dentistry to undergo specimen processing and testing that will include biochemical analysis of the saliva and microbiologic and molecular characterization of the organisms present in both plaque and saliva. Any specimens not depleted during specimen testing will be returned to JHU/Baltimore and stored at -80°C. The specimens will be destroyed upon completion of the study. The specimens will not be used in future research.

iii. If genetic/genomic analyses are planned, address whether the data will be contributed to a GWAS or other large dataset. Address returning unanticipated incidental genetic findings to study participants.

No human genetic testing will be performed. The only genomic analyses that will be performed will be on bacteria identified in the saliva and plaque specimens.

iv. If clinical or laboratory work will be performed at JHU/JHH, provide the JH Biosafety Registration Number.

There is no clinical or laboratory work at JHU/JHH planned at this time.

v. If you will perform investigational or standard diagnostic laboratory tests using human samples or data, clarify whether the tests are validated and/or the lab is certified (for example is CLIA certified in the U.S.). Explain the failure rate and under what circumstances you will repeat a test. For all human testing (biomedical, psychological, educational, etc.), clarify your plans for reporting test results to participants and/or to their families or clinicians. Address returning unanticipated incidental findings to study participants.

The laboratory testing will be performed in collaboration with Dr. Nini Tran the UCLA School of Dentistry. We anticipate retesting 5% of specimens by 16S rRNA for identification of bacterial taxa. No human biological testing will be performed.

6. Data Custody, Security, and Confidentiality Protections

VI. Data Security and Confidentiality Protections:

A. Personally Identifiable Information (PII):

Please identify the Personally Identifiable Information (PII) that you may be collecting and using at any of the following stages of your study: ***Recruitment,*** ***Consent,*** *and* ***Study Implementation***.

Name, signature, initials, or other identifiable code	☒
Geographic identifier: address, GPS location, etc.	☐
Dates: birth, death, clinical service, discharge, etc.	☒
Contact information: phone numbers, email address, etc.	☒
ID: Social Security Number, driver's license number, etc.	☐
Health record identifiers: medical record, insurance plan number, etc.	☒
Account numbers	☐
Device identifiers: e.g., implants	☐
Internet identifiers: IP address, social media accounts	☐
Biometric identifiers, including finger and voice prints	☐
Audio recordings	☐
Video or full face photographic images	☐
Genomic/genetic data	☐
Any other unique identifying number, characteristic, or code (note: this does not mean the unique code assigned by the investigator to code the data)	☐

Other: **Click here to enter text.**	☐

B. Recruitment:

Will you collect identifiers for the purpose of contacting potential participants?
Yes ☒ No ☐
If **yes**, will you retain the identifiers after the recruitment contact has been made? Yes ☒ No ☐

C. Data Collection:

In what form will you collect and store PII? When you respond, think of PII collected for recruitment, consent, and other study purposes.

1. **Hard Copy/Paper:** Yes ☒ No ☐

If yes, please answer the following:

a. How will the data be kept secure during transfer from study collection site to storage site?

Copies will be kept in investigator's possession during transport. Recruitment and consent forms will not be taken back to the study office by study staff immediately after consent and/or recruitment is completed and will be stored in a locked cabinet. They will not be taken into the field in any circumstance. Data collection forms will all be completed via REDCap on password protected tablets/computers. The computers and tablets will be in possession of the study staff member.

b. Will the data be secured in a locked cabinet or room? Yes ☒ No ☐

c. Are the data collection forms and study data stored without personal identifiers and separate from the study IDs/code? Yes ☒ No ☐

d. How long after study completion will you keep the hard copy/paper forms? We will keep them up to 3 years after completion of the study

2. **Electronic:** Yes ☒ No ☐

If yes, please answer the following:

a. Will the data be collected/stored on a portable device (laptop, mobile phone, tablet, PDA) protected by encryption? Yes ☒ No ☐

b. Will the data be stored on a secure server or in the Cloud/Web?

Secure Server ☐ Cloud/ Web ☒

c. Will it be encrypted? Yes ☒ No ☐

d. Will you be backing up your data? Yes ☒ No ☐

3. **Audio Recording:** Yes ☐ No ☒

If yes, please answer the following:

a. Will you store the audio recording securely in a locked cabinet/room until transcription is complete?
Yes ☐ No ☐

b. Will the audio recording be destroyed after transcription? Yes ☐ No ☐

If no, why not?

4. **Photograph/Video:** Yes ☐ No ☒

If yes, please answer the following:

a. Will the photographs/videos be stored securely in a locked cabinet or room?
Yes ☐ No ☐

b. Will the photograph/video be destroyed? Yes ☐ No ☐

If yes, when?

D. PII De-Identification of Data Used for this Study:

When will you destroy the PII and/or the code linking the PII with the study ID?
All consent forms will be stored until the completion of the study, after which they will be destroyed. The Master Roster, which will link the PII with the study ID and the initial contact forms, will be destroyed at the end of the study

E. Data Storage and Analysis:

One of the keys to protecting PII is the proper use of tools to share and conduct your analysis. JH and JHSPH offers several options for you to consider. Please select the system that you plan to use to protect your study data by clicking the box. Consult JHSPH IT for assistance if needed.

☐ **JH Virtual Desktop**: IT@JH provides (for a monthly fee) a virtual Windows desktop.

☐ **JHSPH SharePoint and File Shares**: These systems provide a managed and secure platform for your research project. They also provide a built-in encrypted backup solution.

☒ **JHSPH RedCAP or HPCC**: These are departmentally managed applications.

☒ **JHBox**: Johns Hopkins Box (JHBox) is a secure cloud-based file sharing and file storage service.

☐ **Independent Departmental Servers and Systems**: These servers are typically managed by departmental or research team IT staff.

☐ **Other**: Please provide details regarding any other systems being utilized.

F. Other Data Security Measures:

In addition to the details regarding data collection, please review the following questions. This additional information will be utilized to assist in the development of a comprehensive Data Security plan. This would include the systems used to analyze the data, data security contacts and additional requirements.

1. Do you have a designated person on your research team other than the PI who is the technical contact for a Data Security plan? Yes ☐ No ☒
   If yes, please provide a contact name:

2. Does your sponsor have other specific data security requirements for the study data?
   Yes ☐ No ☒
   If possible, please explain:

Please add any other information that you believe is relevant to data security. Hard copies of data collection materials include only one identifier (participant's date of birth) and an ID code. Data collection materials will be locked in a secure cabinet or room with limited access by specified individuals. Copies will be kept in investigator's possession during transport. A unique code linking the data to subjects' personal information will be stored separately on a secure computer and JHBox, and will only be accessible by authorized study staff..

Electronic data collected using REDCap will be stored on a secure Johns Hopkins server that is accessible by logging into the REDCap system using a unique, individual-specific username and password. Only the personal identifier of participants' date of birth is included in the database. The data are stored on a computer that is password protected with a secure server. Any electronic documents that links IDs to identifying information (i.e., names/signatures on consent forms and logs) are stored on a computer in accordance with JHSPH Data Security guidance. Transfer or storage on portable devices (e.g., laptops, flashdrives) will be encrypted. The devices on which this information is stored will be accessible only to individuals who need access to these data (i.e., study personnel).

a. *Who controls access to the data?*

Only specified research study staff have access to the data. The on-site study coordinator, the field manager and the PI are responsible for ensuring only specified study staff have access to the data.

b. *Will data be shared only if de-identified?*

Yes.

c. *What additional security controls will be in place?*

All study staff who are also JHU employees, will be trained to the highest standards of confidentiality expected by JHU. All study staff including the PI, Co-Is Study Managers, local study coordinator and study staff will be extensively and repeatedly trained in confidentiality procedures, including:

- Human subjects protection
- HIPAA training including risks for legal and civil penalties for breaches of confidentiality
- Informed consent/assent
- Professional conduct
- Research ethics

All study personnel will be told that confidentiality breaches will be grounds for termination.

Johns Hopkins faculty at the Center for American Indian Health have a 30-year history employing and training individuals from the Navajo community within the study site to carry out research that requires strict maintenance of participant and tribal confidentiality.

D. Describe any plans for destroying data including if, when and how that will be done.

All hard copies and electronic versions of data files will be until completion of the study, after which they will be destroyed through paper shredding and removal of all electronic copies from all computers and data bases and servers.

b. Data Storage

Note: Identifiers include name, address, SSN, hospital record number, etc., and other indirect identifiers (e.g., date of birth) that, when combined with other variables, may make a subject identifiable. These categories reflect minimal standards; you may impose more stringent protections. See the JHSPH Data Security Guidance at www.jhsph.edu/irb > Policies & Guidance > Guidance for additional information regarding best practices.

Hard Copy of data collection form: **Indicate your choice by typing an X in the appropriate box on the left:**	
	This activity will not involve receiving and/or accessing hard copies of data.
	Data collection forms RECORD NO PERSONAL IDENTIFIERS connecting study participants, and there are no codes providing a link. Data are anonymous.
X	Data collection forms INCLUDE IDENTIFIERS. The forms are locked in a secure cabinet or room with limited access by authorized individuals. Forms will be kept in study team's possession during transport and will not be left unattended in a vehicle. When possible, de-identified copies will be used for coding and analysis.

	Data collection forms ARE CODED with study participants' random study ID numbers. Codes/links between study IDs and identifiers are stored securely in a separate place (locked storage cabinet or secure electronic database.)
X	Other (describe): Hard copies of Master Roster include three identifiers (participant's name, date of birth, and contact phone number) and an ID code. The Master Roster will be kept in a secure cabinet or room with limited access by specified individuals. Hard copies of data collection materials include only one identifier (participant's date of birth) and an ID code. Data collection materials will be locked in a secure cabinet or room with limited access by specified individuals. When possible, redacted (de-identified) versions of the data collection sheets will be used for coding and analysis. ALL HARD COPIES WILL BE KEPT IN INVESTIGATOR'S POSSESSION DURING TRANSPORT.
Electronic Databases: Indicate your choice by typing an X in the appropriate box on the left: :	
	The data do not contain personally identifiable information
X	These data are stored on a secure server protected by limited access and strong password systems. Data are coded when possible. Portable electronic devices will not contain identifiable information unless encrypted.
	Other (describe):
3. Other Identifiable Data Storage, Retention, and Destruction (Audiotapes, videotapes, photographs, etc.) will be retained and stored securely (locked in cabinet or room) until:	
	Transcription is complete, then will be destroyed.
	Analysis is complete, then will be destroyed.
	Study is complete and file is closed.
	Indefinitely. Provide justification for indefinite retention:
4. Existing Biospecimens to be used in this study:	
	HAVE NO PERSONAL IDENTIFIERS.
	INCLUDE IDENTIFIERS AND ARE CODED; the PI will not have access to the link or code connecting the identifiers to the specimens.
X	INCLUDE IDENTIFIERS, and the PI has access to those identifiers or to the link/code connecting specimens to individuals. The identifiers and/or code will be stored securely until the study is complete.

G. Will you use clinical data of 500 records or more from Johns Hopkins Hospital and its affiliates?

Yes ☐ No ☒

If yes, please complete the JHM Data Security Checklist available on the JHSPH IRB website: www.jhsph.edu/irb and upload a copy of the checklist to the "Miscellaneous" section.

. Will the study data be protected by a Certificate of Confidentiality? If yes, explain who will apply and maintain the Certificate.

Yes, the study team will apply for a Certificate of Confidentiality. The Certificate of Confidentiality will be obtained by the PI, Allison Barlow. The Certificate of Confidentiality

obliges the researcher to protect the privacy of participants and not reveal anyone's private information collected through the study. The highest standards of confidentiality protection procedures will be followed.

H. Will you use clinical data of 500 records or more from Johns Hopkins Hospital and its affiliates?

Yes ☐ No ☒

If yes, please complete the JHM Data Security Checklist available on the JHSPH IRB website: www.jhsph.edu/irb and upload a copy of the checklist to the "Miscellaneous" section.

7. Risks:

A. Describe the risks, discomforts, and inconveniences associated with the study and its procedures, including physical, psychological, emotional, social, legal, or economic risks, and the risk of a breach of confidentiality. These risks should be described in the consent documents.

All participants will be informed about any potential risks at the time of informed consent. The primary potential risks associated with study participation are: (a) participant discomfort in completing the assessments or the intervention sessions (some individuals may be uncomfortable during sessions because feeding of children and obesity prevention can be perceived as sensitive topics); and b) someone finding out the individual is in the study or information the individual shared during the study.

There is very little risk to participants of the oral health component who will undergo specimen collection and brief tooth eruption evaluations. Trained staff will collect specimens and conduct the tooth eruption evaluations, which will take around 5 minutes combined. Participants will experience minimal discomfort during each of these.

B. Describe the anticipated frequency and severity of the harms associated with the risks identified above; for example, if you are performing "x" test/assessment, or dispensing "y" drug, how often do you expect an "anticipated" adverse reaction to occur in a study participant, and how severe do you expect that reaction to be?

We do not expect an adverse reaction to any of the assessments, the intervention or specimen collection.

c. Describe steps to be taken to minimize risks. Include a description of your efforts to arrange for care or referral for participants who may need it

Participation in the study is completely voluntary and participants will have the opportunity to withdraw at any point. All participants will be informed about any potential risks prior to enrollment. We will clearly communicate the purpose and expectations of the study at the time of informed consent and employ AI study staff members from the local community trained in active listening, maintaining confidentiality, and other relevant procedures to ensure the comfort and well-being of each participant. All activities associated with the oral health components are voluntary and will be conducted by trained personnel to mitigate any discomfort and risks associated with these activities.

Following the self-report assessment, Family Health Coaches will receive a summary form which will indicate if the participant's score on the CES-D indicates they are at risk for clinical depression (score of 16 or greater). If the score indicates they are at risk for clinical depression, the health coach will discuss with the participant and provide appropriate referrals, which will primarily consist of a referral to the Indian Health Services counseling services. Additionally, all staff will complete the Applied Suicide Intervention Skills Training (ASIST) prior to interacting with participants. Through this training, health coaches will be able to better identify one's risk for suicide and have strategies to intervene and help prevent the immediate risk of suicide. If a health coach believes a participant is at immediate risk for suicide, they will immediately call the Field Manager or PI as well as local authorities.

d. Describe the research burden for participants, including time, inconvenience, out-of pocket costs, etc.

The primary burden to participants is the amount of time required to complete the intervention and evaluations. The full intervention (including up to 6 45-minute FSN sessions) will take up to 270 minutes. Participants also need to be home to receive the water provided as a part of this study, which could take time. Additionally, participants will need to complete evaluations at 7 time points. Each assessment will take between 25 and 105 minutes to complete plus another 15 to 25 minutes if they consent to participate in the nested oral health study. The total time required to complete all evaluations including the oral health study assessments is 645 minutes (10 hours and 45 minutes). We will explain to participants during the informed consent process and also throughout the study that they are volunteers and are not required to complete any sessions or assessments. Staff will work with participants to make sure they know they may always quit the study or skip assessment questions.

e. Describe how participant privacy will be protected during data collection if sensitive questions are included in interviews.

The highest standards of confidentiality protection procedures will be followed. Participants will complete their assessments in a confidential location; study staff will be available to answer questions, but will ensure that participants have privacy when filling out the assessments via hard copy or on the computer. The identity of participants will not be revealed in the presentation or publication of any results from the project.

8. Benefits:

A. Describe any potential direct benefits the study offers to participants ("payment" for participation is not a direct personal benefit).

Mothers and infants in this study may benefit from receiving early childhood and parenting education from the FSN program. They will receive additional support and learn strategies for

healthy living that may decrease their risk for obesity and tooth decay. They may also benefit from the water they receive as a part of the study. The infant oral examination completed by trained research dental personnel in the home of the participant at 12 months postpartum could identify dental treatment needs, and if so, will result in a referral of the infant to dental care.

B. Describe potential societal benefits likely to derive from the research, including value of knowledge learned.

The community may benefit in the long-term from the study if it results in a decrease in risk behaviors and in obesity and tooth decay among the participating infants. If the intervention proves effective, the study may provide American Indian communities and other low resource communities with a prevention intervention targeting early childhood obesity and tooth decay that could impact health over the life course. Additionally, if we find that water insecurity impacts sugar sweetened beverage intake among infants the study may provide additional leverage to promote programs to increase safe drinking water around the Navajo Nation.

9. Payment:

A. Describe the form, amount, and schedule of payment to participants.

Enrolled mothers will be given a $10 gift card and a gift package (valued at $15) at the completion of the baseline self-report assessment. Thus, the total value of participant remuneration, upon completion of the baseline assessment is $25. Mothers that complete the baseline assessment in two sittings will receive the gift package at the first sitting and the $10 gift card at the second sitting. After the completion of the 4-month assessment, participants will receive a package including toiletries, baby care items and other items needed for the home. The value of these items will total $10. At the completion of the 6, 7, 8 and 9 month assessments, participants will receive drinking water for their household. At the completion of the 12-month assessment, they will receive a $10 gift card.

Participants who consent to the oral health components will receive an additional $20 at each study visit when these activities are conducted (baseline, 6, 9 and 12 months).

B. Include the possible total remuneration and any consequences for not completing all phases of the research.

Total possible remuneration for participants in the study is $20 in gift cards, a gift package worth $15, a gift package worth $10, and drinking water for the family. For participants who consent to the oral health components, additional total possible remuneration is $80 in gift cards. There is no penalty for leaving the study early; however, participants will not receive gift cards for assessments that are not completed.

10. Study Management

a. Oversight Plan

1. Describe how the study will be managed.

The investigator team located in Baltimore and Albuquerque will train local field-based staff in study procedures and monitor study progress. A Field Manager, Nicole Neault, MPH and Field

Coordinator, Reese Cuddy, MPH, who have extensive experience and training in study procedures, will directly oversee study progress and ensure fidelity to the study protocol. Ms. Neault has directed the field study staff for other related research projects conducted by Navajo and JHU for over 10 years, and Ms. Cuddy has experience working with the local site team on the implementation of nutrition projects. The Field Coordinator will oversee a Local Coordinator, Leonela Nelson who will ensure proper data management and program implementation. Weekly study calls between the investigator team, the Albuquerque team and the Shiprock-based study team will be conducted to review study progress and address any concerns.

2. *What are the qualifications of study personnel managing the project?*

The investigator team located in Baltimore, Dr. Allison Barlow (PhD) (PI), Dr. Summer Rosenstock (PhD), Dr. Lindsay Grant (PhD) and Ms. Allison Ingalls, MPH, along with the investigator team in Albuquerque, NM, Ms. Nicole Neault, MPH (Field Manager) and Ms. Reese Cuddy, MPH (Field Coordinator) will manage the program and be on-call at all times. They will train staff extensively in all study procedures. All of the local staff who will be employed for this study already have extensive experience working with community members. If staff members need any kind of assistance with participants, they will be able to reach Allison Barlow, Nicole Neault or Reese Cuddy immediately. Additionally, on-site support will be provided by the Local Site Coordinator.

All personnel involved in the study have extensive experience implementing and/or overseeing implementation of qualitative and quantitative research studies in the Navajo community. The investigator team is well versed in program management principles and human subject's research protection.

3. *How will personnel involved with the data collection and analysis be trained in human subject's research protections? (Use the JHSPH Ethics Field Training Guide on our website.)*

At the beginning of the study period, the PI and other members of the investigative team will provide several in-person training sessions to program staff focusing on study protocol and procedures and protection of human subjects and confidentiality. Throughout the duration of the study, the Investigator team will have weekly conference calls with program staff to monitor study progress and assure that the study is being implemented according to protocol. The PI and/or other members of the investigative team located in Baltimore will make 3-4 trips and the Albuquerque based management team will make 6-8 trips to the study site during the study's duration to assess study progress, fidelity to study protocol, protection of human subjects, and assurance of data quality and safety. The PI and both Program Managers will be available throughout the study timeline to ensure fidelity to procedures and administration of the post-assessments.

4. *If the PI will not personally be on-site throughout the data collection process, provide details about PI site visits, the supervision over consent and data collection, and the communication plan between the PI and study team.*

Throughout the duration of the study, the PI will have weekly conference calls with study staff to monitor study progress and assure that the study is being implemented according to protocol. One senior member of the investigator team will conduct regular visits to the study location to assess fidelity to study protocol, protection of human subjects, and assurance of data quality

and safety. An on-site coordinator will provide in-person oversight and monitor consent and data collection to ensure the study is progressing according to protocol.

Fidelity monitoring of FSN intervention implementation will be performed on 10% of all FSN intervention sessions conducted. Fidelity monitoring will be conducted by the Field Manager, Field Coordinator or the on-site coordinator. 10% of all sessions will be randomly selected and be observed in person. Study staff performing quality assurance will complete a feedback form and review the feedback form with the FSN Health Coach. Additional training will be conducted as necessary. A description of the fidelity monitoring process is included in the consent and assent documents. Fidelity monitoring data will be stored following the same criteria as participant data (see above).

b. Recordkeeping:

The Local Coordinator will be trained in study procedures and will oversee data collection and storage. They will work with the Field Manager and Field Coordinator to ensure fidelity to the study protocol. The Field Manager and Field Coordinator will discuss all concerns with the investigator team. As noted above, the PI and other members of the investigator team will conduct in-depth quality assurance checks during the study period. The PI will be responsible for reporting to the IRB.

C. Safety Monitoring

1. Describe how participant safety will be monitored as the study progresses, by whom, and how often. Will there be a medical monitor on site? If yes, who will serve in that role?

The Principal Investigator assumes responsibility for the safety of study participants. We do not anticipate significant problems with participant safety. Program staff will be trained to monitor for safety of study participants and report any concerns immediately to the PI. All study staff will be trained in human subject's research and will be required to complete the CITI ethics and HIPAA modules prior to any interaction with participants or study data. Certificates of training in human subject's research are kept on file at the Center for American Indian Health's office in Baltimore. Our Center for American Indian Health has extensive experience administering home-based programs in American Indian communities. As described in the consent, the program team will be trained to respond appropriately if there are any concerns with the safety of a participant.

2. If a Data Safety Monitoring Board (DSMB), or equivalent will be established, describe the following:

Not Applicable

3. Describe plans for interim analysis and stopping rules, if any

Please see our Data Analysis plan.

a. Reporting unanticipated problems/adverse events (AE's) to the IRB. Describe plan for reporting to the IRB and (if applicable) to the sponsor. Include plan for government-mandated reporting of abuse or illegal activity.

The Field Manager will immediately alert the Principal Investigator in the event of an adverse event or unanticipated problem. The Principal Investigator will report serious adverse events to the JHSPH IRB. If there is any child abuse reported during study participation, the Field Manager will immediately report this information to the PI. The PI will report this to appropriate Tribal Authorities; on the Navajo Nation potential abuse must be reported to Tribal Social Services. With experience from previous studies with the Navajo Nation community, the study team is knowledgeable of how to report this type of event without revealing study participation.

A. Other IRBs/Ethics Review Boards: *If the research will require review by other IRBs, provide the name and contact information for each IRB/ethics review board and its Federal Wide Assurance, if it has one (available on OHRP's website at http://www.hhs.gov/ohrp/assurances).*

This project has been approved by Chapters within the Norther Navajo Agency. After approval is received from the JHSPH IRB, the protocol will be sent for review and approval to Navajo Nation Human Research Review Board (NNHRRB). (The NNHRRB has requested that protocols be sent to their IRB for review, only after approval has been received from the academic institution overseeing the research).

B. Collaborations with non-JHSPH Institutions

For studies that involve collaboration with non-JHSPH institutions, complete the chart below by describing the collaboration and the roles and responsibilities of each partner, including the JHSPH investigator. This information helps us determine what IRB oversight is required for each party. Complete the chart for all multi-collaborator studies.

Insert Name of Institutions in Partner column(s); add additional columns if necessary.

	JHSPH	UCLA School of Dentistry	Partner 2
Primary Grant Recipient	X		

For the following, indicate "P" for "Primary", "S" for "Secondary" as appropriate to role and level of responsibility.) Add additional items if useful.

1	Human subjects research ethics training for data collectors	P		
2	Day to day management and supervision of data collection	P		
3	Reporting unanticipated problems to the JHSPH IRB/Sponsor	P		
4	Hiring/supervising people obtaining informed consent and/or collecting data	P		
5	Execution of plan for data security/protection of participant data confidentiality, as described in Sect. 5.	P		
6	Biospecimen processing, storage, management, access, and/or making decisions about future use	P		
7	Biospecimen testing and interpretation		P	

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IRB Approved Protocol Amendments Summary

3/1/17	Clarified water delivery procedures.
7/19/17	Increased baseline assessment window of completion, and updated recruitment procedures to include access to EHR via HIPAA waiver approval.
10/18/17	Corrected time points for the administration of the home safety scan.
3/28/18	Increase number of allowable consents to 150.
8/1/18	Added information about the UCLA partner lab.