Engaging Navajo Elementary Schools in Randomized Controlled Trial of Yéego! Healthy Eating & Gardening

Study Protocol

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I. RATIONALE AND BACKGROUND

Navajo families are at increased risk for obesity, diabetes and cancer,[3-5] in part due to low fruit and vegetable consumption. For children, these behaviors are greatly influenced by their school and home environments. Research has found that as availability and accessibility of fruits and vegetables increases, so does consumption. Furthermore, recent studies of effective child obesity prevention programs, have shown that school-based interventions that incorporate nutrition education and gardening can increase both children and their parents' healthy eating and gardening behaviors.[21-23] Our study aims to increase consumption of fruits and vegetables, through a curriculum focused on increasing knowledge and self-efficacy to grow and prepare healthy foods, as well as increasing their availability through a school garden.

Poor availability and accessibility of fruits/vegetables is a significant barrier to healthy eating in Navajo communities due their high cost, poor quality, and long distances to reach supermarkets that stock fresh produce.[6] Our previous research suggests that the schools in this area provide an opportunity to increase engagement of both children and their parents in health promotion interventions, including targeting behaviors that, unchecked, lead to obesity early in the lifespan. The impact of this study on knowledge, self-efficacy and behavior around healthy eating will be significant for both the participating school children and their families. Establishing health behaviors, including healthy eating choices, in childhood has been associated with positive health in adulthood and the potential to have a long-term/sustainable impact on health.[24,25] Children's behaviors can also influence adult family member behaviors. Many intervention studies around diet and physical activity have focused on schoolchildren for this reason.[26,27]

Incorporating cultural traditions in interventions is vital to sustaining behavioral change. Maintaining language and cultural traditions has been recognized as being important for both a strong ethnic identity and health in racial/ethnic minority populations in the United States.[28,29] Traditional growing practices, augmented with modern methods of irrigation, and eating traditional foods have been associated with positive health in American Indian populations.[1,30,31] Our previous studies have identified a strong interest in promoting Diné language and cultural practices, and school-based gardens have the potential to be effective because they draw on the same cultural traditions and strengths of Navajo communities and intergenerational transfer of knowledge.[32,17] This model is consistent with other school-based gardens occurring in Native American communities, including the Navajo Nation, and why Navajo adults believe strongly in the importance of educating youth on Navajo farming heritage.[33] The curriculum we have designed and are implementing at a Navajo elementary charter school in Shiprock incorporates elements of Diné philosophy, Navajo language and culture and holds promise in making a significant health impact in the community.

II. SPECIFIC AIMS

The Navajo Nation (Diné people) has identified gardening and healthy eating as priorities, demonstrated in the recent Diné College Food Sovereignty report, by the junk food and soda tax instituted in 2015, and in the advocacy by tribal leaders for expanding gardens across the Nation.[1,2] Navajo families are at increased risk for obesity, diabetes and cancer in part due to low fruit and vegetable consumption.[3-6] Over the past nine years, we have worked with community leaders from the Navajo Nation to research effective ways to promote gardening and healthy eating, and are now poised to estimate the efficacy of a school-based intervention to promote healthy eating and gardening in Navajo children. Previously, we have shown that gardening is a culturally appropriate intervention strategy for improving healthy eating in this population.[7,8] Community members have shared with us the importance of family in shaping their health behaviors, and a desire to protect the health of the next generation by encouraging healthy eating habits. Therefore, we developed and piloted a school-based intervention to promote gardening and healthy eating among Navajo elementary school children. The "Yéego! Healthy Eating & Gardening" intervention was developed based on social cognitive theory, on previous school-based gardening interventions reported in the literature, [9] and our own formative work in Navajo communities. We collaborated with a Navajo elementary charter school in Shiprock, NM to develop an integrated curriculum and school-based garden incorporating Diné philosophy of thoughtful allocation of local and natural resources. The intervention aims to build students' self-efficacy to grow and eat fruits and vegetables, as well as making other healthy food choices. While Navajo leaders have shown their

commitment to health through adoption of policies to encourage healthy eating among Navajo children, we know that these policies must be paired with successful interventions that are rigorously evaluated to inform additional wellness policy within schools. These interventions and policies, when broadly implemented are expected to reduce the risk of being overweight in children, including Diné children, who are at higher risk for diabetes and for the more than 13 specific cancers linked to obesity. Note: We use Navajo and Diné interchangeably in this grant.

In this study we will estimate changes in healthy eating and gardening behaviors associated with the intervention using a randomized controlled trial design, with the comparison arm receiving a delayed intervention in the following school year. Combining community engagement with rigorous design and analysis is a significant contribution of this study to the Cancer Health Disparities partnership. In parallel with implementing the randomized trial, we will actively maintain the collaborations with our charter Navajo school partners and with our longstanding collaborators in Shiprock, Tsaile and Crownpoint, by inviting them to be advisors and champions for the new trial. In particular, our specific aims are to:

Aim 1. Engage and recruit Navajo elementary schools to participate in a randomized controlled trial of "Yéego! Healthy Eating & Gardening" intervention, an integrated healthy eating and gardening curriculum and school-based garden. This phase will include meetings with school leadership, parents and teachers and assessing eligibility. A formal protocol including a run-in period will ensure willingness and capacity to participate in the study for at least two years.

Aim 2. Estimate the efficacy of the "Yéego! Healthy Eating & Gardening" intervention to increase healthy eating and gardening behaviors in Navajo elementary school children. The primary outcomes are child measures: a) tendency to choose vegetable and fruit items to eat; b) healthy eating score from a Navajo foods picture sort; c) gardening at home and d) self-efficacy to garden.

We anticipate 4 to 6 schools will participate in the main study. We will also assess process outcomes, including: recruitment, retention and intervention fidelity, and secondary intervention effects on parent healthy eating and gardening behaviors. Assessments will be conducted in a sample of the elementary school children in grades 3 and 4 at each school and in one of their parents (or other adult caregiver in the household that is the index adult for analysis), at the beginning and the end of the first school year. We use a culturally appropriate tool that includes foods commonly eaten by Navajo people to measure food choices in both children and parents. Choosing fruit and vegetables to eat at meal times in children and gardening participation and self-efficacy in children will be assessed using instruments from other studies. Secondary outcomes include measures of child weight and of academic achievement, as well as parent measures of healthy eating and gardening. Analyses estimating the intervention effect will assess the differential change over the first school year between the two groups of schools, adjusting for school level clustering. After the follow-up evaluation, the delayed intervention group will receive the intervention. A final descriptive assessment will be included at the end of the second school year. Continued engagement and skill strengthening will occur through quarterly parent workshops. Attendance at these will be tracked. This proposal is timely as the Navajo Nation consider their policy on dietary and activity benchmarks for schools as part of a rounded curriculum.

III. RESEARCH APPROACH

A. Overview and Design

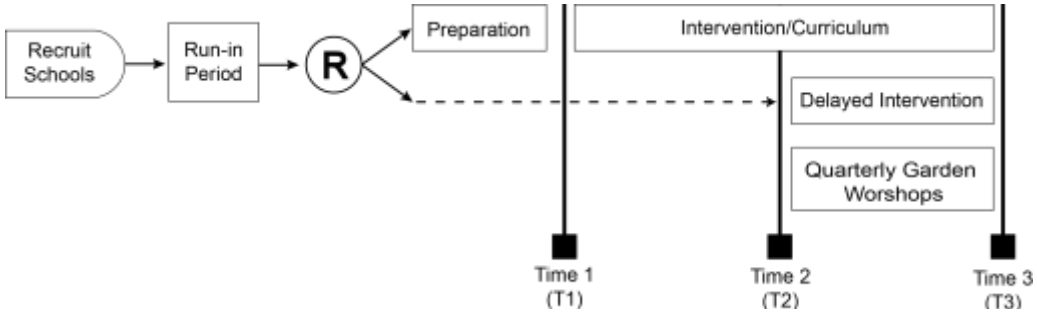
The small randomized controlled trial of an intensive curriculum and school garden intervention will be implemented in elementary schools in two communities (Shiprock and Tsaile). The study will begin in year 1 with a period of engagement and recruitment of schools in each community; with the goal of recruiting three schools *in each community* to start the run-in phase (see Figure 1). The run-in period will include time for greater engagement with the school community, an assessment of the potential garden site and an assessment of evaluation readiness. Depending on whether all three schools in the community qualify for the study at the end of run-in, or only two schools per community, we will randomize three or two schools to intervention or delayed intervention status in each community. We will have either two intervention schools and 4 delayed intervention schools, or 2 intervention schools and 2 delayed intervention schools, depending on the run-in information. We will conduct baseline data collection (T1) at the beginning of the school year in Year 2

with both children and parents. Students in the intervention group will receive the curriculum and school garden during that academic school year. At the end of the school year, we will conduct the T2 assessment in children and parents. The main evaluation period is between T1 and T2, and the statistical analysis methods refer to the T2 versus T1 change in outcome measures (healthy eating and gardening). After that, at the beginning of the next school year (Year 3), the delayed intervention schools will receive the intervention. During Year 3, we will also conduct quarterly community gardening workshops for adult family members in all schools. Attendance at these will be tracked. A final assessment (T3) will be conducted at the end of the second school year in all the randomized schools to describe behaviors in children and parents over time, using a quasi-experimental design that estimates change in the delayed intervention group between T2 and T3, attributable in part to the delayed intervention.

B. Research Team

The research team includes investigators from NMSU, Fred Hutch and Diné College with complementary expertise in the development and evaluation community and school-based health behavior interventions, gardening, education, and community engagement. The team also includes staff and consultants with

Figure 1: Study Design



expertise in Navajo culture, farming and agriculture. The project will be led by Drs. Kevin Lombard, Associate Professor of Horticulture at NMSU and Director of the NMSU Agricultural Science Center (ASC) sited on the Navajo Nation land and Shirley Beresford, Full Member at the Fred Hutch and Professor of Epidemiology at UW. This study draws on the complementary strengths of all institutions and investigators involved.

Fred Hutch

Dr. Beresford's role is to provide guidance on study design, dietary assessment and statistical inference, adhering to the most rigorous evaluation methods while honoring the community collaborative nature of this project. Because of her long history of cross-discipline collaboration, she is able to leverage some of the institutional strengths of the Fred Hutch, including cancer prevention randomized trials (group and individual level) and state of the art dietary assessment methodology and statistical expertise. Dr. Ornelas, an Associate Member at Fred Hutch and Associate Professor in Health Services at UW brings expertise in community engagement, working with American Indian populations, and designing and implementing health promotion interventions. Her role in the project is to provide guidance in each of these areas.

New Mexico State University (NMSU)

Dr. Lombard's role is to provide guidance in gardening and horticultural issues, and to continue to foster and grow the already strong relationship with Navajo community partners. The relationships the NMSU ASC has with Navajo tribal leaders are essential for conducting community-engaged research in the region. Dr. Lombard and his team made up of both NMSU and Diné College scientific staff will be responsible for recruitment of participating elementary schools, assessment at three time points, implementation of the intervention and continued community engagement. All data collection and intervention implementation work will be based at NMSU ASC and Diné College, with assistance provided by FHCRC investigators and staff. Dr. Lombard will assume responsibility for oversight of the Dine college staff as they contribute to the

activities outlined above.

Diné College

Several investigators from Diné College bring expertise in education and health in Navajo communities (Mark Bauer, Professor Public Health; Kathryn Hartzell, science faculty in Public Health; Geraldine Garrity, Chair of the Diné Teacher Education Program and Interim Provost, Diné College). Dr. Bauer has conducted previous gardening and health promotion studies in Shiprock and Tsaile. Dr. Hartzell has experience in curriculum and instructional design and implementation. Dr. Garrity brings expertise in the Navajo language, culture and educational system. The intervention coordinators, TBD (based in Shiprock) and Felix Nez (based in Tsaile) are both Navajo and have a background in gardening education. The investigators and staff will be paid by a subcontract through NMSU.

Team Meetings

Core investigators and research staff will have weekly team meetings by phone and video conference to make joint decisions about the study. In addition, Fred Hutch investigators and staff will travel semi-annually to the study sites to assist with study coordination.

C. Study Sites

Shiprock is situated at an important road junction (U.S. 499 and U.S. 64). It is home to several important Navajo institutions: the annual Northern Navajo Fair, a branch campus of Diné College, the Bureau of Indian Affairs, an Indian Health Service (IHS) hospital, a branch office of the Tri-State Agricultural Extension Service, a branch office of NMSU Cooperative Extension, and a branch office of the Navajo Special Diabetes Unit. According to 2010 Census estimates, the household population is 8,295 (52% female), with 2,706 housing units. More than 96% of the population is Navajo and about 64% of the population speaks Navajo at home. Also 37% of Shiprock residents live in poverty and about 45% under the age of 65 do not have health insurance, relying on IHS clinics for primary health care.[43] There are significant areas of irrigated farmland due to Shiprock's close proximity to the San Juan River. During the short growing season, common crops are alfalfa for animal grazing, along with corn and squashes. One full-service grocery store sells fruits and vegetables year-round. There are eight fast food restaurants in town. The closest major service center is Farmington, NM about 30 miles from Shiprock.

Tsaile is home to one of the first tribally controlled higher educational institutions, Diné College. Founded in 1968, the institution now operates in seven satellite locations across the Navajo reservation. Tsaile also houses its own land grant extension office as part of the 1994 land grant extension. According to 2010 Census, the household population is 1,198 (55% female), with 335 housing units. [44] More than 72% of the population is Navajo and about 50% of the population speaks Navajo at home. About 46% of Tsaile residents live in poverty, with a median age of 19. Occupations in the administrative, educational, and food service sectors make up the most available job opportunities. Diné College is the largest employer followed by the Tsaile public school and the satellite Indian Health Service clinic.[45] Tsaile is about 25 miles from Chinle and 50 miles from Window Rock grocery stores and restaurants. Food purchases are mainly through gas stations, trading posts and roadside stands. There are no fast food restaurants in Tsaile due to the isolation and remoteness of the community, other economic ventures include livestock production, some farming, and arts and crafts.[45]

D. School Engagement and Recruitment

Our first aim is to engage and recruit elementary schools from two communities on the Navajo Nation for the randomized control trial of the Yéego! Healthy Eating & Gardening intervention. We recognize that personal interactions with key stakeholders is an essential part of community engagement. This will require the assistance of "key influential" in the school system, faculty educators at Diné College, and local residents who are Navajo members of our research team. Based on our previous experience in recruiting of organizations for group-randomized trials, we plan to implement the following steps to recruit and engage potential schools as research partners. In defining the population of schools from which to recruit, we note there are about 90 elementary schools in the Navajo Division of Education system, including 16 in Shiprock and 11 in Tsaile. We will identify schools in Tsaile and Shiprock who meet the eligibility criteria for the study. The eligibility criteria will include having been in existence for at least three years, school size (have between 40 to 100 students in grades 3 and 4 combined), have more than two-thirds Navajo students and satisfy a garden site checklist that can overcome garden barriers (e.g. have access to water) (Figure 2). Information about potential schools will come from the initial phone screening and a school questionnaire. Each school will be contacted by phone and letter to assess their initial interest in participating in the study. After initial conversations, study staff will arrange a meeting with school faculty meeting to discuss the intervention and study procedures in detail. The meeting will provide detailed information on the student recruitment and data collection process and emphasize efforts to minimize disruption of daily classroom routine. For interested schools, we will also do an initial assessment of the school resources and garden site. From these meetings we hope to identify at least six schools, three in each community for further engagement. Our next phase with the schools will serve as a "run-in" period to the trial. During this time we will hold meetings with teachers and parents, and conduct initial surveys to gauge their level of interest, ability to engage in the types of evaluations used in the main study, and likelihood of engaging fully in the curriculum and school garden intervention. Our goal is to randomize a minimum of four schools (two in each community) that will participate for the duration of the project. If all schools qualify for the study on completion of run-in, we will randomize all six schools, two to intervention and four to delayed intervention.

Figure 2: Garden Site Pre-intervention checklist:

- ☐ Supportive leadership and staff (for developing a garden)
- ☐ Staff and volunteer interest in conducting garden maintenance
- ☐ Garden site near the main school building(s)
- ☐ Access to water at the garden site
- ☐ Fencing and/or security for the garden or school to prevent animal browing and vandalism

IV. INTERVENTION AND ASSESSMENT

A. Yéego! Healthy Eating & Gardening Intervention

Our intervention has two main components: a school garden and a healthy eating and gardening curriculum for students. It also has an ancillary component: family workshops to promote healthy eating and gardening at home. The theoretical framework for the intervention draws on the Social Ecological Model, which states that there are determinants at multiple levels that influence health behaviors, including the social and physical environment, organizations, and family.[46] We have also incorporated Social Cognitive Theory, which states that environmental factors influence individuals and groups, but that individuals and groups can also influence their environment and regulate their own behavior.[46] The school garden is an environmental feature that reinforces the skills, knowledge and behaviors taught in the curriculum, which in turn promote the collective efficacy of the students and their families to maintain healthy eating and gardening behaviors.

School Gardens. At each school, we will establish a school garden following guidelines outlined by Life Lab and previous school garden projects.[47] Ideally, school gardens will be located in a highly visible location in full sun, near a water source, fenced within a school play yard and accessible to the central school building, as well as school staff, students and family members. Gardens will consist of four durable raised garden beds (approximately 24 square feet each) filled with amended soil. The region is semi-arid so we will install appropriate irrigation systems that utilize available water resources efficiently including drip irrigation and rainwater harvesting. The garden will serve as a place for school staff and students to garden,

as well as an additional outdoor classroom for both student lessons and family workshops. The school will have primarily responsibility for maintaining the garden. However, they will receive technical assistance from the study team throughout the growing season related to planning, planting, maintaining and harvesting what is grown during the school year. We will continue to assist during the summer (between Years 2 and 3), when students and teachers are on summer break. However, we will encourage schools to identify staff or volunteers who can assist with maintenance during the summer months. [47] Plant selection will include vegetables that have grown well in our previous garden projects and informed by staff, student and family preferences. We envision a combination of cool season (e.g.leafy greens like kale and root crops, potatoes, onion) and warm season crops (fruiting crops) like tomato, chili pepper, and the "Three Sisters": Navajo corns, squashes, and beans. As crops mature and are harvested, research staff and students will measure the garden yield by weight and counts, in order to assess how much the garden space can produce. The fruits and vegetables harvested from the garden will belong to the school. Many Navajo schools provide breakfast, lunch and a snack to their students. We will work with cooking staff to ensure that they can use the produce harvested from the garden for meals and snacks provided by the school. Teachers will also be encouraged to use the garden and its contents (social, insects, plants) as a teaching space for other subjects. Garden infrastructure and plant names with their culinary/medicinal/traditional uses will be posted on signs in both Navajo and English.

Table 5. Healthy Eating Curriculum

Unit	Learning Objectives	Example Activity
1. Introduction & Kitchen Safety	Kitchen safety Define personal and community health	Practice kitchen safety skills Prepare and decorate journals
2. Food Sovereignty	Explain food access and availability Read a recipe to create a snack	Community guest speaker to teach significance and prep. of kneel down bread
3. Whole Foods & Nutrition	Identify whole and processed foods Choose healthy food options	Prepare snack from a recipe Analyze food labels and images
4. Empty Calories	Choose healthier sweeteners and low sugar drinks	Taste test varieties of same drink with different sweeteners
5. Fruits and Vegetables	Identify different fruits and vegetables and understand why them is important Recognize My Plate	MyPlate drawing activity Practice knife skills
6. Fiber	Identify strategies for incorporating more fiber into diet with fruits and vegetables	Compare seed anatomy
7. Traditional Foods	Identify traditional foods and their nutritional or medicinal importance	Community guest speaker will teach significance and prep. of blue corn mush Draw and press plants and herbs into notebook
8. Food and Family	Share foods and traditions from their family Learn to double a recipe for a group	Read "Who's in my family" about different family structures
9. Garden to Table	Describe participants and steps in a community food system	Prepare a snack with local and seasonal ingredients, discussing where they came from
10. Breakfast and Lunch	Understand the importance of making healthy food choices at home and school	Use kitchen skills to help prepare foods for lunch or snack at school
11. Celebrations and Gatherings	Prepare healthier meals for celebrations and gatherings	Practice using a cookbook to find and prepare a recipe for next garden celebration
12. Garden Celebration	Plan and lead a harvest celebration Redefine personal and community health based on what they've learned	Harvest and prepare foods from the garden for a celebration with the school community

Healthy Eating and Gardening Curriculum. We will provide schools with our curriculum (developed and implemented in our current pilot study) for both healthy eating and gardening that covers the entire school year. Each content area consists of 12 lessons throughout the year and coordinated with the growing season (See Tables 4 & 5, total of 24 lessons). Lessons will be scheduled based on input from school staff, but will occur approximately two times per month. The curriculum was designed based on both formative research with the target population, previous school garden interventions, investigator expertise in theory-based interventions to promote healthy eating and gardening, and instructional design.[9,36,48] The curriculum draws on Social Cognitive Theory, which posits that self-efficacy and observational learning are critical for promoting self-regulation and maintaining healthy behaviors.[46] The curriculum meets N.M state standards in health education, science, and

social studies for grades 3 and 4. By integrating the lessons into regular classroom activities, the interventionist can also help with required student assessment (i.e. pre/post learning) demonstrating growth relative to the state standards.

Lessons will be co-led by our interventionist and a teacher from the school as part of the regular school day, consisting of about 45 minutes for each lesson. Our curriculum is focused on children in third and fourth grade. Lessons will be implemented for both grade groups on the same day, but at different times, according to the teachers' schedules. This will allow for smaller groups and a lower teacher to student ratio.

For the healthy eating curriculum, each lesson consists of an introduction to the topic, an activity that addresses the learning objectives for the lesson, snack preparation, writing tasks associated with their garden notebook, and a handout with the day's recipe for the students to take home (Table 5). Lesson structure for the gardening curriculum is similar but includes time for garden maintenance in place of the snack preparation (Table 6). Each lesson aims to increase student self-efficacy in performing gardening and healthy eating-related behaviors, through demonstration and activities. Self-regulation and healthy behaviors are reinforced by observational learning and opportunities to practice the desired behavior (e.g. weeding, food preparation). Students will receive a handout based on the lesson content that can be taken home, so that families are aware of what their student is learning and have information to start or maintain their own gardens. Many of the lessons incorporate reading from children's books that were chosen based on their relevance to Navajo culture and/or the content of the lesson.

Teacher Curriculum Discussion Groups. Third and fourth grade teachers from Shiprock and Tsaile area schools will be invited to participate in a group discussion on how to enhance the existing curriculum for the current study. Teachers will have the opportunity to provide feedback on how best to integrate Diné and AZ/NM state standards into the curriculum and provide suggestions for new content or materials needed to facilitate the curriculum within their schools. Teachers that attend the group discussion will be provided with light refreshments and receive $30 for their time. At the end of the academic school year, 3rd and 4th grade intervention teachers will be contacted for a 60-minute phone interview to learn about their perceptions of the Yéego! Healthy Eating and Gardening curriculum. The goal is to seek to improve the curriculum through understanding teacher perceptions of what worked well, what needs improvement and wat additional support is needed for future implementation. It will also help to understand how delivery of the intervention contributes to study outcomes. Teachers will receive $30 for their time.

Table 6. Gardening Curriculum

Unit	Learning Objective	Example Activity
1. Planning a garden	Use seed packet information Understand how sun affects garden design	
2. Sowing and transplanting	Follow garden plan Use proper technique for planting seeds	Make garden plan. Make garden labels in English and Navajo
3. Garden maintenance	Perform weeding, watering and thinning Identify common weeds Explain what is needed to make a plant grow	Read "Corn is Maize". Model and have students practice weeding and watering
4. Water	Describe the water cycle, and how humans impact it. Explain how water quality affects human health	Read "Snail Girl Brings Water: A Navajo Story" Model the water cycle.
5. Compost	Explain why compost is important	Collect compost samples and examine them with magnifying glass. Record observations.
6. Plant anatomy	Identify plant parts and function Describe traditional uses and cultural significance of traditional craft	Harvest and classify plants. Plant scarlet runner beans in observation cups.
7. Traditional gardening practices	Describe traditional growing and farming practices and how they related to food sovereignty	Hear about traditional growing practices from local community member Implement one traditional garden practice
8. Pollination	Explain how pollination, fruit and seeds are linked Describe how and why to manage pests	Read "Zinnis, or How the Corn was Saved." Plant wildflowers.

9. Seasonal crops	Understand how seasons affect plants Descript how home and school gardens help localize the food system	Create garden calendars. Observe seed and plant growth.
10. Native plants and ecology	Identify native plants and describe their traditional uses	Plant native plants in the garden
11. Food presentation and seed saving	Describe methods for food preservation Identify food safety considerations	Quick pickle vegetables for a snack. Create seed packets for saved seeds.
12. Harvest	Measure amount of produce harvested Practice safe food storage and preparation	Weigh harvested produce and compare across garden plots using a bar graph.

Family Workshops. In the second year of the intervention (Year 3), there will be quarterly healthy eating and gardening workshops for family and community members to attend. These events will focus on engaging school staff, students and their families in the garden and provide an opportunity for families to learn gardening and healthy eating topics together. They will also be open to the entire community (Shiprock or Tsaile), in order to help promote positive social norms about healthy eating and gardening. For this reason, this component is considered ancillary, and will be evaluated separately from the main intervention components, by tracking attendance. Each workshop will focus on a specific skill that families can use at home to either grow or prepare healthy food. Participants will also receive small prizes for attending, such as plants, gardening tools, seeds or cooking utensils. These events will be based on similar events conducted during our pilot of the school-based intervention that were well attended and well received by the Shiprock community.

Due to COVID-19 Family Workshops Go Online. Due to the Navajo Nation, New Mexico, and Arizona responses to the COVID-19 pandemic, the planned in-person family workshops have pivoted to a video workshop series. The series is housed on the NMSU Agricultural Science Center website. The "how to" workshop series provide family and community members the opportunity to learn about gardening and healthy eating through a short video. The video series includes:

1. Raised Bed Construction (with media mixes)
2. How to Make Blue Corn Mush (from heathy eating curriculum activity)
3. How to Make Apple Donuts (from heathy eating curriculum activity)
4. Planting Peach Seeds
5. Transplanting Nursery Fruit Trees
6. Fruit Tree Pruning
7. Cool Season Crops
8. Seed Saving/Storage
9. Tunnel Construction
10. Frost Cover/Row Cover/Plastic Mulches (with ways to purchase resources)
11. Navajo Spinach Food Preservation

Videos are filmed by NMSU Agricultural Science Center staff, Diné College Extension Agents, Extension Agents from the San Juan County Cooperative Extension, Utah State University. The original workshops and the video workshop series are designed to be open to the entire community. Accordingly, the videos will be promoted and uploaded to the NMSU Agricultural Science Center website https://farmingtonsc.nmsu.edu/, an open-access public website. The NMSU website is maintained by the main NMSU campus in Las Cruses New Mexico, Dr. Kevin Lombard will be the direct contact. Student participants in the Yéego! Healthy Eating and Gardening Project will receive a promotional e-flyer through their school announcing the video series.

Video Production Timeline:

B. Data Collection/Assessment

After the end of the run-in period, we will obtain assent and consent from parents of children in the participating schools that are eligible to be randomized. This assent and consent will be for all the study assessments during the entire study period. In Year 2, we will survey the children and a parent (or index adult caregiver) at baseline (T1) which is at the beginning (August) and at follow-up (T2) which is at the end (June) of the school year. Timing of assessments will be staggered so that presence in the school at any one time point will occur on non-consecutive days, to minimize disruption in the classroom. Data assessment is quite

time consuming since the surveys have to be read to the respondent in an interview format conducted individually. We will use electronic data collection methods to capture the responses from both the interviewer-administered survey and from a culturally adapted virtual picture sort method.[49,41] Response options will be bar-coded on a screen displaying the picture of the groups of foods.

Prior to the start of the school year, and after a successful run-in, information regarding the study will be sent out to all families in randomized schools. They will also be invited to attend an information night timed to coincide with a parent orientation or chapter house meeting to learn about the study in detail. Information about the study will also be visible in the school newsletter prior to the start of recruitment, posted on school websites and posters displayed at the school to invite students to participate in the study. The project will ask from the school administration staff the first and last name of students, grade and teacher in order to create individualize recruitment packets. Students will receive a recruitment packet from their teacher to be sent home with their daily schoolwork. The packet will include information about the study, child assent and adult caregiver permission and self-consent to participate in the study. Students will be encouraged to return their packets in one week to be eligible for a school-wide raffle. Raffle for past studies included gift certificates to a local restaurant, movie theatre or activity for the family. The top raffle prizes will be a $50 gift card for the family, additional prizes include tote bags and backpacks. After the first week, a second round of packets will be distributed to the remaining students to reach the required recruitment goal of 60% of third and fourth grade students. In addition, to compensate teachers for their support of the packet process, classes that reach the 60% enrollment goal will receive $50 worth of classroom teaching supplies. The teachers will nominate what supplies their classroom will need. Study staff will purchase the items up to $50 and deliver to the teachers. For the students consented to participate in assessment, study staff will identify a series of after school times for students to complete the baseline survey. Student and adult caregivers who are not able to attend an assessment session after school, will be provided the opportunity to conduct the assessment at their home or place of their choosing. Each student/adult pair completing the assessment will receive a monetary gift in the form of cash, gift card or small gifts for children valued at $5 (e.g., flashlight, water bottle, cinch-sack/backpack). The starting cash amount for parent survey is $20 and child is $5. In order to maximize retention at later time points the survey incentive will increase by $5 at each time point. Other retention efforts include phone, email and text reminders. A school champion for each school will be assigned by the principal to assist with enrollment and assessment logistics for each school. The champion coordinates times for the assessment team to pick up completed enrollment packets, deliver new packets to teachers and assist with delivery of raffle prizes to schools and families. As a token of appreciation for their assistance, an honorarium of $100 will be provided at the end of the 2020 and 2021 school year.

Follow-up Assessment Notification

About a month before the start of the follow-up surveys (T2 in 2020 and T3 in May 2021), teachers will send a notice home with consented students who participated in the Baseline (T1) survey informing them and their parents of another survey coming. The study staff will follow the same procedures outlined for the baseline assessment of the students.

<u>Parent/guardian survey</u>.

There are four methodologies for completing the parent/guardian survey.

1. From the consented family, the parent completed the baseline survey and is available to complete the FU survey.
2. From the consented family, the parent consented, but did not complete the baseline survey. They will be invited to complete the follow-up survey.
3. From the consented family, the parent completed the baseline survey but is unable to complete the FU survey at any time in the follow-up window (T2 is April-May 2020).
4. A 3rd or 4th grader or their family are requesting an opportunity to participate at follow-up but have not yet completed the family packet or consent or assented their child.

1. The assessment coordinator will contact the parent who completed the baseline (the index parent/guardian) to again participate in the follow-up surveys (T2, and later T3).
2. The assessment coordinator will contact the parent who consented to the baseline but did not complete the survey (the index parent/guardian), to participate in the follow-up surveys (T2, and later T3).
3. If it is found that the index parent/guardian is not able to complete the survey, a new index parent/guardian can be appointed. The new index parent/guardian will be contacted to complete *Parent Survey and Verbal Participation Consent Form* approved by IRB. The verbal consent will be read and must be verbally affirmed by the parent/guardian prior to completing the parent survey interview. At the top of the parent follow up survey, there is a space for the interviewer to notate change in survey completer.

New Student Enrollment: New students will not be actively recruited to participate in the study at T2 or T3. If the new student or their parent wishes to participate on their own accord, they can request an enrollment packet from their teacher. In this way, students enrolled at a participating school in the 3rd or 4th grade after the baseline assessment was completed will have the opportunity to participate in the assessment. The first step is for them to take home the enrollment packet for their parent/guardian to complete. The child cannot participate in the survey without a completed packet. As before, the packet will include information about the study, child assent and adult caregiver permission and self-consent to participate in the study, and a Parent Family Survey (all documents IRB approved – see section VI List of Approved Documents). The student and parent/guardian must complete the enrollment documents and return the sealed packet to the teacher. The teacher will give the sealed packets to the school designated school champion to be securely locked in the assessment file cabinet until retrieved by the study staff. Procedures for obtaining student follow-up survey and parent follow-up survey will follow similar steps to those used at the baseline survey.

CONTEXT

New Mexico and Arizona State have mandated closure of all schools for the duration of the school year in response to slowing COVID-19 spread. The study has had to revise its protocol for obtaining the primary outcome measure that includes student follow-up assessment in April/May 2020.

Student Follow-up Assessment (amended due to COVID-19)

Preparation

Yéego! Healthy Eating & Gardening project has mailing addresses (including PO Box numbers) for almost all of the 3rd and 4th grade students in all six schools. For those students for whom the study has no address, contact will be made via phone and email requesting mailing address. It is anticipated that we will obtain mailing addresses that will reach ALL the 3rd and 4th grade students.

In addition to the mailed survey, parents/guardians that provided email addresses will be sent an email with a secure link to the follow-up survey. The weblink will send participants to a new virtual server with more restrictive access. The Yeego Server and the process to protect the files stored locally at Fred Hutch was approved by Information Security Office and IRB 08-12-2019.

Awareness communication plan

- Text blast/robocall: Yéego! staff will work with the principals of the enrolled schools for permission to use the teacher text blast or robocall system currently in place at the school. Text blast/robocall will be sent only to enrolled 3rd and 4th graders. The text blast/robocall will alert the student's parent/guardian that Yéego! staff will be in contact by email and/or phone regarding the follow up survey.

Individual Communication to provide tailored link and survey modality choice

- Email push: The Nutrition Assessment Shared Resources (NASR) will generate a standard email with a unique/personalized participant log-in link so students and parents/guardians can complete the follow-up survey online. 96% of parents/guardians provided an email when enrolling into the study.

- Text/Phone: The data collection team will contact participants by phone or text at the number provided on the Family Survey during enrollment. The call will take place after the text blast/robocall to participants and the email push. The purpose of the call is to determine the best modality for administering the survey. Prior to the phone call, the data collector will check to confirm whether an online survey has been completed. The data collector will let the participant know they can complete the survey online, by mail or by phone. The call could lead to a phone survey completion.

Follow-up survey delivery

- Online: The participant can complete the survey online. The Yeego study will be adding the capacity to collect online follow-up data directly from participants. An additional virtual server has been set up to host follow-up questionnaires. Data transmission from the participant to the questionnaire site will be encrypted via transport layer security (TLS). The questionnaire server will send participant responses to the encrypted study database, which is hosted on a separate server that is not accessible outside the Hutch network. Participants will be sent a participant-specific link by email. The link will direct them to the follow-up questionnaires. There is no personally identifying information presented or requested in the follow-up questionnaires.
- Mail: A packet will be sent to the mailing address provided. It will contain a cover letter, student/child survey with face sheet, parent/guardian survey with face sheet*),*and a *r*eturn postage-paid envelope.

  Note: For a household where the parent/guardian did NOT complete a baseline survey, no parent follow-up survey will be included.

  The assessment goal is to get as many of the original students and parent/guardians who completed baseline survey to complete the follow-up survey. In order to achieve a high response rate, the cover letter will include a phone number for the student/parent guardian to call if they prefer to conduct the interview over the phone, and an email to request a web-link if the student/parent guardian prefers to complete the survey online. The cover letter will also include a description of the incentives for completing the survey(s).

- Phone: The parent/guardian of the child will be contacted by phone (see individual communication and modality above). The parent can choose to have the child complete the interview over the phone at that time with a data collector, or can schedule a more convenient time to complete the survey by phone. The student/child survey and parent survey participants can use the hardcopy mailed survey as a guide for the phone interview.

Non-responder calls:
Two weeks after the initial mailing, non-responders will be contacted by phone to confirm they received the mailed packet, and to check their preferred modality for completing the survey (paper, phone or online). Once this preference is communicated (via mail, phone or email) with the study interviewer, they will arrange a time with the student (and the parent/guardian for the subset completing parent surveys) to complete the survey over the phone. The student can use the paper survey as a guide.

Note: For those participants without phone numbers, a second mailing will be sent two weeks after the original mailing.

C. Outcome Measures

The primary outcomes for this randomized controlled trial are differences in changes from T1 to T2 in healthy eating behaviors and gardening participation and self-efficacy in the **children** from the intervention school relative to the **children** from the delayed intervention school(s). Assessments are restricted to 3rd and 4th grade because of greater reliability among children aged 8 or older.

Child Healthy Eating Behaviors. *Tendency to Choose Fruit and Vegetables to Eat,* Assessing dietary intake in elementary school age children is notoriously difficult. Different simple approaches to approximating choices or eating behaviors have been attempted[50-52], including use of self-efficacy scales[37,38]. Questions using

a 4 point Likert scale were modified from two other studies of children, using 5-point[53] and 3-point Likert[54] scales. Seven questions ranging from "At lunch, I usually choose to eat vegetables, such as celery sticks or carrots" to a reverse code of "During snack time, I usually choose to eat cookies or crackers" are combined and averaged for an overall score. In a recent study in children,[55] the scores ranged from 1.14 to 3.86, with an average of 2.44 (s.d. =0.48). *Healthy Eating Score.* We will use the picture sort method developed in our current study, which allows us to estimate the frequency of eating foods that comprise ten major food groupings of the Navajo diet,[41] including breads; vegetables and salad; fruits; beverages; soups or stews; cereals; dairy and eggs; rice, pasta etc; meat, chicken or fish; and desserts and snacks. Sufficient detail within the broad groupings was retained to allow estimation of six of the eleven components of the AHEI. [42] Elements of the index that we were able to include are vegetables, fruits, whole grains, nuts and legumes, as well as sugar sweetened beverages and fruit juice, and red/processed meat. Trans fat, long chain fats, PUFA, sodium and alcohol will not be assessed in the children. The resulting Healthy Eating Score has a range of possible values from 0 to 47, and in our current study, the mean score was 14.6.

Child Gardening Participation and Self-efficacy. *Gardening at Home*. We will ask children if they have a garden at home, and if so how often they do gardening activities there. Responses had good variability in our current study – just over half reported affirmatively for "like to garden" and "have a place to garden" (Table 3). The analytic variable used will be proportion reporting gardening at home at least sometimes. *Gardening self-efficacy*. Self-efficacy questions regarding how confident they are in their ability to perform the behaviors come from the LA Sprouts studies.[9,36] The measures were evaluated for validity and reproducibility in schools in the Los Angeles area.[36] The self-efficacy variable used in the analysis will be a combined six-item likert scale.

Parent dietary behaviors. Dietary intake questions include fruit and vegetable consumption using an instrument used in the 5 a Day study, as well as soda and fast food consumption. This set of obesity related dietary behaviors[56] will be combined into an index (Barrington & Beresford, personal communication). The parent will also complete the virtual picture sort frequency method following the approach used in our current study (originally developed in an African American community[49] and modified for this study using foods commonly consumed by Navajo)[41]. Again, the weekly frequencies will be converted to a relative healthy food ratio (healthy foods to total foods) for the parent, based on AHEI categories[42].

Parent gardening behaviors. Our parent gardening frequency measure assesses typical frequency of gardening per week in the past three months, which we have adapted and modified from our previous studies to date. We will also ask about the presence of a garden at the home, frequency of participation in any gardening in the child's school or, if applicable, their home garden. Additional questions concerning degree of familiarity about what is being planted/grown/harvested in the school garden will be included.

Intermediate outcomes. For children, these include determinants of dietary behavior consistent with the approach used in the *LA Sprouts study*,[9] and the vegetable intake, food security and family relationships measures used in the *Community Gardening Project in Oregon*. [57] Gardening capability questions will be developed for children to indicate how well they know how to do specific gardening tasks that are taught in the curriculum (e.g. planting, weeding, watering, harvesting). We will also assess the participation of the students in the school garden, and the adoption by the students of positive attitudes towards growing vegetables, fruits and making healthy food choices.

D. Process Measures: Recruitment, Retention and Fidelity

We will assess recruitment, retention and fidelity using logs, tracking forms and checklists kept by the Project and Intervention Coordinators. We will also take minutes at all meetings with project staff, school staff and community advisors where recruitment, retention, reach, participant satisfaction, and fidelity will be regularly discussed. Recruitment. Data collectors will document the number of participants approached and recruited into the study in both the intervention and delayed intervention comparison group. Retention. Data collectors will document the number of eligible participants that complete each assessment. Intervention Fidelity. We will use checklists to assess fidelity to the intervention protocol during lessons. Teacher/Interventionist Checklist: Teachers will complete checklists at the end of each lesson to gauge fidelity of curriculum implementation. Based on previously outlined session themes and activities, instructors will report to what degree session specific content was addressed. Instructors will also be asked to comment on

session materials and preparation, noting things that inhibited or facilitated their ability to deliver program content, or any variation in participation. Observer Checklist: A data collector will be present at each lesson to complete an observation checklist, reporting the degree to which the intervention protocol is followed. This will include monitoring attendance, level of participation/exposure, content covered, and session logistics including materials provided and degree of preparation. Data collectors will also note barriers and facilitators to participation and engagement in session activities. Data from the checklists will be analyzed to assess fidelity to the intervention protocol.

E. Analysis Plan

Two of our four primary outcome measures in children (tendency to choose fruit and vegetables to eat during snacks/meals and gardening self-efficacy) will be measured through questions that use a Likert-type scale with four response options. With numeric codes assigned to each response option, means and standard deviations will be calculated per question and overall. Thus, possible mean values range from one to four. The intention to treat analysis will be a t-test comparing the change in mean values from baseline (beginning of school year at T1) to follow-up (end of school year at T2) in the intervention schools to those changes in mean values in the schools receiving the delayed intervention. This differential change in groups between T1 and T2 is the estimated intervention effect. The estimated effect of the intervention will also be analyzed using linear mixed models with T2 individual outcome as the dependent variable and intervention assignment as the

independent variable, adjusting for T1 individual outcome and school random effect. It will also allow for adjustment for additional covariates (school within intervention group if applicable) and for known or probable individual level confounders. Information from all responding students will be included in the analysis, with adjustment for repeated measures (expected to be the majority of the students). This will assess robustness of inferences from the simpler model. A sensitivity analysis without adjusting for possible intra-school correlations will be performed using linear regression models. In addition, the Akaike Information Criterion will be compared between the simpler model and the theoretically correct multilevel model to check model fit.

The picture sort method uses references to 26 commonly consumed food items by Navajo[41] chosen to represent six of the broad food components captured within the AHEI,[42] and four other Navajo food groups. Frequency of consuming foods from each group, with specific focus on the six AHEI relevant components will be estimated and compared across schools. The healthy components are fruits, vegetables, whole grains, and nuts and legumes, and the so-called “unhealthy” components based on AHEI scoring are sugar-sweetened beverages and fruit juice, and red/processed meat.[42] Differential change in the derived healthy eating score will be estimated, and evaluated using a t-test, conservatively, assuming a Normal distribution for the score, based on the Central Limit Theorem. Similarly, the proportion of children who participate in gardening at home will be calculated for each school, and the differential change estimated and evaluated using a z-test for proportions.

Secondary outcomes, including those collected from the parents of participating children, will be analyzed similarly. Mean values and standard deviations for scored variables will be calculated, and intervention effects estimated, and evaluated using t-tests. Frequencies will be estimated for categorical outcomes and intervention associated differences in frequency distributions across categories will be evaluated using Pearson's Chi-square test. Since both parent and child data will be collected, parent-child pairs will be created and explored, including the use of generalized mixed models to account for within-family correlations. The form of dyad analysis used will take into account that the members of the dyad are distinguishable.[58,59]

V. Protection of Human Subjects

A. Risks to Human Subjects

Human Subjects Involvement, Characteristics, and Design. The primary study population is children, both male and female, in grades 3 or 4. One member of their adult family (21 years or older) is included in the secondary study population. Because of the multicomponent nature of the intervention, including the school garden, and parent workshops, participation in the intervention activities will include children in other elementary grades and other parents. The proposed study will take place in elementary schools within the Shiprock, NM and Tsaile, AZ area; both rural areas located within the Navajo Nation. The majority of the

participants in the study will be American Indian (AI), primarily members of the Navajo Nation. It is anticipated that as many as 960 participants will be formally enrolled in the study: 80 3rd and 4th grade students within each of 6 distinct schools (three in Shiprock, 3 in Tsaile), plus one parent/caregiver for each child. Participants will be recruited through the enrolled, participating elementary schools selected.

Study Procedures, Materials, and Potential Risks. Schools will be recruited to the study and will take part in a "run-in" including planning with the study, and an evaluation of readiness to complete study surveys. We will recruit from 6 elementary schools in two communities (two schools in Shiprock, NM and three schools in Tsaile, AZ). We will recruit and enroll children in grades 3 and 4 (ages 8-11) who attend the selected elementary schools participating in the proposed study.

Data will be collected for research purposes only. Materials to be obtained include interviewer-administered questionnaires and anthropometric measures (height and weight) at three time points of the proposed study; at the beginning-T1 (August) and end-T2 (June) of the intervention school year and the end of the second school year-T3, once the delayed intervention has completed the intervention. We will assess process evaluation measures including recruitment, retention and intervention fidelity.

The interviewer-administered questionnaires will be completed online with questions constructed from items taken from the IRB approved previous study, "Engaging School and Family in Navajo Gardening for Health" and valid measures adapted minimally to be culturally relevant and understood by children and adult members of the Navajo community. The questionnaire for children will include healthy eating behaviors and gardening participation and self-efficacy including fruit and vegetable consumption at meals, relative frequency of health foods, gardening participation, and gardening self-efficacy. The parent/caregiver questionnaire will include dietary intake questions, fruit and vegetable consumption using the instrument from the 5 A Day study, as well as soda and fast food consumption, obesity related dietary behaviors and gardening frequency measures. Both parent and child will complete a virtual picture sort frequency method following the approached used in our current study. (originally developed in an African American community and modified for this study using foods commonly consumed by Navajo). Weekly frequencies will be converted to a relative healthy food ratio (healthy foods to total foods) based on the Alternative Healthy Eating Index (AHEI) categories.

There are minimal risks associated with participating in the survey assessments. It is possible that some participants (adult or child) may experience discomfort when answering questions about their health behavior. Participants will be informed that they do not have to answer any questions that make them feel uncomfortable. Finally, risks may include feelings of embarrassment, for children, during body measurements (height and weight). All staff will be trained to be aware of such discomfort, how to react in this situation, how to ease participants, and provide outside resources when needed.

As a physical out-door activity, the act of gardening can occasionally produce risks including cuts, scrapes, and sunburn. In most circumstances, accidents occurring in a garden are superficial. When proper precautions are taken (i.e. wearing appropriate footwear, sunscreen, hat, gloves) and training is given on the appropriate use of tools, accidents are usually preventable. Participants will be informed of the risk of out of door activities and advised to wear appropriate clothing, sunscreen and hat and to drink plenty of water.

B. Adequacy of Protection Against Risks

Informed Consent and Assent. Prior to the start of the school year, and after a successful run-in, information regarding the study will be sent out to all families in randomized schools. They will also be invited to attend an information night to learn about the study in detail. Information about the study will also be visible in the school newsletter prior to the start of recruitment, posted on school websites and posters displayed at the school to invite students to participate in the study. The project will ask from the school administration staff the first and last name of students, grade and teacher in order to create individualize recruitment packets. Students will receive a recruitment packet from their teacher to be sent home with their daily schoolwork. The packet will include information about the study, child and adult caregiver assent and consent to participate in the study. We will obtain assent and consent from parents of children in the schools. This assent and consent will be for all the study assessments during the entire study period.

For the students consented to participate in assessment, study staff will identify a series of after school times for students to complete the baseline survey. Student and adult caregivers who are not able to attend an assessment session after school, will be provided the opportunity to conduct the assessment at their home or place of their choosing.

Protections Against Risk. All individuals who participate in the surveys will be told that they can decline to answer any specific questions. All will be told they can stop participation at any time. Any paper records will be kept in a locked cabinet for up to three years.

Confidentiality of the study participants will be protected in this project. All participants will be assigned a study identification (ID) number. Information linking the participant name and study ID number is kept in a password protected computer file, separate from the survey responses and other data collected in the study. Access to the linked data is under the oversight of the Joint PIs, Dr. Lombard, at the NMSU-ASC, Farmington and Dr. Beresford of the FHCRC, who are responsible for maintaining the confidentiality. Questionnaire data is coded and managed as data files in a separate, protected part of the computer network. No information is released that could lead to the identification of any participating individual. Access to computer-stored information will require simultaneous knowledge of the data format, computer language, file name, and password. No individuals will be identified in any reports from the study.

We regard the risk of participation in this project as relatively slight. We will take care that every interviewer/facilitator is trained to handle an adverse situation sensitively and empathically, if a participant does experience significant distress during focus groups, interviews, or questionnaire completion. We will be prepared to consult with our IRB and/or human resources in the event that an adverse situation is reported. All participants will be given the name and number of a person in IRB to contact if an adverse situation should arise.

In the school gardens, participants will receive training in appropriate use of garden tools and be encouraged to wear appropriate attire.

Vulnerable Subjects. The individual level, school level, family level and community level intervention focuses on improving health of children and their parent/caregiver by integrating healthy eating and gardening throughout Shiprock, NM and Tsaile, AZ area. While the study is considered minimal risk, it is understood that permission to participate in the study means the agreement of parent or guardian to the participation of their child.

The institutional review board at the Fred Hutchinson Cancer Research Center has strict guidelines regarding the participation of children in research. All policies and recommendations will be followed. The IRB will approve all mechanisms for soliciting the assent of the children and the permission of their parents or guardians.

C. Potential Benefits of the Proposed Research to Participants and Others

Many aspects of the proposed study may be beneficial to the participants and their families. Benefits may include learning about healthy eating and how to garden, greater communication about healthy meals among families, gaining satisfaction knowing that they are providing information that may help other people within the Navajo community and their families in the future.

D. Importance of Knowledge to be Gained

This study will provide important information about preparation, storage, health benefits of foods and using school gardens to improve the vegetable and fruit consumption and general health among people of the Navajo Nation. Given the broad engagement with the school communities in project, our hope is that the schools and families involved will also become health champions in their communities, passing on their knowledge of healthy eating and gardening to others in their community and encouraging participation in our future studies. The project also serves to maintain an important relationship between the Navajo Nation tribal leaders and the NMSU ASC for their other collaborative research projects. This relationship makes it possible for us to sustain our efforts with our Navajo partners and provides a mechanism to transfer research findings directly to Navajo Nation policy makers.

The knowledge gained will lay the groundwork for an R01 type proposal, including specification of both the intervention and outcome measures, that would formally evaluate intervention effectiveness of the intervention using an experimental design.

E. Data Safety Monitoring Plan

This plan pertains to the intervention activities involving the garden. The risk of intervention activities is small due to the modest levels of exertion of the proposed project and the care in implementation of all gardening activities. Anticipated risks, if any, may include minor strain injuries sustained while being physically active. At the end of each class, staff will ask participants if they have experienced any muscle soreness or strains or other concerns. The research staff will record positive responses. The research staff will carry a first aid kit to all events to attend to any minor bruises, cuts or other injuries experienced by youth. Each week the research staff will send a report to the PIs. The PIs will track the concerns/problems and assess for any patterns that might emerge. If a trend or pattern emerges, the PIs will consult with the FHCRC IRB and adjustments to the program will be made accordingly.

Should any adverse event occur, the staff monitoring the intervention will inform the Community field manager within the hour. The community field manager will inform the PI of any adverse event within 24 hours. The PI will file an adverse event form with FHCRC IRB. The PI will send a copy of an adverse event report submitted to the FHCRC IRB to the NIH within 48 hours. We will track expected and adverse research related events and monitor over time.

VI. LIST OF STUDY DOCUMENTS

A. Participant Recruitment & Enrollment

1. Parent Consent – approved 8/31/19
2. Youth Assent – approved 8/31/2018
3. Parent Consent 2 – approved 3/29/19
4. Parent Consent 3 – approved 7/11/2019
5. Youth Assent 2 – approved 7/11/2019
6. Parent Consent 4 – approved 9/05/2019
7. Youth Assent 3 – approved 9/05/2019
8. Parent Verbal Consent – 01/16/20

B. Assessment

1. Baseline Questionnaire – approved 8/31/2018
2. Parent/Guardian Baseline Questionnaire – approved 7/3/19
3. Family Survey – approved 7/3/19
4. 3rd and 4th grade Student Baseline Questionnaire – approved 7/3/19
5. Baseline Questionnaire (T1) – Parent/Child electronic survey – approved 8/12/19
6. Follow Up Questionnaire (T2) – approved 01/16/20

C. Study Approach Documents & Intervention

1. School Information Sheet – approved 7/3/19
2. Assessment Overview Document – approved 7/3/19
3. Recruitment packet documents – approved 7/3/19
    a. Intervention Later Information Sheet
    b. Intervention NOW Information Sheet
    c. Parent Instruction Sheet
4. Study Logo – approved 7/11/2019
5. Principal Support Letter template – approved 7/11/2019
6. Intervention Curriculum – approved 8/12/19

7. Follow up Assessment Parent/Guardian Postcard – approved 01/16/20
8. Follow up Assessment Child/Student Postcard – approved 01/16/20
9. Follow up Assessment Parent/Guardian Call Script – approved01/16/20
10. Revised Intervention Curriculum Part I – approved 1/28/20
11. Revised Intervention Curriculum Part II – approved 3/12/20
12. Family Update Letter – COVID-19 – approved 3/19/20

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