# Developing a Technology-Based Type 2 Diabetes Mellitus Prevention Intervention for Reservation-Based Navajo Youth

Toyin Ola

April 2017

## Purpose of Grant

Type 2 diabetes (T2DM) is an epidemic in the United States (U.S.), and its prevalence continues to increase [Centers for Disease Control and Prevention (CDC), 2016c]. Unfortunately, children and adolescents are not immune to this growing epidemic [Dabelea *et al*., 2014]. Though type 1 diabetes (T1DM)—an autoimmune disorder for which there is currently no method of prevention—used to be the diabetes of youth, young people are increasingly being diagnosed with T2DM, which can be prevented and managed through diet and exercise [Pettitt *et al*., 2014]. Some [Colberg *et al*., 2010] suggest that one in three individuals born in the year 2000 or later will develop T2DM at some point in their lifetime. Currently, Native American youth have the highest rates of T2DM of any racial/ethnic group [Dabelea *et al*., 2014]. This proposal seeks funds to implement an electronic health (eHealth)/mobile health (mHealth) intervention designed to prevent T2DM among Navajo youth aged 10 to 17 years who live on the Navajo Nation Reservation in Arizona.

## Epidemiological Assessment

### Diabetes: A Costly Chronic Condition

After adjusting for age and sex, the latest CDC Diabetes Statistics Report [2016a] estimated that, in 2012, healthcare costs were 2.3 times higher for individuals with diabetes compared to those without diabetes. In 2012 alone, diabetes cost the U.S. roughly $176 billion in direct medical costs and $69 billion in indirect costs, such as disability, work loss, and premature deaths [CDC, 2016a]. Diabetes is also costly in terms of lost years of life. As of 2010, diabetes is the seventh leading cause of death in the U.S. [CDC, 2016a]. Among residents of the Navajo Nation, diabetes is the fourth leading cause of death, close behind heart disease [Navajo

Epidemiology Center, 2012], another chronic condition that individuals with T2DM are twice as likely to develop compared to their non-diabetic counterparts [CDC, 2016b].

**T2DM: No Longer a Disease of Middle and Older Adulthood**

The ongoing SEARCH for Diabetes in Youth study began in 2001 with the objective of assessing the growing prevalence and incidence of T1DM, T2DM, and other types of diabetes in youth under the age of 20 [Pettitt *et al*., 2014]. The study is unique in that it is one of the first not to focus on T1DM, which is the most commonly diagnosed type of diabetes in youth under the age of 20 [Pettitt *et al.*, 2014]. SEARCH researchers collaborated with the Indian Health Service (IHS) to collect data among youth living on reservations in Arizona and New Mexico [Pettitt *et al.*, 2014]. Based on data collected in SEARCH, Native American youth have the lowest prevalence of T1DM of any racial/ethnic group [Dabelea *et al.*, 2014]. Conversely, Native American youth have the highest prevalence of T2DM of any racial/ethnic group at 1.22 per 1,000, compared to 1.06 per 1,000 for African-American youth, 0.79 per 1,000 for Hispanic youth, and 0.17 per 1,000 for White youth [Dabelea *et al.*, 2014].

**Room for Change: Health Behaviors of Navajo Youth**

While the risk of developing T2DM is notably higher for Native American youth, there is a silver lining. Countless research [Chen, Magliano & Zimmet, 2012] has shown a clear link among dietary habits, physical activity, and the onset of T2DM. This is where there is room to intervene, as indicated by data from the most recent Navajo Youth Risk Behavior Survey (NYRBS), a joint venture of the IHS and the CDC.

In 2011, two versions of the NYRBS, one for middle schoolers and one for high schoolers, were disseminated in public middle and high schools and Indian Bureau of Education schools “on or near the Navajo Reservation” [Navajo Nation Division of Health (NNDH), 2013a;

NNDH, 2013b]. The survey revealed that 24% of Navajo middle schoolers had abstained from eating for 24 or more hours in an effort to lose or maintain weight [NNDH, 2013b]. Among Navajo high schoolers surveyed, 15.7% admitted to failing to consume food for at least 24 hours in the past 30 days in order to prevent weight gain [NNDH, 2013a]. Approximately 4% of Navajo middle schoolers reported that they had ever used weight loss supplements (powders, pills, or liquids) without consulting a healthcare professional, and 6% of high schoolers reported having used those substances sans medical advice in the past 30 days [NNDH, 2013a; NNDH, 2013b]. Navajo students' use of purging was also analyzed: 6.3% of middle school students reported that they had ever used laxatives or induced vomiting to lose or maintain weight, while 6.6% of high school students had engaged in those behaviors in the past 30 days [NNDH, 2013a; NNDH, 2013b]. With regard to physical activity, only 42.3% of middle school students surveyed had engaged in physical activity for at least 60 minutes per day for five or more days in the past seven days [NNDH, 2013b]. Similarly, only 45.9% of Navajo high school students reported having been physically active for at least 60 minutes per day on five or more days within the past seven days—compared to 47.9% of non-reservation-based Native American high schoolers and 49.5% of all U.S. high schoolers [NNDH, 2013a]. Approximately 13% of Navajo high schoolers reported no physical activity for the past seven days [NNDH, 2013a]. As discussed, diet and exercise are closely related to the development and progression of T2DM: This is a fact which many Navajo youth may not know since—of the thousands of Navajo students surveyed—more than 50% of middle schoolers and almost 40% of high schoolers reported that they had never been taught about diabetes in school [NNDH, 2013a; NNDH, 2013b].

Among Navajo high schoolers in particular, distressing trends have emerged since the NYRBS was first implemented. The obesity rates have risen 47.5% since 1999 such that Navajo

high schoolers are 33.8% more likely to be obese and 15.8% more likely to be overweight than U.S. high school students [NNDH, 2013a]. As of 2011, 17.6% of Navajo high school students were overweight based on their body mass index (BMI) compared to 15.2% of all U.S. high school students [NNDH, 2013a]. Approximately 17% of Navajo high schoolers were obese based on their BMI, whereas 13% of U.S. high school students were obese [NNDH, 2013a]. Clearly, the health behaviors of Navajo youth are prime targets for intervention.

## Target Population

### Intended Reach

According to the Navajo Epidemiology Center of the Navajo Department of Health [2016], there are 332,129 Navajos, including individuals who are mixed race, living in the United States (on the Navajo Reservation and elsewhere) as of September 2016 [Navajo Epidemiology Center, 2013]. There are 130,576 Navajo youth [Navajo Epidemiology Center, 2016]. As youth comprise almost 40% of the total Navajo population, it is essential that the youth are protected in order to ensure the future health of the Navajo people. The target population of the proposed intervention is Navajo youth aged 10 to 17 years who live on the Reservation in AZ. To assess the size of this subpopulation, 2010 U.S. Census data must be used. Per the 2010 Census, 34,583 Navajo youth aged 17 years and younger live on the AZ portion of the Reservation, and 16,411 are between to ages of 10 and 17 years [Arizona Rural Policy Institute, n.d.]. Assuming that the SEARCH prevalence rates are still accurate, 0.122% of Navajo youth between 10 and 17 years of age (approximately 2,003 individuals) already have T2DM. Thus, the proposed intervention aims to reach the 14,408 reservation-based Navajo youth aged 10 to 17 years living in AZ who have not yet developed T2DM, with a particular focus on those living in the more remote, resource-poor areas.

**Challenges and Strengths**

The Navajo Nation is sizable and spans three states (Arizona, New Mexico, and Utah), though the majority of the Navajo Reservation and its people reside in Arizona (AZ). The Nation's size and expanse is a "double-edged sword." There are more data on the Navajo and their health than most Native American tribes in the U.S. because they have succeeded in maintaining their traditional culture and integrating it with modern life [Navajo Tourism Department, n.d.]. Nonetheless, there is a great disparity in the availability of resources throughout the Nation since some areas are geographically isolated and sparsely populated. For the purposes of the proposed intervention, the Nation's location in three U.S. states poses another issue: It may be difficult to establish whose jurisdiction presides over the youth involved since the Nation has "parallel sovereignty" with the United States [Lenzerini, 2006; Duthu, 2008].

The Navajo people face many challenges. Of reservation-based Navajos, 41.3% are living within 100% of the Federal Poverty Line (FPL), and 69.5% live within 200% of the FPL [Bureau of Health Systems Development (BHSD), 2015]. For comparison, only 18.2% of Arizonans live within 100% of the FPL, and 39.2% live within 200% of the FPL [BHSD, 2015]. The median household income on the Navajo Nation is just under $25,000 per year compared to $50,000 per year for Arizonans overall [BHSD, 2015]. Approximately 26% of the Navajo Nation is unemployed, while only 10.6% of Arizonans as a whole are unemployed [BHSD, 2015]. Access to healthcare is another area in which the Navajo are disadvantaged. The Navajo Nation is a medically underserved area by both state and federal standards, meaning there is a shortage of primary care providers [Navajo Regional Partnership Council, 2010; HRSA Health Workforce, 2016]. In 2015, the AZ Department of Health Services [BHSD, 2015] estimated that the population to primary care provider ratio in the Navajo Nation was 1,631 to 1 compared to 449

to 1 in AZ as a whole. Moreover, the average travel time to the nearest primary care provider is more than 80 minutes [BHSD, 2015].

In addition to the economic and resource shortages, the geographic layout of the Navajo Nation presents a challenge. The proposed intervention seeks to mitigate the effect of the Nation's geography on healthcare access through the use of eHealth and mHealth. Historically, cell phone reception and internet access have been limited throughout most of the Nation, particularly in remote areas far from the capital of Window Rock, AZ [Smith, 2012; Navajo Tribal Utility Authority (NTUA), 2016]. However, this is in the process of changing. In the summer of 2016, the NTUA received a $23.5 million loan guarantee from the Indian Affairs Office of Indian Energy and Economic Development to enhance cell phone reception and to establish reliable internet access throughout the Reservation [Native News Online Staff, 2016; NTUA Broadband Initiative, n.d.]; this is in addition to the $32 million that NTUA received in 2009 as part of the federal stimulus [NTUA, 2016]. Furthermore, AZ cell providers have recently expanded their 4G-LTE mobile data coverage to include much of the Navajo Nation [Weaver, 2013].

## Existing Research and Interventions

As previously discussed, the SEARCH for Diabetes in Youth study has monitored the prevalence and incidence of T2DM among reservation-based youth in Arizona and New Mexico since 2001, but the focus is on surveillance rather than prevention. There are several Native American- and Navajo-targeted prevention interventions for adults currently in existence—namely, the IHS' Special Diabetes Project for Indians and the Navajo Nation Special Diabetes Project—but they do not target youth [IHS, n.d.; Navajo Nation Special Diabetes Project, n.d.]. Furthermore, these T2DM prevention efforts are concentrated around Window Rock, AZ or

other large cities like Tuba City, AZ. In 2015, the nonprofit organization Partners In Health (PIH) began collaborating with IHS and local food providers to start the Fruit and Vegetable Prescription Program. Through this program, overweight patients and their families receive "prescription" coupons for free, fresh produce that they can redeem at local retailers. PIH's objective is to reach three-quarters of the Navajo Nation's population by the end of this year [PIH, n.d.]. Though this intervention is not specifically geared at youth or T2DM prevention, it is likely to impact both.

Recently, Pulgaron & Delamater [2014] explicated the epidemiology of T2DM, and its correlate obesity, in children and adolescents, but they simply touched on the potential efficacy of family behavioral treatment for reducing weight and improving health outcomes. Their research concluded with a call to action to research prevention strategies specifically targeted at youth. Similarly, Rothman *et al.* [2008, p. e912] presented "the most comprehensive examination of self-management behaviors and perceive barriers to care of adolescents with T2DM to date" without providing any specific interventions to improve poor self-management behaviors or to mitigate perceived and/or actual barriers to self-management. A group of nursing students [Henley, Toburen, & Howsden, 2012] identified only twelve evidence-based T2DM prevention interventions specifically designed for adolescents after reviewing 165 articles. None of the interventions were designed for Native American youth, and most would be difficult to adapt as they revolve around structures (e.g. YMCA centers) that are not present in the remote areas of the Navajo Nation. Even the National Institute of Diabetes and Digestive and Kidney Disorders does not publicize evidence-based interventions for childhood/adolescent T2DM prevention, per se. The organization does offer two publications for youth—*Tips for Teens: Lower Your Risk for Type 2 Diabetes* (NDEP-087) and *How to Help Your Children Stay Healthy: Tips to Lower Their*

*Chances of Getting Type 2 Diabetes* (NDEP-098)—though the second pamphlet, for young children, is addressed to parents. The NIDDK is collaborating with a Mount Sinai researcher on a promising adolescent, mHealth intervention, titled Teen HEED, that is currently being pilot tested among ethnic-minority teenagers in Harlem, New York City [ClinicalTrials.gov, n.d.; Vangeepuram, n.d.]. The intervention relies on peer-support and is anchored by community-based participatory research tenets [ClinicalTrials.gov, n.d.; Vangeepuram, n.d.]. Nonetheless, the pilot test will continue through 2017; thus, its effectiveness is, as yet, unknown. Moreover, it seems unlikely that an intervention designed for a heavily populated, urban community would lend itself to adaptation for Navajo youth living on the Reservation.

## Program Plan[1]

### Choice of Approach

Ultimately, we hope to disseminate this intervention to the thousands of Reservation-based Navajo youth aged 10 to 17 years and to reduce the prevalence of T2DM among Navajo youth. In the interim, the objectives of this project are: to develop a culturally relevant T2DM prevention mHealth intervention for Navajo youth; to pilot test the intervention among 100 Navajo youth living in the Kayenta and Tuba City Agencies of the Navajo Nation; to increase participants' knowledge about the etiology of T2DM; to increase participants' perceived control over their development of diabetes; to increase participants' belief that their lifestyle impacts their health; and to reduce markers of metabolic dysfunction[2] known to be precursors of T2DM. We aim to achieve these objectives by way of a mHealth intervention.

[1] To guide review of the program plan, please see the logic model in Appendix A.
[2] The following indicators of metabolic dysfunction will be evaluated in this study: fasting plasma glucose (FPG), glycosylated hemoglobin (A1c), low density lipoprotein (LDL)—colloquially known as "bad cholesterol"—body mass index, and blood pressure (BP).

There is no shortage of T2DM prevention interventions for adults. However, few evidence-based T2DM prevention interventions exist for youth, and none are specifically designed for Native American youth. While there are many forms that such an intervention could take, we have decided to rely on technology since the usage of technology has skyrocketed in recent years, particularly among children and adolescents [Biddiss & Irwin, 2010]. According to the Pew Research Center [Poushter, 2016] median internet usage and smartphone ownership rose from 45% in 2013 to 54% in 2015 across a sample of 21 "emerging and developing countries"; among countries with more advanced economies, usage hovers around 87% [Poushter, 2016]. If we think of the Navajo Nation as a sovereignty independent of the U.S., then it is reasonable to assume that its median internet and smartphone usage falls between 54% and 87%. Though accessing the internet and obtaining cell phone reception has historically been problematic on the Reservation, NTUA has received significant funding to improve the Nation's telecommunications, even in less densely populated areas like the Kayenta Agency, located in the westernmost corner of the Nation. Thus, an mHealth intervention is not only appealing but also feasible.

We have chosen to disseminate our intervention using technology as we believe this mode of transmission will be less burdensome for the participants. From the Health Belief Model, we know that an individual's perception of barriers or costs associated with behavior change can alter his/her desire to engage in behavioral change. Given that the average travel time to primary care is 80 minutes within the Navajo Nation [BHSD, 2015], asking individuals who live in the Nation's more remote corners to attend weekly, on-site health education sessions over the course of several months would be excessive.

**Evidence Base**

Currently, there are no technology-based interventions geared toward Navajo youth. To our knowledge, there are no interventions specifically designed for Navajo youth that do not rely on either the school or parental involvement. Thus, this will be the first individual T2DM intervention for Navajo youth. There is a pre-existing curriculum, *Food for Life: Healthy Eating and Cooking to Beat Diabetes in Indian Country*, that we plan to adapt. Though the program has not been formally evaluated, there is positive anecdotal evidence (e.g. weight loss among overweight participants, individuals stopping their diabetes and hypertension medication, etc.) of its effectiveness [Physicians Committee for Responsible Medicine, n.d.]. The curriculum—which is centered around the importance of returning to the plant-based diet "enjoyed by the ancestors of many Native Americans," [Physicians Committee for Responsible Medicine, n.d.], symbolized by the Power Plate—was created by the Physicians Committee for Responsible Medicine in conjunction with Kiowa chef, cultural anthropologist, and food historian Lois Ellen Frank and Navajo chef Walter Whitewater and the support of several organizations, including the Navajo Nation Special Diabetes Project [Physicians Committee for Responsible Medicine, n.d.]. The curriculum [Physicians Committee for Responsible Medicine, n.d.] was originally designed for in-person delivery over the course of six weekly, two-hour sessions. The program structure will need to be adapted to suit the present modality and target population.

Adaptation of the *Food for Life* curriculum will primarily focus on program delivery. First, the curriculum will be delivered in 12 weekly, one-hour narrated, interactive modules accessed through a mobile application. The content provided in the original curriculum's fourth session, which was designed to include a grocery shopping trip, will be replaced by a virtual reality grocery shopping and meal planning game located in a separate section of the mobile application. The in-person cooking demonstrations included in each of the original sessions will

be replaced with video demonstrations. Other components of the original curriculum, namely the Power Plat-o bingo game and recipes, will be available as separate activities in the mobile application. To compensate for the loss of social support that would be gleaned from an in-person intervention, the mobile application will include a chat room through which participants can interact and share information. One key difference from the original curriculum is that our participants will be asked to record their dietary intake at least three times per week for the entirety of the intervention—rather than create weekly meal plans—in order to encourage mindful eating.

In addition to being asked to log their food intake, youth will be asked to record their physical activity each day. Numerous authorities [Fedewa *et al*., 2014; Pate & O'Neill, 2012; World Health Organization (WHO), 2016a; Who 2016b] agree that daily physical activity is important not just for T2DM prevention but also youth's general health and physical development. There are varying recommendations about the amount of physical activity needed to stave off T2DM. The American Diabetes Association [2016] provides a general recommendation of at least 150 minutes of moderate activity each week, while the WHO [2010] suggests that, irrespective of race, ethnicity, or income, youth between the ages of 5 and 17 years complete at least 60 minutes of moderate-to-vigorous physical activity each day. In their Global Recommendations on Physical Activity for Health [2010], the WHO notes that this physical activity does not have to be planned or to take place during a consecutive 60 minutes. Play, walking for transportation, etc. all count as physical activity [WHO, 2010]. Nonetheless, the mobile application will include a customizable "activity builder" in the event that youth want some direction and structure for their daily physical activity. By not prescribing specific exercise

routines, we aim to increase youth's enjoyment of physical activity, which is important for increasing and maintaining activity among youth [Biddiss & Irwin, 2010].

It is worth noting that the safety of promoting a vegan diet among youth has been considered. Studies [Messina & Mangels, 2001; Rauma, 2009] have shown that vegan diets are safe for growing children and adolescents, provided that they are carefully planned. For this reason, the curriculum sessions pertaining to how one can obtain complete nutrition from a plant-based diet will be divided and expanded in our adaptation of the intervention.

***Community input.*** Though the *Food for Life* curriculum has the endorsement of the Navajo Nation Special Diabetes Project, we cannot discount the fact that neither the original curriculum nor the adaptation to be featured in the present intervention have been implemented with the present target population. Therefore, input from those who are intimately familiar with the interests, values, norms, etc. of the target population will be essential. To that end, feedback from community members and other stakeholders will be sought at various phases of the curriculum and mobile application development. For instance, as participants are recruited, those who are deemed ineligible could still participate by providing their perspective on the intervention and feedback as to how it could be improved.

**Engagement**

The first step in engaging the community and recruiting participants will be to make contact with the local IHS health centers (e.g. Tuba City Regional Health Care, Kayenta Health Center, Inscription House Health Center, Dennehotso Health Station, etc.) in the Tuba City and Kayenta Agencies that administer adult T2DM prevention and/or self-management programs and care for adult diabetic patients. From this pool of patients, we plan to hire two community navigators who are over the age of 65 and who are interested in preventing T2DM among Navajo

youth. It would be ideal if these community navigators were either trained community health workers (CHWs) or graduates of diabetes education programs since they would be intrinsically motivated to perpetuate health through their community. With the help of these community navigators, we aim to recruit 100 eligible youth whose parents are current or past members of the aforementioned T2DM education programs. Community navigators will be charged with recruitment responsibilities since they will have the clout and connections to engage youth and their parents. Our logic is that parents enrolled in such programs who are actively trying to manage or to prevent T2DM will be likely to provide consent for their children to participate in a T2DM prevention intervention. Moreover, both parents and children can benefit from the social support in making behavior changes [Satterfield, Burd, Valdez, Hose, & Shield, 2002]. Though social support is important, we will not exclude children whose parents have not participated in a T2DM prevention/management program.

Since we intend to pilot test the present intervention in areas of the Reservation where residents tent to uphold Navajo tradition, one may worry that our mHealth intervention will not be well-received. However, this concern is unsubstantiated, if past experiences are any indication. Thanks to government-subsidized cell phone programs, technology has been known to infuse even traditional careers like sheepherding throughout the Navajo Nation [Peterson, 2006]. Conversely, one may wonder if the same youth who are interested in a technology-based intervention would respond to a prevention curriculum based on traditional values. Data [Navajo Nation Division of Health, 2013a, 2013b] suggests that this too should not be an issue. Among youth who completed the 2011 NYRBS, 43% of middle school and high school students reported living in a home where English is not the primary language spoken. Furthermore, 47.4% of middle schoolers and 78.6% high schoolers indicated that they participate in traditional

ceremonies, rituals, blessings, etc. [Navajo Nation Division of Health, 2013a, 2013b]. Thus, there seems to be a desire to uphold traditional Navajo culture.

We do not anticipate having difficulty engaging with community stakeholders as there is a push for T2DM prevention in Arizona as a whole and within the Navajo Nation. As we are adapting a curriculum that they have already endorsed, we anticipate that the Navajo Nation Special Diabetes Project will be a willing collaborator. Other potential stakeholders include: IHS, Arizona Diabetes Coalition, Navajo County Public Health Services District, Navajo Nation Health Education Program, Partners In Health, Tuba City Regional Health Care, Flagstaff Medical Center, Diné Youth, and University of Arizona's Center for Rural Health. The present efforts to implement a T2DM prevention intervention for youth would be a complement, not a duplicate, of the services that these organizations offer. Furthermore, should the above help the present intervention, they would be one step closer to fulfilling their share mission to eradicate T2DM in Arizona and among the Navajo.

**Activities**

***Staff.*** As noted in the logic model, key staff will include: research assistants (preferably graduate students), community navigators, a registered dietitian, a certified personal trainer, a computer programmer, and a diabetes educator. These staff will need to be recruited before the development of the mobile application can begin. The phlebotomists and nurse practitioners will not be needed until participants have been recruited and are ready to be assessed physically; they will not need any additional training beyond that required to obtain their credentials. Primary oversight will fall to the Principle Investigator, Toyin Ola, a public health and social work graduate student at the University of Pittsburgh.

***Training.*** As discussed, it would be ideal if the community navigators were CHWs so that they would have a solid health promotion foundation in addition to the intervention-specific training they will receive. If the community members are not CHWs, they will be trained through the AZ community Health Workers Association. In addition to their CHW training, community navigators will receive training on *the Food for Life* curriculum to be adapted, along with the non-clinical staff, from Caroline Trapp, Director of Diabetes Education and Care at the Physicians Committee for Responsible Medicine. The Food for Life curriculum will be taught on a condensed timeframe (i.e. staff will receive one session each day so that the material can be covered in six days rather than six weeks).

***Experimental Design.*** Since neither the efficacy nor effectiveness of the Power Plate curriculum has been established via experimental or quasi-experimental design, we feel it is necessary to employ a more rigorous scientific method to the present pilot test. To that end, we will use a waitlist control design. First, we will recruit 100 Navajo youth aged 10 to 17 years living in the western agencies of the Navajo Nation (Tuba City Agency and Kayenta Agency) until we have 50 youth aged 10-13 years and 50 youth aged 14-17. This may take some time as we must exclude those potential participants who are found to already have diabetes upon physical assessment. Next, the participants will be randomly assigned to either the immediate intervention (II) group or the delayed intervention (DI) group. Participants will be randomized using a computer-based random number generator. The DI group will complete the initial pre-intervention assessments (Q1) along with their II counterparts. These assessments will be repeated three months later when the DI group begins the intervention (Q2); the II group will be completing the intervention and undergoing their 3-month post-intervention at this time. The II group will undergo a 6-month post-intervention physical assessment at the time that the DI group

is completing the intervention as completing their 3-month post-intervention physical assessment (Q3). Finally, the DI group will receive their 6-month post-intervention (Q4). If we observe little-to-no change among DI participants between Q1 and Q2, but we do observe change between Q2 and Q3 and between Q3 and Q4, then we will have evidence supporting the effectiveness of the intervention.

***Dose***. All pre- and post-intervention physical and psychosocial assessments, as well as the one-time technology training, will take place at Kayenta Health Center, an IHS facility that offers primary care, health education, 24/7 emergency care, etc. Once pre-intervention assessments are complete, participants will return to their respective homes to complete one 45-minute intervention module each week for twelve weeks on the following topics: (1) Diabetes Overview; (2) Basic Nutrition & Physical Activity; (3) Introduction to The Power Plate; (4) The Three Sisters (Beans, Squash, and Corn); (5) All About Fiber, Fat, & Protein; (6) Complete Nutrition from a Plant-Based Diet; (7) Grains, the Staff of Life; (8) Tricky Situations: Away from Home; (9) Sugar Addiction; (10) Success Stories; (11) Recipe Makeovers; and (12) Handling Holidays, Feast Days, and other Celebratory Gatherings. In addition to completing these weekly sessions for three months, participants will be asked to log their food intake and physical activity through the mobile application for six months (three months post-intervention). Participants will receive weekly reminders about the modules and their required logging via weekly SMS; SMS message will occur weekly for six months.

**Sustainability**

Our goal is to create a web-based version of the mobile intervention once its effectiveness has been demonstrated. Creating a web-based version of the intervention as well as making the mobile application universally available on Google Play or iTunes for a small fee would be two

ways to disseminate the intervention to Navajo youth who are already in possession of smartphones and web-enabled devices. Moreover, this would reduce the need to purchase and provide devices; thus, reducing the funds needed to keep the intervention operational[3]. Though costs can be reduced, they most likely cannot be eliminated as the technology will need to be maintained.

There are several opportunities for procuring sustainable funding. Once our pilot test demonstrates the effectiveness of the mHealth intervention, we plan to establish a formal partnership with a Native-led organization, such as Diné Youth, so that they can assume primary oversight responsibilities long-term. This will serve two purposes: (1) to reduce staff costs, further reducing the cost of implementing the intervention and (2) to make the intervention's sponsoring organization eligible for grants from the Notah Begay III Foundation, which seeks to promote health among Native youth. We also aim to secure monetary support from local insurance companies since children are less likely than adults to receive uninsured medical care and endocrine and metabolic diseases are in the top ten reasons for youth's hospital stays [Witt, Weiss & Elixhauser, 2014]. If our intervention prevented one case of T2DM, we could save an insurance the $5,683 to $7,900 per person per year that it typically costs to treat diabetes if insulin is not needed [American Diabetes Association, 2013; CDC, 2011].

[3] Please see the one-year program budget and cost per participant in Appendix B.

**Timeline**

This timeline was designed with the goal that the intervention with the two II groups will begin in late spring/early summer as: (1) the school-aged participants will have more time for extracurricular activities since the academic year will be ending; (2) confounding influences such as school curriculum, school structure, etc. that might interfere with our assessment of the intervention will be minimized; (3) inclement winter weather will be less of a hindrance to transportation, outdoor physical activity, or the procurement of fresh produce; and (4) research assistants and, potentially, other staff can be full-time students since there will be no conflict with their academic year.

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Engage stakeholders | | | | | | | | | | | | | | | | |
| Hire key staff | | | | | | | | | | | | | | | | |
| Train key staff | | | | | | | | | | | | | | | | |
| Hire contract staff | | | | | | | | | | | | | | | | |
| Recruit potential participants | | | | | | | | | | | | | | | | |
| Finalize curriculum adaptation | | | | | | | | | | | | | | | | |
| Develop mobile application | | | | | | | | | | | | | | | | |
| Receive community input on intervention | | | | | | | | | | | | | | | | |
| Intervention with II groups | | | | | | | | | | | | | | | | |
| Intervention with DI groups | | | | | | | | | | | | | | | | |

## Evaluation Plan[4]

### Deliverables

Through this pilot test, we aim to demonstrate the effectiveness of our mHealth intervention such that we secure the requisite sustainable funding to implement the intervention with all Reservation-based Navajo youth aged 10 to 17 years. Ultimately, we believe that widespread use of this intervention will lead to a quantifiable reduction in the prevalence and incidence of T2DM among Navajo youth. Before these long-range impacts can occur, we will complete several steps to ensure the success of the present pilot test. After hiring and training key staff and consultants, the following will be done:

(a) Adapt *Food for Life* curriculum for use with Navajo youth
(b) Create mobile application, an original platform through which the adapted *Food for Life* curriculum and other components of the intervention (food log, activity log, etc.) will be delivered
(c) Develop app encouraging physical activity and healthy diet
(d) Screen for T2DM/prediabetes (FPG, Alc, BMI, BP)
(e) Refer individuals w/ T2DM to diabetes educator
(f) Recruit 100 Reservation-based Navajo youth aged 10-17 years to pilot test app/intervention, with aid of community navigators
(g) Administer MHLC and PedsQL™ 4.0 pre-intervention
(h) Distribute one tablet (containing the app), cell phone, and activity tracker to each participant
(i) Provide one training session on how to use technology provided
(j) Deliver SMS prompts and instructions weekly to participants regarding how to engage with the application
(k) Perform physical assessment every 3 months
(l) Administer MHLC and PedsQL™ 4.0 at 3 months

[4] Please see Appendix C for a concise overview of in the evaluation matrix.

## Data Collection

***Curriculum Adaptation and Application Development.*** Before the pilot test can begin, the mobile application will be developed. Though the software developer will be responsible for building the technical aspects of the application. The following key staff will adapt the curriculum: certified clinical exercise physiologist, registered dietitian, research assistants, community navigators, community stakeholders, and PI. As part of the adaptation process, staff will be asked to provide their candid feedback at the end of each weekly meeting: Handwritten or typed comments will be placed in a ballot box to be read by the PI at a later time. Comments will be discussed at subsequent staff meetings. This same "secret ballot" method of providing feedback will also be used when the beta version of the application is being tested. During beta testing, focus groups of community stakeholders who were not involved in the adaptation of the curriculum will also be conducted. These focus groups will be led by the PI, while the research assistants observe and take notes. Throughout the application development process, community navigators will be charged with engaging potentially eligible Navajo youth; as they obtain parental consent and youth assent, they will enter each youth's information in the participant log spreadsheet.

***Physical and Psychometric Assessment.*** Since we have decided to use a rigorous experimental design to structure the pilot test, there will be a significant amount of data to be collected. The intermediate intervention (II) group will be assessed three times (Q1, Q2, Q3), while the delayed intervention (DI) group will be assessed four times (Q1, Q2, Q3, Q4). The content of the assessments will be the same for both the II and DI groups, but the timing of the assessments will vary.

During Q1, the first pre-invention assessment, II and DI participants will complete the psychometric instruments (the PedsQL™ 4.0 Generic Core Scales and the MHLC) on paper with an ink pen at the Kayenta Health Center. The research assistants and the PI will label each instrument with each participants' unique identifier[5] before distributing them. Once participants have completed these instruments, they will be collected by the research assistants. The research assistants will be responsible for scoring the instruments and entering the score into a spreadsheet. The PI will review the scored instruments and the data entered to ensure accuracy. For Q1, all of the participants will be completing their written assessments in their respective groups, so the staff should be able to ensure that the majority of participants complete them.

Q1 will also include a physical assessment of each participant; these will be conducted individually to ensure HIPAA compliance. Phlebotomists will be responsible for drawing blood for A1c, FPG, and LDL and ensuring that the specimens are properly labeled and packaged for transport. Research assistants will be responsible for transporting the blood specimens to Tuba City Regional Health Care for processing. They will also be responsible for entering bloodwork results into the aforementioned spreadsheet once the specimens have been processed. The CRNPs will be responsible for recording each participants' height, weight, blood pressure, family history of T2DM, and any significant medical history/comorbidities. CRNPs can record this data on paper or electronically as the research assistants will be responsible for entering the information into the spreadsheet with participants' other assessment data. Once CRNPs have

[5] Each participant will be assigned a random number that will be used to randomize them into either the II or DI group. This same number will be used to label their psychometric instruments, blood specimens, activity logs, etc. The only exception will be in the case of siblings (or any participants who reside in the same household). Siblings will be identified with a single random number with the addition of a unique letter for each sibling. For example, 17598A 17598B, and 17598C would de three siblings. This identifying scheme will be employed so that siblings are assigned to the same group (II or DI) since it would be impossible to avoid contamination and to preserve the integrity of the experimental design if participants living in the same home were assigned to different intervention conditions.

completed the physical assessments, the research assistants will be responsible for calculating BMI and BP since there are no pre-determined normal/abnormal values for children and adolescents; instead, whether a BMI or BP is in the normal range is dependent on the percentile in which the child/adolescent's measurements fall [Baylor College of Medicine, n.d.; National High Blood Pressure Education Program (NHBPEP), 2005]. Research assistants will use the age-graded percentiles provided in the NHBPEP Working Group on Children and Adolescent's fourth report [NHBPEP, 2005] to determine whether participants are hypertensive. Research assistants will use Baylor College of Medicine's Children's BMI-Percentile-for-Age Calculator to assist in calculating participants' BMIs.

The content and procedure for Q2, Q3, and Q4 will be identical to that of Q1, with one exception. Only DI participants will be assessed at Q4. Q2 will be the II group's first post-intervention assessment, three months after the start of the intervention. The DI group with start the intervention after being assessed at Q2. The II group's second post-intervention assessment will take place at Q3; this will be their final formal assessment. Q3 will be the first post-intervention assessment for the DI group; their final assessment will occur three months later at Q4.

***Active Intervention*.** Once Q1 is complete, each II group participant will receive one cell phone, tablet, and activity tracker. They will then be taught to use the technology by the PI. The research assistants will be present in case participants have any individual questions. This same process will be repeated at Q3 with the DI participants.

In addition to the data collection required during the four assessment periods, the research assistants and the PI will be responsible for monitoring participants' activity tracker data on a weekly basis through the Misfit Shine's web-based application. We will also monitor

participants' self-reported food and activity logs as well as the exchanges among participants in the chatroom on a weekly basis. By monitoring participants' interactions with each other, we seek to learn about any unforeseen outcomes that may arise throughout the intervention. Our final weekly task will be to send out an SMS to all participants with prompts and instructions. The number from which the weekly text messages will be sent will be programmed into the participant cell phones before they are distributed.

**Tools**

Since we are adapting the Food for Life curriculum for use among Navajo youth for the first time, we will not have hard data to substantiate its validity and reliability until the intervention has concluded. Nonetheless, we will assess the face validity of the curriculum based on community navigator and stakeholder input throughout the adaptation and beta testing processes. We do not have to worry about implementation fidelity since the curriculum will be delivered through the mobile application. This delivery method will also enable us to determine whether participants completed each of the 12 weekly sessions (the videos will be programmed so that participants cannot fast forward once the session begins). Despite its advantages, the mHealth intervention is not taking place in a controlled environment; we do not know whether the participants will be distracted by their surroundings. However, the interactive nature of the sessions is meant to assess the degree to which participants have comprehended the material.

The tools that will be used to assess the efficacy of the intervention—the PedQL$^{TM}$ and MHLC–have been deemed valid and reliable by previous studies [Furnham & Steele, 1993; Varni, Burwinkle, Seid & Skarr, 2003]. Both tools have even been used among Native American youth [Egan *et al*., 2009], though not extensively. To our knowledge, these tools have not been used among rural, Reservation-based, Navajo youth; however, the MHLC has been used

successfully in research of Native American youth living in Arizona [Egan *et al*., 2009]. Overall, we feel confident that these tools will be appropriate for use with the target population. However, to ensure their appropriateness, we will conduct a focus group with the community navigators and other community stakeholders to ascertain whether any concepts presented are wholly foreign in Navajo culture.

**Reporting Out**

We intend to perform rigorous statistical analysis of the changes participants sustain from pre- to post-intervention in Stata. This will be done with the intent of publishing a series of papers in a peer-reviewed journal about the adaptation of the *Food for Life* curriculum and the efficaciousness of the mHealth intervention in reducing Navajo youth's risk of T2DM. A simplified, age-appropriate summary of these findings will be compiled into a newsletter that will be distributed to participants and their parents. A similar newsletter will be provided to all of the community stakeholders who helped throughout the process. In order to disseminate our newfound knowledge among Native-run organizations who share the desire to ensure Native youth have healthy futures, we plan to present at the Notah Begay III Foundation annual conference, which is generally held in the American southwest. One of the pilot test participants will have the opportunity to accompany us to this presentation and to share his/her experiences. The community navigators will also be invited to attend and present. We also hope to have features published in Navajo media (e.g. *Navajo Times*) so that individuals living in other parts of the Navajo Reservation can learn about our work.

# Appendix A
# Logic Model

**Problem Statement:** Reservation-based Navajo youth have the highest prevalence of T2DM of any racial/ethnic group.

| INPUTS | OUTPUTS | | OUTCOMES -- IMPACT | | |
|---|---|---|---|---|---|
| | ACTIVITIES | PARTICIPATION | SHORT [A] | MEDIUM [B] | LONG |
| Staff:<br>• 2 Community Navigators [C]<br>• 2 Phlebotomists [D]<br>• 2 CRNPs [E]<br>• 1 Registered Dietitian [F]<br>• 1 Certified Clinical Exercise Physiologist [G]<br>• 1 Software Developer [H]<br>• 2 Research Assistants [I]<br>• 1 Diabetes Educator<br><br>Funding:<br>• CDC<br>• IHS<br>• NIDDK<br><br>Materials:<br>• 100 tablets<br>• 100 pre-paid cell phones<br>• 100 activity trackers | • Develop app encouraging physical activity and healthy diet<br>• Screen for T2DM/prediabetes (FPG, Alc, BMI, BP) [J]<br>• Refer individuals w/ T2DM to diabetes educator [K]<br>• With aid of community navigators, recruit 100 Reservation-based Navajo youth aged 10-17 years to pilot test app/intervention<br>• Administer MHLC and PedsQL™ 4.0 pre-intervention<br>• Distribute one tablet (containing the app), cell phone, and activity tracker to each participant<br>• Provide one training session on how to use technology provided [L]<br>• Deliver SMS prompts and instructions weekly to participants regarding how to engage with the application<br>• Perform physical assessment [M] every 3 months<br>• Administer MHLC and PedsQL™ 4.0 at 3 months | • 100 Navajo youth aged 10 to 17 years living on the Reservation | • Increase participants' perceived control over development of T2DM<br>  • ≥ 6-point increase in MHLC Internal subscale score [N]<br>  • ≥ 6-point decrease in each MHLC Chance, Powerful Others, Doctors, and Other People subscale scores<br>• Increase participants' physical activity to ≥ 150 minutes per week (through activity tracker and self-reported in app)<br>• Increase participants' dietary awareness<br>  • Calorie counts reported through app ≥ 3 times/week<br>  • Servings of each food group reported through app ≥ 3 times/week<br>• Increase in participants' belief that their lifestyle impacts their health<br>  • ≥ 25-point increase in transformed score on PedsQL™ 4.0 Generic Core Scales [O] Psychosocial and Physical Health Summary Scores | • Decrease prediabetic participants' A1c to < 5.7% [P]<br>• Decrease prediabetic participants' fasting glucose to < 100mg/dL [Q]<br>• 5 to 7% decrease in overweight/obese participants' body weight [R]<br>• Weight maintenance in participants w/ BMI in normal weight range<br>• Increase participants' fruit/vegetable consumption to ≥ 5 servings per day | • Implement intervention with all Navajo youth aged 10 to 17 years<br>• Reduce prevalence and incidence of T2DM among Navajo youth such that they are on-par or lower than that of other races/ethnicities |

**ASSUMPTIONS**

- The Health Belief Model posits that individuals must perceive that they are at-risk for developing a health condition before they are inclined to change their health behavior.
- One key construct of the Theory of Planned Behavior is that individuals must believe that they have control, can engage in behavioral change, and are able to effect the desired outcome.

**EXTERNAL FACTORS**

- NTUA progress on expanding reliable internet access and 4G LTE mobile data coverage throughout the Navajo Nation
- Flagstaff Medical Center and Tuba City Regional Health Care support [S]
- Electricity availability among participants living in traditional Navajo housing (hooghans) and/or in rural areas of the Navajo Nation

[A] These goals are designed to be reached three months from the start of the intervention (i.e. once the application has been developed).
[B] These goals should be met six months from the start of the intervention.
[C] The community navigators will be two Navajo older adults (preferably, at least 60 years of age who have completed a T2DM prevention/management program. The rationale is that youth will be more inclined to participate if respected elders are affiliated since deference for older adults is a traditional belief among the Navajo. They will be full-time staff.
[D] The phlebotomists will be contract staff. Their services would only be needed at the pre-intervention assessment and every three months thereafter to draw blood specimens.
[E] The certified registered nurse practitioners (CRNPs) will be contract staff. Their services would only be needed for participants' pre-intervention assessments and every three months thereafter. Measurements such as weight, height, blood pressure, etc. will be taken.
[F] The registered dietitian will be full-time during the application development phase; thereafter, s/he will be a consultant who is contacted as needed.
[G] The certified clinical exercise physiologist will be full-time during the application development phase; thereafter, s/he will be a consultant who is contacted as needed.
[H] The software developer will be full-time staff during the application development phase and a consultant thereafter. S/he will be contacted if/when alterations and/or repairs need to be made to the application.
[I] The research assistants will be full-time staff who will assist with data management, data analysis, distribution of intervention materials, etc.
[J] FPG = fasting plasma glucose; A1c = glycosylated hemoglobin; BMI = body mass index; BP = blood pressure
[K] Youth found to already have T2DM will be excluded from the pilot test. They will be referred to the diabetes educator to receive coaching on how to manage their condition in the hope of preventing future complications.
[L] Troubleshooting will be available throughout the intervention via video chat.
[M] The physical assessment will consist of the same testing conducted pre-intervention to screen for T2DM/prediabetes.
[N] The Multidimensional Health Locus of Control Scale (MHLC) is used to assess perceived control in health contexts [Wallston & Wallston, 1981]. There are five subscales within the MHLC (Internal, Chance, Powerful Others, Doctors, and Other People) to assess where an individual believes control over their health lies [Vanderbilt University, n.d.]. Since the subscales are independent of each other, there is no total score on the MHLC [Vanderbilt University, n.d.].
[O] The PedsQL™ 4.0 Generic Core Scales are non-disease-specific health-related quality of life instruments designed for children, adolescents, and young adults aged two to 25 years [Varni, 2014]. Transformed scores range from 0 to 100, with higher scores indicating a higher health-related quality of life [Varni, 2014].
[P] Per the American Diabetes Association [2016], an A1c level of 5.7% is the threshold for a diagnosis of prediabetes. A1c levels below 5.7% are considered normal. An Alc level is essentially an average of an individual's blood glucose levels over the last 2-3 months.
[Q] Per the American Diabetes Association [2016], a fasting glucose of 100 mg/dL is the threshold for a diagnosis of prediabetes.
[R] The Prevent Diabetes STAT toolkit [n.d.], a joint venture of the American Medical Association and the Centers for Disease Control and Prevention, and the American Diabetes Association [2016] agree that a 5 to 7% reduction in body weight can reduce an individual's chances of developing T2DM by more than 50%.
[S] Support is anticipated from Flagstaff Medical Center in the form of expert advice and insights from their telemedicine program and from Tuba City Regional Health Care in the form of specimen processing (i.e. analysis of participants' blood samples) in their laboratory.

**Appendix B**
**One-Year Program Budget**

| LINE ITEM | Name | Salary | Level of Effort (FTE) | Funder Request |
|---|---|---|---|---|
| **Personnel** | | | | |
| ***Principal Investigator***<br>PI will be responsible for primary oversight of all activities related to the present research study including hiring and managing staff, reviewing data entry and analysis, etc. PI will also navigate the IRB process through the University of Pittsburgh and ensure that the pilot study is on-budget. | Toyin Ola | 50,000.00 | 1.000 | $ 50,000.00 |
| ***Research Assistant* x 2**<br>Research assistants will aid with any tasks assigned by the PI, primarily data collection and entry and preliminary analysis. They will be graduate students; thus, they will receive academic credit and authorship on any publications that result from this pilot study in addition to monetary compensation ($25,000 each). They will also receive free housing at the Kayenta Medical Center. | To be hired | 50,000.00 | 1.000 | $ 50,000.00 |
| ***Community Navigator* x 2**<br>Community Navigators' primary responsibilities will be recruiting participants and aiding with community engagement. They will each be paid the Bureau of Labor Statistics (BLS) median annual salary for community health workers: $40,150. | To be hired | 83,000.00 | 1.000 | $ 83,000.00 |
| **Personnel Wage Subtotal** | | | | **$ 183,000.00** |
| ***Fringe Benefits***<br>Calculated at 38% of applicable salary for employee health insurance, FICA, Workers Compensation, Life Insurance, Long-term Disability, and Unemployment Insurance. | | | | **$ 69,540.00** |
| **TOTAL PERSONNEL** | | | | **$ 252,540.00** |
| **Travel** | | | | |
| ***Local Travel***<br>The distance between Kayenta Health Center and Tuba City Regional Health Care is 74.1 miles. We estimate that staff will need to travel (roundtrip) between the two centers at least four times (148.2 miles). The 2017 federal reimbursement rate [IRS, 2016] is $0.17 per mile for medical purposes: **[(148.2*4)*$0.17]*2 vehicles = $201.56** | | | | $ 201.56 |
| **TOTAL TRAVEL** | | | | **$ 201.56** |
| **Equipment** | | | | |
| ***Vehicle* x 2**<br>Two used, four-wheel-drive vehicles that can handle the terrain and climate will be purchased for use by community navigators and research assistants. **$15,000*2 =$30,000** | | | | $ 30,000.00 |
| Large-capacity centrifuge, medical-grade refrigerator/freezer, and other medical laboratory equipment needed to store, prepare, draw, and analyze participants' blood specimens will be provided courtesy of Tuba City Regional Health Care medical laboratory | | | | n/a |

| | | | | |
|---|---|---|---|---|
| **TOTAL EQUIPMENT** | | | | **$ 30,000.00** |
| **Supplies** | | | | |
| ***Pre-paid Cell Phone* x 100**<br>Each participant will receive a cell phone so that they can receive weekly SMS message. Naked Mobile, a company based in the Four Corners region of the southwestern United States that partners with well-known networks to provide coverage to remote areas, provides a variety of Android pre-paid phones for $39.<br>**$39*100 = $3,900** | | | | $ 3,900.00 |
| ***Smartphone* x 5**<br>The personnel who will be full-time for the duration of the project (PI, community navigators, and research assistants) will be provided with Naked Mobile smartphones to conduct work-related business.<br>**$200*5=$1,000** | | | | $ 1,000.00 |
| ***Data Plan* x 105**<br>Naked Mobile offers unlimited talk, text, and data plans for $45 per month. Six-months of cellular coverage and data (shared w/ tablet) for 100 participants, and 12-months of 5 cellular coverage and data for personnel/staff will cost: **$[(45*6)*100] + [[(45*12)*5]= $29,700** | | | | $ 29,700.00 |
| ***Laptop* x 5**<br>Both research assistants and the principle investigator will receive laptops to complete data collection and analysis. The Software Developer will also receive a laptop. We will also have one laptop on reserve to be used when other laptops are being repaired or for use by clinical staff when they are completing physical assessments.<br>**$1,000*5 - $5,000** | | | | $ 5,000.00 |
| ***LTE-Enabled Tablet* x 110**<br>Currently, there are several commercially available tables that can using both wireless internet (WiFi) and LTE (the same technology that allows cell phones to access the internet and mobile applications without being connect to a WiFi network). Although the application will be downloaded to the tablets before the intervention begins, some additional features like the chat room will require WiFi or data usage. Each participant will receive one tablet. The remaining 10 tablets will be used by the Software Developer and personnel/staff to develop/test the intervention and by community stakeholders providing feedback during focus groups. The least expensive LTE-enabled tablet on the market is the Amazon Kindle Fire HD 8; it can run Android mobile applications.<br>**$90*110 = $9,900** | | | | $ 9,900.00 |
| ***Activity Tracker* x 100**<br>According to El-Amrawy & Nounou [2015], the Misfit Shine is one of the most accurate and precise activity tracker currently available. It also has the option of viewing trends through a web-based app, which will make it easier for research assistants to monitor participants' activity levels.<br>**$100*100 = $10,000** | | | | $ 10,000.00 |

| | | | | |
|---|---|---|---|---|
| ***Solar Panel and Battery Pack* x 100**<br>To our knowledge, the least expensive, commercially available solar charging system designed for use with small electronics is the Grape Solar GoCharger 7.5-Watt Portable Solar Panel and Grape Solar 5200mAh Rechargeable Lithium Portable Battery Pack for Cell Pones, Smartphones, and Other Portable Electronics purchased at Home Deport. The two components of the system are $48.37 and $28.00, respectively. Thus, providing each of the 100 participants with a complete solar system will cost **($47.37 + $28.00)*100 = $7,537.00**. Since the pilot test is targeting youth living in parts of the Reservation that favor adherence to traditional Navajo life, including residing in hooghans without electricity, we want to ensure that lack of electricity will not be a barrier. | | | | $ 7,537.00 |
| ***Multidimensional Health Locus of Control Scale (MHLC)***<br>This instrument is available free-of-charge online from a variety of sources, including the Vanderbilt University School of Nursing and Pearson Higher Education. | | | | n/a |
| ***PedsQL™ 4.0 Generic Core Scales***<br>Since this pilot test is funded by federal agencies, it falls under in the "funded academic research" licensing tier in the owner's cost structure. Therefore, we will need to pay a fee of **$990** to gain access to the measure. This fee is "per study"; it is not associated with a particular time period or number of participants. | | | | $ 990.00 |
| ***Bulk Ballpoint Pens* x 4**<br>Participants will complete the PedsQL™ and MHLC on paper. At Staples, one bulk box of 60 ballpoint pens is **$6**. Four bulk boxes of pens will be purchased in anticipation that some will be lost. | | | | $ 24.00 |
| ***Printing***<br>Participants will be given hardcopies of the PedsQL™ and MHLC. One hundred copies of each assessment will be needed for Q1 and for Q2, and 50 copies of each assessment for Q3 and for Q4. Assuming each assessment is 4 pages long: **[8*(200+200+100+100)]*$0.20 = $960** | | | | $ 960.00 |
| ***Misc. Office Supplies*** (for 12 months)<br>$100*12 = $1200 | | | | $ 1,200.00 |
| **TOTAL SUPPLIES** | | | | **$ 70,211.00** |
| **Contractual** | | | | |
| ***Phlebotomist* x 2**<br>A well-trained, certified phlebotomist should be able to draw at least 5 patients per hour so we estimate that the two phlebotomist will work a **combined total of 40 hours** to complete two physical assessments for each participant. They will receive the BLS median hourly salary of **$15.21/hour**. | To be hired | $15.21/hour | | $ 608.40 |
| ***Software Developer***<br>This contract staff person will design the mobile application used to deliver the intervention. This person will work full-time for the 6 months that the mobile app is being developed. Their salary during this time will be based on the BLS median **annual salary of $100,690**. For any additional work that is done after the app has been developed (repairs, etc.) s/he will be paid the BLS mean hourly wage of $48.41/hour. | To be hired | $100,690/year | 0.500 | $ 50,345.00 |

| | | | | |
|---|---|---|---|---|
| ***CRNP* x 2**<br>The CRNPs will only be needed to conduct the pre- and post-intervention physical assessments for both groups of participants. We estimate that each physical assessment will take one hour per participant; thus, the two CRNPs will work a **combined total of 200 hours** over the course of the pilot. They will be paid the BLS median salary of **$50.36/hour** for each hour worked. | To be hired | $50.36/hour | | $ 10,072.00 |
| ***Diabetes Educator***<br>A Certified Diabetes Educator can have a variety of degree backgrounds [NCBDE, n.d.], but we will seek out an individual who is also a registered nurse; therefore, we will pay the BLS median hourly salary for registered nurses: **$32.45/hour**. We estimate that the diabetes educator will work up to **16 hours** counseling individuals who are excluded due to a new T2DM diagnosis. | To be hired | $32.45/hour | | $ 519.20 |
| ***Certified Clinical Exercise Physiologist (CEP)***<br>A CEP is a Bachelor's level professional with a degree in sports medicine or kinesiologist plus several hundred hours of clinical experience [ACSM, n.d]. They are specifically trained to provided exercise prescriptions for individuals with or at-risk for cardiovascular, pulmonary, and metabolic disease [ACSM, n.d]. The CEP will be full-time for the 6-month app development phase; s/he will be compensated based on the BLS median **annual salary of $47,010**. Any consultant work thereafter will be compensated at a rate of $22.60, the BLS median hourly wage. | To be hired | $47,010/year | 0.500 | $ 23,505.00 |
| ***Registered Dietitian***<br>The contract staff person will be full-time for 6 months during the app development phase to ensure that any nutritional advice provided is appropriate. During that period, s/he will be compensated based on the BLS **median annual salary of $57,910**. Any additional work after the app development phase will be compensated at the BLS median hourly wage of $27.84/hour. | To be hired | $57,910/year | 0.500 | $ 28,955.00 |
| **TOTAL CONTRACTED** | | | | **$ 114,004.60** |
| **Other** | | | | |
| ***Food***<br>Healthy snacks will be provided for participants at the one-time training session. | | | | $ 300.00 |
| ***Biomedical Waste Disposal***<br>Participants' analyzed blood specimens will be safety disposed of courtesy of Tuba City Regional Health Care. | | | | n/a |
| ***Housing***<br>Kayenta Medical Center provides housing for its staff. The PI and research assistants will be able to live there free of charge for the duration of the intervention. | | | | n/a |
| **TOTAL OTHER** | | | | **$ 300.00** |
| **TOTAL DIRECT COSTS** | | | | **$ 467,257.16** |
| **Indirect Cost** | | | | n/a |
| **TOTAL COSTS** | | | | **$ 467,257.16** |

| | |
|---|---|
| **Unit Cost Per Person:** | **$ 3,972** |

**Appendix C**
**Evaluation Matrix**

| Evaluation Question | Indicator or Performance Measure | Method | Tool or Data Source | Frequency | Responsibility |
|---|---|---|---|---|---|
| Develop mobile application to deliver intervention | Intervention application | Laptop/tablet | Laptop/tablet<br><br>Secret ballot<br><br>Focus groups | Weekly for 6 months | Software developer; certified clinical exercise physiologist; registered dietitian; research assistants; community navigators; community stakeholders; PI |
| 100 youth aged 10 to 17 years engaged in pilot test | Number count | Participant log | Laptop | Repeated (until 100 eligible participants secured) | Research assistants; community navigators; PI |
| Distribute technology (tablet, pre-paid cell phone, and activity tracker) to 100 participants | Number count | Participant log | Laptop | Twice (once for immediate intervention [II] group and once for delayed intervention [DI] group) | Research assistants; PI |
| Train 100 youth to use the technology provided | Number count | Participant log/Sign-in sheet | Laptop | Twice (once for II group and once for DI group) | Research assistants; PI |
| Deliver SMS prompts throughout intervention to guide participants' interaction with the intervention app | Text message | Cell phone | Cell phone | Weekly for 6 months, once the intervention beings | Research assistants; PI |
| Increase participants' perceived control over development of T2DM | ≥ 6-point increase in MHLC Internal subscale score<br><br>≥ 6-point decrease in each MHLC Chance, Powerful Others, Doctors, and Other People subscale scores | Self-administered assessment | Multidimensional Health Locus of Control Scale (MHLC) | Twice per group (pre- and post-intervention) | Participants; research assistants; PI |

| | | | | | |
|---|---|---|---|---|---|
| Increase in participants' belief that their lifestyle impacts their health | ≥ 25-point increase in transformed score on PedsQL™ 4.0 Generic Core Scales (Psychosocial and Physical Health Summary Scores) | Self-administered assessment | PedsQL™ 4.0 Generic Core Scales | Twice per group (pre- and post-intervention) | Participants; research assistants; PI |
| Increase participants' physical activity to ≥ 150 minutes per week | ≥ 150 minutes physical activity per week | Self-report<br><br>Objective data from wearable activity tracker | Intervention app<br><br>Misfit Shine web-based app | Daily for 6 months, once the intervention beings | Participants; research assistants; PI |
| Increase participants' dietary awareness | Food log/daily calorie counts<br><br>≥ 5 servings fruit and vegetables per day | Self-report | Intervention app | ≥ 3 times per week for 6 months | Participants |
| Improve participants' metabolic risk factors | Decrease prediabetic participants' A1c to < 5.7%<br><br>Decrease prediabetic participants' fasting glucose to < 100mg/dL<br><br>5 to 7% decrease in overweight/obese participants' body weight<br><br>Maintenance/attainment of healthy BP based on age<br><br>Weight maintenance in participants w/ BMI in normal weight range | Physical assessment | Bloodwork (FPG, Alc, LDL)<br><br>BP<br><br>Weight and height (BMI) | 3 times for II group; 4 times for DI group | Nurse practitioners; phlebotomists; Tuba City Regional Health Care medical laboratory; research assistants |

## Bibliography


ACSM. (n.d.). ACSM Certified Exercise Physiologist: Motivate People with a Prescription for Health. Retrieved from: https://certification.acsm.org/acsm-certified-exercise-physiologist

American Diabetes Association. (2013). Economic costs of diabetes in the US in 2012. *Diabetes care*, *36*(4), 1033-1046. doi:10.2337/dc12-2625

American Diabetes Association. (2016, November 21). Diagnosing Diabetes and Learning About Prediabetes [Webpage]. Retrieved from http://www.diabetes.org/diabetes-basics/diagnosis/?referrer=https://www.google.com/

Arizona Rural Policy Institute. (n.d.) Demographic Analysis of the Navajo Nation Using 2010 Census and 2010 American Community Survey Estimates. Retrieved from: http://gotr.azgovernor.gov/sites/default/files/navajo_nation_0.pdf

Baylor College of Medicine: Children's Nutrition Research Center. (n.d.). Children's BMI-percentile-for-age calculator. Retrieved from: http://www.bcm.edu/cnrc/bodycomp/bmiz2.html

Biddiss, E., & Irwin, J. (2010). Active video games to promote physical activity in children and youth: a systematic review. *Archives of pediatrics & adolescent medicine*, *164*(7), 664-672.

Bureau of Health Systems Development. (2015, May 3). Navajo Nation Primary Care Area Statistical Profile – 2015. Retrieved from http://www.azdhs.gov/documents/prevention/health-systems-development/data-reports-maps/primary-care/navajo/8.pdf

Bureau of Health Systems Development. (2015, May 3). Navajo Nation Primary Care Area Statistical Profile – 2015. Retrieved from http://www.azdhs.gov/documents/prevention/health-systems-development/data-reports-maps/primary-care/navajo/8.pdf

Centers for Disease Control and Prevention. (2011, April 27). Medical Costs for Youth with Diabetes More Than $9,000 a Year: *CDC study finds annual cost of care is six times higher than for young people without diabetes.* Retrieved from: https://www.cdc.gov/media/releases/2011/p0427_youthdiabetes.html

Centers for Disease Control and Prevention. (2016a). *National Diabetes Statistics Report, 2014*. Retrieved from https://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf

Centers for Disease Control and Prevention. (2016b, June 13). Putting the Brakes on Diabetes Complications. Retrieved from https://www.cdc.gov/features/preventing-diabetes-complications/index.html

Centers for Disease Control and Prevention. (2016c, July 25). Working to Reverse the US Epidemic At a Glance 2016. Retrieved from https://www.cdc.gov/chronicdisease/resources/publications/aag/diabetes.htm

Chen, L., Magliano, D.J., & Zimmet, P.Z. (2012). The worldwide epidemiology of type 2 diabetes mellitus—present and future perspectives. *Nature Reviews Endocrinology*, *8*(4), 228-236.

ClinicalTrials.gov. (n.d.) Community-based Adolescent Diabetes Prevention Program. Retrieved from https://clinicaltrials.gov/ct2/show/NCT02458131

Colberg, S.R., Sigal, R J., Fernhall, B., & Regensteiner, J. (2010). Exercise and Type 2 Diabetes: The American College of Sports Medicine and the American Diabetes Diabetes Association: joint position statement executive summary. *Diabetes Care*, *33*(12), 2692-2696

Dabelea, D., Mayer-Davis, E.J., Saydah, S., Imperatore, G., Linder, B., Divers, J., ... & Liese, A.D. (2014). Prevalence of type 1 and type 2 diabetes among children and adolescents from 2001 to 2009. *Jama*, *311*(17), 1778-1786.

Dunham, L., & Kollar, L. M. (2006). Vegetarian eating for children and adolescents. *Journal of Pediatric Health Care*, *20*(1), 27-34. doi:10.1016/j.pedhc.2005.08.012

Duthu, N.B. (2008). *American Indians and the Law*. New York: Penguin Group.

Egan, J. T., Leonardson, G., Best, L. G., Welty, T., Calhoun, D., & Beals, J. (2009). Multidimensional health locus of control in American Indians: the strong heart study. *Ethnicity & Disease*, *19*(3), 338-344. Retrieved from: http://imap.ishib.org/journal/19-3/ethn-19-03-338.pdf

El-Amrawy, F., & Nounou, M. I. (2015). Are currently available wearable devices for activity tracking and heart rate monitoring accurate, precise, and medically beneficial?. *Healthcare Informatics Research*, *21*(4), 315-320.

Fedewa, M. V., Gist, N. H., Evans, E. M., & Dishman, R. K. (2014). Exercise and insulin resistance in youth: a meta-analysis. *Pediatrics*, *133*(1), e163-e174.

Furnham, A., & Steele, H. (1993). Measuring locus of control: A critique of general, children's, health-and work-related locus of control questionnaires. *British journal of psychology*, *84*(4), 443-479. doi:10.1111/j.2044-8295.1993.tb02495.x

Henley,S., Toburen, A.J., & Howsden, L. (2012). Evidence-based adolescent type 2 diabetes prevention. *Pharmacy and Nursing Student Research and Evidence-Based Medicine Poster Session.* Paper 46. Retrieved from http://digitalcommons.cedarville.edu/pharmacy_nursing_poster_session/46

HRSA Health Workforce. (2016, October). Health Professional Shortage Areas (HPSAs). Retrieved from https://bhw.hrsa.gov/shortage-designation/hpsas

Indian Health Service. (n.d.). Special Diabetes Program for Indians FY 2016 Community-Directed Grant Programs. Retrieved from https://www.ihs.gov/sdpi/includes/themes/newihstheme/display_objects/documents/factsheets/SDPI_FY2016_CD_GrantPrograms.pdf

IRS. (2016, December 13). 2017 Standard Mileage Rates for Business, Medical and Moving Announced. Retrieved from: https://www.irs.gov/uac/2017-standard-mileage-rates-for-business-and-medical-and-moving-announced

Lenzerini, F. (2006). Sovereignty Revisited: International Law and Parallel Sovereignty of Indigenous Peoples. *Texas International Law Journal*, *42*(155), 155-189. Retrieved from http://www.tilj.org/content/journal/42/num1/Lenzerini155.pdf

Messina, V., & Mangels, A. R. (2001). Considerations in planning vegan diets: Children. *Journal of the American Dietetic Association*, *101*(6), 661-669.

National High Blood Pressure Education Program Working Group on Children and Adolescents. (2005). The fourth report on the diagnosis, evaluation, and treatment of high blood pressure in children and adolescents. (NIH Publication No. 05-5267). Retrieved from: https://www.nhlbi.nih.gov/files/docs/resources/heart/hbp_ped.pdf

Native News Online Staff. (2016, June 29). Indian Affairs Approves $23.5 Million Loan Guarantee for Navajo Tribal Utility Authority. *Native News Online*. Retrieved from http://nativenewsonline.net/currents/indian-affairs-approves-23-5-million-loan-guarantee-navajo-tribal-utility-authority/

Navajo Epidemiology Center. (2012). *Navajo Nation Mortality Report, 2006-2009*. Retrieved from http://www.nec.navajo-nsn.gov/Portals/0/Reports/Vital%20Statistics%20Report%202006%20to%202009%20FINAL.pdf

Navajo Epidemiology Center. (2013, December). Navajo Population Profile: 2010 U.S. Census. Retrieved from http://www.nec.navajo-nsn.gov/Portals/0/Reports/NN2010PopulationProfile.pdf

Navajo Epidemiology Center. (2016, September 3). Navajo Population Profile. Retrieved from http://www.nec.navajo-nsn.gov/

Navajo Nation Division of Health. (2013a). *2011 Navajo Nation High School Youth Risk Behavior Survey Report*. Retrieved from http://www.nec.navajo-nsn.gov/Portals/0/Reports/2011%20NYRBS%20HS%20Report%20-%20Final.pdf

Navajo Nation Division of Health. (2013a). *2011 Navajo Nation High School Youth Risk Behavior Survey Report*. Retrieved from http://www.nec.navajo-nsn.gov/Portals/0/Reports/2011%20NYRBS%20HS%20Report%20-%20Final.pdf

Navajo Nation Division of Health. (2013b). *2011 Navajo Nation Middle School Youth Risk Behavior Survey Report*. Retrieved from http://www.nec.navajo-nsn.gov/Portals/0/Reports/2011%20NYRBS%20MS%20Report%20-%20Final.pdf

Navajo Nation Division of Health. (2013b). *2011 Navajo Nation Middle School Youth Risk Behavior Survey Report*. Retrieved from http://www.nec.navajo-nsn.gov/Portals/0/Reports/2011%20NYRBS%20MS%20Report%20-%20Final.pdf

Navajo Nation Special Diabetes Project. (n.d.). Mission [Webpage]. Retrieved from http://www.nnsdp.org/About_Us.aspx

Navajo Regional Partnership Council. (2010, August 10). 2010 Needs & Assets Report Navajo Nation. Retrieved from https://www.azftf.gov/WhoWeAre/Board/Documents/Sept27,10%20Board%20Materials/Attachment_11l_Navajo%20Nation%20_NA_2010%20RPT.pdf

Navajo Tourism Department. (n.d.). Navajo History, Retrieved from: http://www.discovernavajo.com/navajo-culture-and-history.aspx

Navajo Tribal Utility Authority Broadband Initiative. (n.d.). Retrieved from http://www.ntua.com/word%20and%20pdf%20files/BBANDMAPS.pdf

Navajo Tribal Utility Authority. (2016, July 14). *NTUA's Tribal Broadband Overview*. Retrieved from https://ecfsapi.fcc.gov/file/108162597929477/REDACTED%20Presentation%20Related%20to%20NTUA%20and%20NTUA%20Wireless%20(D0272354x8DF41)%20(2)%20(D0273550-2x8DF41).PDF

NCBDE. (n.d.). Discipline Requirement. Retrieved from: http://www.ncbde.org/certification_info/discipline-requirement/

Partners In Health. (n.d.). Navajo Nation. Retrieved from http://www.pih.org/country/navajo-nation

Pate, R. R., & O'Neill, J. R. (2012). Physical activity guidelines for young children: an emerging consensus. *Archives of pediatrics & adolescent medicine*, *166*(12), 1095-1096.

Peterson, L.C. (2006). *Technology, ideology, and emergent communicative practices among the Navajo* (Doctoral dissertation). University of Texas at Austin. Retrieved from: https://repositories.lib.utexas.edu/bitstream/handle/2152/6795/petersonl15314.pdf?sequence=2&isAllowed=y

Pettitt, D.J., Talton, J., Dabelea, D., Divers, J., Imperatore, G., Lawrence, J.M., ... & Saydah, S. H. (2014). Prevalence of diabetes in US youth in 2009: the SEARCH for diabetes in youth study. *Diabetes Care*, *37*(2), 402-408.

Physicians Committee for Responsible Medicine. (n.d.). Food for Life: Healthy Eating and Cooking to Beat Diabetes in Indian Country. Retrieved from: http://www.pcrm.org/health/diabetes-resources/native-american-curriculum/native-american-curriculum

Poushter, J. (2016, February 22). Smartphone Ownership and Internet Usage Continues to Climb in Emerging Economies: But advanced economies still have higher rates of technology use. *Pew Research Center Global Attitudes and Trends*. Retrieved from: http://www.pewglobal.org/2016/02/22/smartphone-ownership-and-internet-usage-continues-to-climb-in-emerging-economies/

Prevent Diabetes STAT. (n.d.) *Preventing Type 2 Diabetes* [Electronic toolkit]. Retrieved from https://www.cdc.gov/diabetes/prevention/pdf/STAT_toolkit.pdf

Pulgaron, E. R., & Delamater, A. M. (2014). Obesity and type 2 diabetes in children: epidemiology and treatment. *Current Diabetes Reports*, *14*(8), 1-12.

Rauma, A. L. (2009). VEGETARIANISM AND VEGAN DIET. *Physiology and Maintenance-Volume II: Enzymes: The Biological Catalysts of Life, Nutrition and Digestion*, 303.

Rothman, R.L., Mulvaney, S., Elasy, T.A., VanderWoude, A., Gebretsadik, T., Shintani, A., ... & Schlundt, D. (2008). Self-management behaviors, racial disparities, and glycemic control among adolescents with type 2 diabetes. *Pediatrics*, *121*(4), e912-e919.

Satterfield, D., Burd, C., Valdez, L., Hosey, G., & Shield, J. E. (2002). The "in-between people": Participation of community health representatives in diabetes prevention and care in American Indian and Alaska Native communities. *Health Promotion Practice*, *3*(2), 166-175.

Smith, Gerry. (2012, April 23). On Tribal Lands, Digital Divide Brings New Form of Isolation. *The Huffington Post*. Retrieved from http://www.huffingtonpost.com/2012/04/20/digital-divide-tribal-lands_n_1403046.html

Vanderbilt University. (n.d.). Scoring Instructions for the MHLC Scales [Webpage]. Retrieved from http://www.vanderbilt.edu/nursing/kwallston/scoringmhlc.htm

Vangeepuram, N. (n.d.). TEEN HEED: An Adolescent Peer Led Diabetes Prevention Intervention. Retrieved from http://grantome.com/grant/NIH/K23-DK101692-02

Varni, J. W., Burwinkle, T. M., Seid, M., & Skarr, D. (2003). The PedsQL™ 4.0 as a pediatric population health measure: Feasibility, reliability, and validity. *Ambulatory Pediatrics*, *3*(6), 329-341.

Varni, J.W. (2014). Scaling and Scoring of the Pediatric Quality of LIfe Retrieved from: http://www.pedsql.org/PedsQL-Scoring.pdf

Wallston, K.A., & Wallston, B.S. (1981). Health locus of control scales. *Research with the locus of control construct, Vol. 1*, pp. 189-243. Retrieved from

http://www.vanderbilt.edu/nursing/kwallston/Health%20Locus%20of%20Control%20Scales.pdf

Weaver, Jenny. (2013, March 11). Verizon Wireless 4G LTE Network Expands Throughout Arizona: From Window Rock to Yuma and in Between, More Customers benefiting from Speed and Capabilities of Most Advanced Network [Press release]. Retrieved from https://www.verizonwireless.com/news/article/2013/03/pr2013-03-12.html

Witt, W, Weiss, A & Elixhauser, A. (2014 December). Overview of Hospital Stays for Children in the United States, 2012. Retrieved from: https://www.hcup-us.ahrq.gov/reports/statbriefs/sb187-Hospital-Stays-Children-2012.jsp

World Health Organization. (2010). Global Recommendation on Physical Activity for Health. Retrieved from: http://apps.who.int/iris/bitstream/10665/44399/1/9789241599979_eng.pdf

World Health Organization. (2016a). Global Report on Diabetes. Retrieved from: http://apps.who.int/iris/bitstream/10665/204871/1/9789241565257_eng.pdf?ua=1

World Health Organization. (2016b). Report on the Commission to End Childhood Obesity. Retrieved from: http://apps.who.int/iris/bitstream/10665/204176/1/9789241510066_eng.pdf?ua=1&ua=1