Study Title: Latinos Combatiendo la Diabetes (Latinos Combating Diabetes)

Identifier: NCT01831921

Version Date: February 15, 2017 (uploaded July 26, 2018)

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Sponsored by the National Institutes of Health,
National Institute of Minority Health and Health Disparities

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I. Background, Rationale and Context

Type 2 diabetes mellitus is a major health concern in the United States, accounting for 90 to 95% of the more than 25 million diagnosed cases of diabetes in 2010[1]. The estimated healthcare burden in the United States for persons with diabetes was more than 150 billion dollars in 2010, making it one of the costliest chronic diseases[2]. Diabetes mellitus increases the risk of mortality from all causes, and is a major risk factor for cardiovascular disease, renal disease, blindness, and lower extremity amputations[3]. Because current treatment does not prevent a substantial proportion of these related complications, and application of proven therapies is inconsistent, prevention of diabetes mellitus is preferable to reducing related sequelae once the disease is established. Racial and ethnic minorities are disproportionately affected by the diabetes epidemic, specifically African Americans, Hispanic Americans, and Native Americans[3].

In the last decade, several large clinical trials have demonstrated the potential for the prevention of diabetes through lifestyle change, primarily through interventions focused on weight loss, physical activity and nutrition[4,5]. In the Diabetes Prevention Program (DPP), a lifestyle intervention produced an average of 7% weight loss and a 0.2% drop in glycosylated hemoglobin (HbA1c) by year 2, and a decrease in the absolute risk of developing diabetes mellitus from 11.0 to 4.8 cases per 100 person-years of follow-up[4]. This change was achieved through increased physical activity and reduced caloric intake and was effective in reducing the incidence of diabetes mellitus by 58% among persons with impaired glucose tolerance[4]. The intervention was delivered through a 16-lesson core curriculum taught by case managers on an individual basis over a 24 week period, after which participants entered a maintenance phase consisting of monthly individual and/or group sessions[6]. Based on these and other results, the American Diabetes Association, the North American Association for the Study of Obesity and the American Society for Clinical Nutrition issued a joint statement recommending weight management through lifestyle modification for the prevention of diabetes in 2004[7].

A number of recent studies have attempted to translate the DPP lifestyle intervention into community-based diabetes prevention programs and have demonstrated encouraging effects across diverse settings, including primary care settings[8-10], cardiac rehabilitation programs[11], churches[12], YMCAs[13], health care facilities[14,15], and community-based facilities (e.g., parks and recreation centers)[16]. Taken together, these interventions typically produce approximately 6% weight loss at one year of follow-up[17]. Although the cumulative evidence suggests that successful translations of the DPP can be implemented across a variety of settings with diverse personnel, numerous barriers to widespread dissemination of diabetes prevention programs in minority populations still exist.

This study is designed to address these barriers by further adapting a community-based lifestyle intervention for Latinos and we have identified several key elements to enhance logistical and fiscal feasibility and long-term dissemination: 1) identifying persons at risk using a diabetes risk screening tool followed by measurement of HbA1c , 2) using a group-based, rather than an individual-based intervention that will be implemented by bilingual Latino Lay Health Advisors (LHAs), and 3) delivering the intervention in a community-based setting. Latinos Combatiendo la Diabetes (La Comunidad) is a group-based, behavioral lifestyle intervention delivered by LHAs and integrated within the Latino community. It will be

population-based, proactive and community member-centered, consistent with the chronic care model.

II. Specific Aims

Our central hypothesis is that a community-based lifestyle weight-loss intervention implemented within the accountability and structure of existing Latino communities will have a more beneficial and clinically meaningful impact on HbA1c, insulin metabolism, and markers of the metabolic syndrome when compared to an enhanced usual care condition.

1. The primary outcome is change in HbAlc.
2. The secondary outcomes consist of clinical (body weight, blood pressure) and biochemical (glucose, HDL, triglycerides) markers of the metabolic syndrome.
3. The tertiary outcomes include biomarkers of insulin sensitivity and inflammation (fasting insulin, homeostatic model assessment [HOMA], CRP, IL-6, leptin, adiponectin, expression of IL-8 in circulating mononuclear cells, Omega 3 and 6 fatty acids, free fatty acids).
4. We also plan to evaluate the program's effect on health-related quality of life (HRQL) and determine the costs and cost-effectiveness of the intervention in terms of the primary and major secondary outcomes.

La Comunidad will provide much-needed information regarding the effectiveness of a community-based, behavioral intervention for the prevention of diabetes mellitus in Latinos. If the proposed approach is cost-effective, it will enable the rapid dissemination of this model to the many areas with Latino communities in the United States. Because many chronic diseases are influenced by activity and diet, this approach should translate into public health benefits in other areas (obesity, hypertension, cardiovascular disease) multiplying the potential social benefits and serving as a model for Latino community-based health promotion programs. Our overarching aim is translating evidence based, lifestyle strategies to eliminate health disparities in diabetes prevention.

III. Methods and Measures

A. Overview of Study Design

La Comunidad is a randomized clinical trial involving 225 Latino participants designed to further build upon the methods successfully implemented in the Healthy Living Partnerships to Prevent Diabetes (HELP PD)[16,18,19]. Participants in the lifestyle weight loss group will take part in a group-based intervention aimed at achieving modest weight loss (5-7%) through promoting healthy eating and increasing physical activity. The intervention sessions will take place at churches and other community locations and will be coordinated and facilitated by LHAs. Content will be delivered by the LHA using educational materials (DVDs, workbook, etc.) provided by the research team. The lifestyle intervention will be delivered in 2 phases: Phase 1 will last for 6 months and consist of weekly group meetings; Phase 2 will last for 6-18 months (depending on date of randomization) and consist of one LHA-led group session or one telephone contact from the LHA per month. Participants in this treatment arm will also receive individual visits with an RD during months 1, 3, and 6 of phase 1. Participants in the-enhanced

usual care group will receive two individual sessions with an RD and monthly newsletters that focus on existing community resources.

Participants will be Latino community-dwelling adults with pre-diabetes as defined by HbA1c of 5.7-6.5% and BMI of 25-45 kg/m^2. Participants will be recruited and pre-screened from a variety of Latino community settings. Screening activities will be conducted at churches and other community settings, with baseline and follow-up visits occurring in the Clinical Research Unit (CRU) of Wake Forest Baptist Medical Center or other WFBH facilities, including Lexington Medical Center, as needed. Following baseline assessment, participants will be randomized to one of the treatment conditions described above. Follow-up exams will occur every 6 months to assess weight, laboratory parameters, and other measures of the intervention effect. Due to the nature of the lifestyle intervention, neither participants nor project personnel can be masked to the participant's intervention status; however, personnel performing laboratory tests and interpreting their results will be masked. The project will operate under the general oversight of the Maya Angelou Center for Health Equity and will use an external safety officer to monitor trial progress and participant safety.

B. Conceptual Framework

The proposed study is guided by a conceptual model that integrates key concepts from social cognitive theory and the literature surrounding group dynamics[20,21]. Weight loss and fitness improvement achieved through a combination of modifying eating and physical activity behaviors is determined by the joint, reciprocal interaction of personal factors (e.g., beliefs and values), social influences (e.g., support and strain), and features of the physical environment (e.g., structure and access to resources). The lifestyle intervention incorporates several components of social cognitive theory: self-efficacy, outcome expectations, and incentives.

Self-efficacy refers to the extent to which individuals believe they can successfully perform specific behaviors, even when confronted with barriers. Research has shown that self-efficacy beliefs are determined by prior behavior, physical symptoms (e.g., pain, fatigue), appetite, affect, and environmental/social factors. Because self-regulatory behaviors are important to successful behavior change, the intervention is designed to increase self-efficacy in relation to goal setting, self-monitoring, and other self-management skills.

Outcome expectations refer to the anticipated costs and benefits of performing a specific behavior; people are more likely to approach a behavior if the perceived consequences of performing it have a favorable cost/benefit ratio. In many instances, people simply do not have the knowledge to understand the negative health effects of being overweight or obese and sedentary or are unduly optimistic about their own fate. Also, people often hold unrealistic expectations about how much weight they can lose through caloric restriction and increased energy expenditure and can become disappointed when the results from lifestyle interventions do not meet their expectations.

Incentives refer to the value that people associate with specific behavioral outcomes. Understanding the role of incentives on lifestyle behavior is a three step process. In relation to weight loss, one must understand (a) the desire that an individual has to lose weight, (b) the goal discrepancy or the degree of satisfaction/dissatisfaction between where one wants to be

and his/her current weight, and (c) the value/commitment to competing behaviors such as responsibilities to families or friends.

The effective use of and change in self-efficacy expectations, outcome expectations, and incentives in the context of lifestyle behavior change requires the acquisition and use of self-regulatory skills in conjunction with a continuous problem-solving model of behavior change. Self-regulatory skills enable people to exert control over their behavior, cognitions, and environment and are an integral part of the lifestyle intervention.

C. Setting

a. Organization

La Comunidad is a collaborative partnership between researchers from Wake Forest School of Medicine, Wake Forest University, and local Latino churches and organizations throughout the community. Churches in the Forsyth County, NC area will serve as intervention sites in La Comunidad when possible. A companion Manual of Procedures and Intervention Manual will provide specific operational details of the project for all study personnel.

The study is managed through several committees with distinct roles and responsibilities. The Steering Committee, made up of the principal investigator, all co-investigators, and senior project staff, will meet monthly. The Steering Committee is responsible for the study protocol, definition of all study outcomes, data analysis confirmation, publications, content approval of the interventional materials, and data collection and management procedures. The Steering Committee assumes full responsibility for the scientific integrity of the study, including protection of human subjects and health information. This committee is responsible for requesting and reviewing study progress reports made by the other standing committees.

The Intervention Committee, made up of investigators and with expertise in behavioral lifestyle interventions, including LHA training and supervision, will plan and oversee implementation of the intervention in La Comunidad. The Intervention Committee will be responsible for the adaptation and translation of intervention materials and procedures and training and supervision of the LHAs. This Committee will also be responsible for developing the intervention documentation procedures and for overseeing documentation of the process of intervention delivery. The Intervention Committee will meet weekly early in the study and at least monthly throughout the course of the study.

The Recruitment and Retention Committee will be responsible for planning, implementing and overseeing the recruitment and retention plans for La Comunidad, including advertisements, mailings (including procurement of mailing lists), development of telephone and in-person screening instruments and procedures, and screening, recruitment and retention monitoring reports. This committee will also monitor all aspects of participant retention, including visit and procedure adherence and will develop strategies and procedures to enhance retention of the LHAs. This Committee will meet weekly early in the study and at least monthly throughout the course of the study. As we anticipate that our relationship with partnering churches and community organizations will be instrumental to the recruitment and retention of

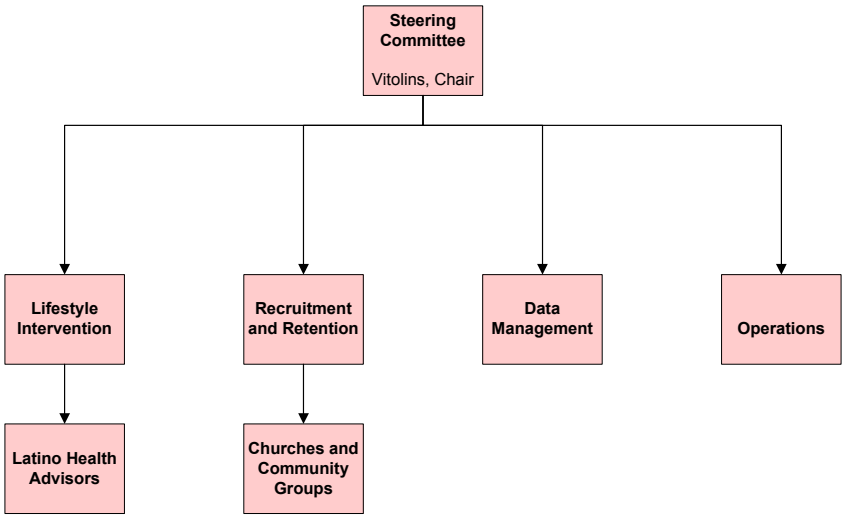
participants in La Comunidad, a member of the Pastoral Care team will be included on this committee.

The Data Management Committee, made up of investigators and staff with special expertise in study design and analysis, will be responsible for development of data collection instruments, data management procedures and data analysis plans, including quality control reports and reports to the study's safety officer. This Committee will meet weekly early in the study and at least monthly throughout the course of the study.

The Operations Committee, made up of the principal investigator and all research staff, meets weekly. This committee is charged with developing the Manual of Operations, reporting study progress, implementing the protocol as directed by the Steering Committee, including any changes, and ensuring that the intervention and data collection are proceeding according to the study timeline.

It is expected that roles and recommendations of these committees may overlap in some areas; it is the responsibility of the Steering Committee to coordinate activities and reconcile any conflicting recommendations. A schematic of study organization is included in Figure 2 and committee rosters are included in Appendix A.

Figure 1. Study Organization



b. Local Latino churches

As churches continue to play an important role in the social structure of the Latino community in which there are long standing associations between religion and health, we plan to base many of our recruitment efforts in local churches with large Latino populations. Local churches have been instrumental in establishing a system for health education in this community. We are also hopeful that we will be able to utilize church facilities to hold screening events and intervention group sessions when possible. Five local churches have initially agreed to take part in the recruitment efforts for this study:

- Our Lady of Mercy Catholic Church
- Calvary Baptist Church
- Green Street United Methodist Church
- El Buen Pastor Presbyterian Church
- Iglesia Nueva Vida Pentecostal Church

We will also identify other local churches and community groups that can play an integral role in the implementation and delivery of this intervention moving forward.

D. Subjects selection criteria

The principles guiding the selection of the following inclusion and exclusion criteria are to ensure the enrollment of participants who meet 3 major criteria: 1) high risk for developing diabetes, 2) no medical contraindications to participate in a lifestyle intervention including unsupervised physical activity and weight loss, and 3) ethical randomization, i.e., there are no compelling reasons that potential participants should be referred for immediate weight loss. Subjects will include 225 overweight or obese adults with pre-diabetes in Forsyth County, NC and the surrounding area. All participants will be required to identify themselves as Hispanic or Latino and we hope to recruit approximately equal numbers of men and women based on their representation in the population of the area. As women are more likely to seek medical care than men, we anticipate at least 50% of our sample to be female. We plan to make concerted efforts to ensure that no less than 40% of our sample is male.

a. Inclusion Criteria

- Demographics: Men and women 18 years of age and older who reside in or near Forsyth County, NC.
- Ethnicity: self-identified as Hispanic or Latino
- Evidence of pre-diabetes: HbA1c of 5.7-6.5%
- Body Mass Index (BMI): 25-45 kg/m^2
- Willingness to Accept Randomization: Potential participants must be willing to accept randomization to either the intensive lifestyle intervention or the comparison usual care condition.

b. Exclusion Criteria

- Weight Loss: Currently involved in a supervised program for weight loss.
- Diabetes: Clinical history of diabetes mellitus, or newly diagnosed diabetes mellitus at screening.
- Recent History of Cardiovascular Disease: Clinical history of cardiovascular disease (CVD) occurring within the past 6 months, including myocardial infarction, angina, coronary revascularization, stroke, TIA, carotid revascularization, peripheral arterial disease, congestive heart failure. All persons with recent CVD should be participating in cardiac rehabilitation (with appropriate supervision as indicated) to reduce their risk of recurrence; hence, randomization might raise ethical concerns.

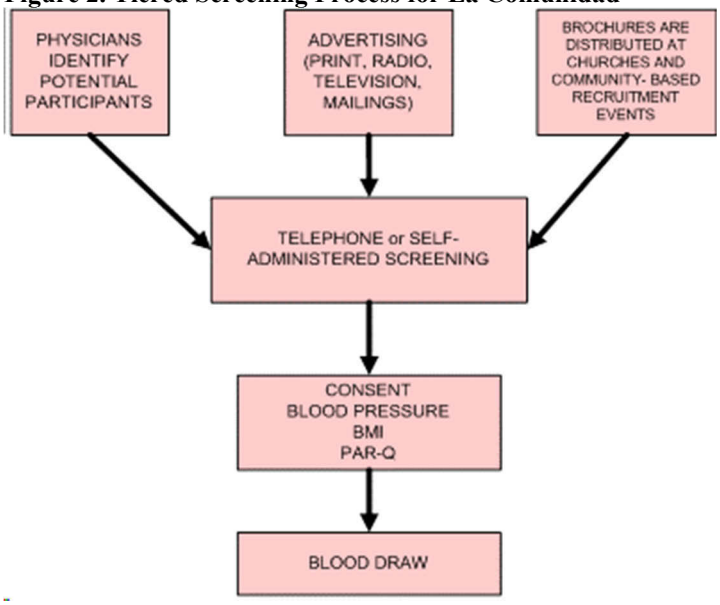
- Hypertension: Uncontrolled high blood pressure: BP $\geq$ 160/100. Potential participants can be re-screened after control has been achieved.
- Pregnancy: Pregnancy, breast feeding, or planning pregnancy within 2 years.
- Other Chronic Conditions: Other chronic disease likely to limit lifespan to less than 2-3 years, including any cancer requiring treatment in past 5 years except non-melanoma skin cancer.
- Medication: Chronic use of medicine known to significantly affect glucose metabolism (e.g., corticosteroids, protease inhibitors).
- Other: Conditions/criteria likely to interfere with participation and acceptance of randomized assignment, including the following: inability/unwillingness to give informed consent, another household member already randomized to La Comunidad, major psychiatric or cognitive problems (schizophrenia, dementia, self-reported active illegal substance or alcohol abuse), participation in another research study that would interfere with La Comunidad.

E. Screening and Randomization

a. Tiered Screening Process

A tiered screening process will be implemented to maximize the efficiency of screening. Interested prospective participants will be identified at the churches, community events, or by advertising, and will complete or be administered an initial pre-screening tool to assess medical history and the diabetes risk screening tool developed by the American Diabetes Association[22]. If potentially eligible, they will then be invited to take part in an interactive question and answer session to learn more about the study, followed by the informed consent process. Those participants still interested and eligible will then have their height, weight, and blood pressure measured and will complete the physical activity readiness questionnaire (PAR-Q). Those participants who have met all other eligibility criteria will then have a blood draw to determine HbA1c. Figure 2 outlines the screening process that we plan to implement.

Figure 2. Tiered Screening Process for La Comunidad



b. Randomization

Potential participants who 1) satisfy the inclusion/exclusion criteria previously described, and 2) provide a signed informed consent will be invited to the CRU or Lexington Medical Center to complete a baseline visit and be randomized to one of the treatment conditions. The number of participants recruited and randomized during a given month will vary, depending both on the flow of interested participants into the screening process and the needs/limitations of the lifestyle intervention arm of the study. We anticipate LHA-led intervention groups of 10-15 participants and for the intervention to begin within one month of randomization. We will recruit participants in waves to ensure that there are sufficient numbers to fill intervention groups. We will adopt a permuted block design with varying block size, as this can lower the time randomized individuals wait for intervention groups to develop and ensure a degree of balance. A list of random study arm assignments will be generated and used by the web based randomization routine to make sequential assignments. Randomization will occur in a 2:1 pattern; for every two participants randomized to the lifestyle intervention, one will be randomized to the usual care group. Table 2 illustrates that the 225 participants will be recruited in 11 distinct waves with 20-21 in each wave. We anticipate the recruitment period lasting from the latter part of Year 1 through Year 3. Based on our 2:1 randomization, approximately 14 participants will be randomized to the intervention condition in each wave. We anticipate a total of 11 LHA-led groups.

Table 1. Planned Recruitment for La Comunidad

	Year 1		**Year 2**		**Year 3**	
Months	1-6	7-12	1-6	7-12	1-6	7-12
Waves		Wave 1	Waves 2-4	Waves 5-6	Waves 7-9	Waves 10-11
Number of Participants		21	61	41	61	41
					Total	225

F. La Comunidad Lifestyle Weight Loss Intervention

a. Goals of the Lifestyle Intervention

The lifestyle intervention is designed to induce weight loss by creating an energy deficit. This will be achieved by decreasing daily caloric intake and increasing daily caloric expenditure through moderate intensity physical activity. We will advise participants to adapt a low-calorie eating pattern, with a goal daily deficit of 500 to 1000 kcal, coupled with an increase in moderate intensity physical activity, by walking for 30 minutes on most days. The primary treatment objectives for the weight loss component of the intervention will be to decrease caloric intake in a nutritionally sound manner so as to produce a weight loss of approximately 0.3 kg per week for the first 6-months of treatment for a total weight loss of 5-7%. After that, participants will be encouraged to continue weight loss as long as their BMI does not fall below 20 kg/m^2, but the primary focus will be on weight maintenance. The primary objective for the physical activity component of the intervention will be to promote an increase in home-based energy expenditure to an eventual goal of 180 minutes per week. The intervention will be tailored to the unique needs of each participant, with daily calorie goals ranging from 1200-1800 calories based on weight.

b. Structure of the Lifestyle Intervention

The lifestyle intervention will be a modified version of the DPP intervention adapted for use in groups, as used in both Look AHEAD and HELP PD[16,19]. The core content was integrated into a DVD video series for HELP PD to assist with standardization of intervention delivery. These DVDs contain information on the physiological, emotional, cognitive, and behavioral basics of losing weight as well as adopting and maintaining an active lifestyle. Each DVD segment also has a series of questions that are then addressed in the LHA-led group sessions. The intervention, including the DVDs, will be adapted and culturally-tailored to make it comfortable and relevant to Latino participants. The physical activity program will be progressive and will focus on walking and other large muscle activities. Physical activity bouts of ten minutes and longer will be counted toward the physical activity goal, but occupational activity will not be counted towards the physical activity goal. We will also provide pedometers to enable participants to self-monitor their physical activity and to set goals for progressively increasing their activity level. Within 3 months of study onset, the goal will be to have participants engaging in 30 minutes or more of moderate intensity activity, for a total of 180 minutes per week. Specific components of the lifestyle intervention are outlined in Table 2.

Table 2. Overview of Lifestyle Intervention

Phase	Contact Schedule	Objectives
PHASE 1 Initial Lifestyle Intervention (Months 1-6)	Weekly LHA-led group meetings, with content delivered via DVD series or by community experts Individual RD sessions in months 1, 3, and 6; Session 1 to occur prior to 1st group meeting	Knowledge: relation of body weight and fitness to disease and health; benefits of weight loss; basics of energy balance and nutrition; appropriate methods for weight loss and increasing physical activity; exercise precautions Diet: reduction of intake by 500-1000 kcal per day; increase in fruit and vegetable consumption to 5 per day; intake of ≥ 3 whole grain servings per day Physical activity: gradual progression to 180 minutes of moderate intensity exercise per week (e.g., 30 min/day of walking, 6 days/week) Behavioral skills: self-monitoring, goal-setting, self-reinforcement, stimulus control, social support, cognitive restructuring Material: core content delivered through DVD videos and community experts
PHASE 2 Extended Care Intervention (Month 7-24, depending on date of randomization))	1 contact per month (alternating each month between an LHA-led group meeting and a telephone contact with the LHA)	Knowledge: proper methods for weight maintenance; appropriate levels of activity, caloric intake and sound nutrition for maintenance of stable weight Diet: isocaloric intake tailored to maintenance of lost weight; continued daily intake of 5 fruits and vegetables and ≥ 3 whole grain servings Physical activity: maintenance of 180 min of moderate intensity exercise per week; coping with injuries and other barriers to the maintenance of exercise Behavioral skills: ongoing or intermittent self-monitoring of weight and habit changes; anticipating/avoiding obstacles to maintenance; coping with setbacks/lapses; building social support for maintenance; developing self reliance skills for

		long-term weight management

c. Empowered Community Partners: Latino Health Advisors

We plan to deliver the intervention using LHAs from the local community, many of whom are part of an established network of Latino LHAs that were identified by their churches because of their leadership skills and community recognition. We will supplement this core group of LHAs with recommendations from our investigative team and study dietitian, as we did previously in HELP PD. The LHAs used in La Comunidad will be adults with a history of diabetes mellitus, pre-diabetes, or metabolic syndrome that have been successful in achieving and maintaining lifestyle changes related to diet and physical activity. They must also have a desire to help community members who are at risk for developing diabetes by leading them through a weight-loss and lifestyle change program, demonstrate leadership ability, and be able to devote at least 10 hours per week to the program. The LHA's that participate in the network have already received structured training at WFUSM (80 hours) for delivering medical education to their communities in topics related to diabetes, metabolic syndrome, and cardiovascular disease, and were tested for knowledge proficiency before and after training.

In La Comunidad, all LHAs will receive 36 hours of training over 4-6 weeks. Major components include: (a) instruction on appropriate diabetes prevention messages, (b) basic counseling skills (e.g., active listening and the basics of group dynamics), (c) how to teach and reinforce self-regulatory skills, (d) overview and use of the intervention materials, (e) a 5-step approach to problem solving that has been used successfully in many weight loss trials, and (f) the structure/goals of telephone contacts. At the end of training, there will be a formal certification process involving a criterion-based assessment of (a) their skills running groups and handling situations within the group, (b) knowledge regarding the intervention protocol and use of the treatment manual, and (c) competence in completing requisite forms. The training will be provided by registered dietitians, one of whom was responsible for training community health workers in HELP PD. In addition to this training, the study RD will meet monthly with the LHAs to discuss intervention implementation and participant progress to maintain consistency across LHAs. Our real-time web-based data reporting system will enable us to monitor intervention delivery by the LHAs, as reflected by participant attendance, adherence measures, and, eventually, outcomes.

d. Intervention Group: LHA Sessions

The peer group counseling sessions will last about 60 minutes and will include 3 segments. The first segment will review participants' progress in implementing strategies recommended for changing their diet or physical activity in the previous session. After a private weigh-in (scales will be provided for each LHA), participants will describe the progress they have achieved, and they will identify any problems they might have encountered. Good progress will be highlighted with strong positive feedback. Difficulties will be dealt with through group support and advice. The second segment will focus on skill training related to cognitive-behavioral self-management skills, nutrition training, or exercise science. This core content will be delivered and discussed via the DVD series. Additional educational materials will be made available in a "toolkit" to enhance the activities as appropriate. The final component will consist of a discussion of the next week's goals. Each participant will be asked to identify specific behavioral goals for the next period and will receive feedback and encouragement from the

group. We anticipate holding all LHA sessions in community settings, starting with the churches that have agreed to participate previously. We also plan to identify other churches and community settings (recreation centers, community centers, YMCAs, etc) as needed to accommodate additional LHA-led groups.

e. Evaluation of the Lifestyle Intervention

The success of this intervention will be dependent, in part, on our ability to monitor the fidelity of intervention delivery. The DVD series will also serve to enhance treatment fidelity by standardizing delivery of the intervention content. We will monitor and track the following: a) adherence to LHA-led group meetings and make-up sessions, b) weight at all sessions, c) self-monitoring data from the participants concerning dietary intake and physical activity behaviors, and d) phone contacts during the maintenance phase of the study. The RD will supervise the LHAs, collate data from individual interactions with participants, and provide written and verbal feedback to LHAs that can be shared with participants. Members of the intervention committee will provide ongoing support and monitor intervention progress, thereby providing ongoing access to expertise in nutrition, behavioral, and exercise science.

G. Comparison Condition

Our comparison intervention condition is designed to exceed the usual care provided to similar community members and to enhance retention. Our comparison intervention will be an individual education program that builds on an increased awareness of existing community resources. Comparison participants will receive 2 sessions with an RD during the first 6 months. The RD will cover basic aspects of healthy eating and activity to support weight loss, and discuss existing community resources. In addition to this, participants will receive a monthly newsletter that includes information on nutrition, physical activity, and healthy living.

H. Data Collection

We plan to collect all screening data for this study in community locations (churches, recreation centers, etc). Those participants that meet all eligibility criteria and provide informed consent will complete baseline and follow-up visits at the CRU or Lexington Medical Center. To enable assessment of the process of implementation, impact and outcomes of the intervention, data will be collected at both the individual and program levels. At the individual level, we will collect information regarding demographics, anthropometry (height, weight, and waist), blood pressure, pulse, medical history, health behaviors (diet, physical activity), health-related quality of life (HRQL), healthcare resource utilization and cost. We will also obtain blood samples to measure HbA1c, glucose, insulin, and lipids and to store for future uses. At the program level, we will collect data related to implementation and cost. A schedule of data collection visits for participants is outlined in Table 3. Participants will be followed from the baseline/randomization visit through 24 months or June 30, 2017 (for those participants randomized after July 2015). Anticipated participation in the study will be at least one year for all randomized participants. Study questionnaires will be included in Appendix B as developed/purchased and approved by the Steering Committee.

Table 3. Planned Data Collection for La Comunidad

Measure	Baseline	F06	F12	F18	F24
HbA1c	x	x	x	x	x
Glucose	x	x	x	x	x
Insulin	x	x	x		x
Lipids	x		x		x
Height, Weight	x	x	x	x	x
Blood Pressure	x	x	x	x	x
Waist Circumference	x	x	x		x
Adverse Events		x	x	x	x
Contact Information	x	x	x	x	x
Demographics	x	x	x	x	x
Medical History	x	x	x	x	x
Medication Review	x	x	x	x	x
IPAQ	x	x	x		x
Food Frequency Questionnaire	x	x	x		x
Short Form 36	x	x	x		x
Behavioral Constructs	x	x	x	x	x
Health Utilities Index	x	x	x		x
Economic Evaluation		x	x	x	x
Stored Blood Samples	x	x	x		x

a. Demographics and Anthropometry

Age (date of birth), gender, race and ethnicity (US Census Definition), and names and contact information for at least 2 informants will be collected. Weight (nearest 0.1 kg), height (nearest 0.5 cm), minimum waist (nearest 0.5 cm) will be measured using standardized methodology as used in HELP PD.

b. Blood Pressure

Blood pressure will be measured using an automated device (Omron HEM 907XL) following standardized procedures as outlined in current clinical practice guidelines. Use of an automated device reduces measurement variability and errors. The presence of hypertension at baseline and follow-up will be assessed using a combination of BP measurement, self-reported diagnosis and use of antihypertensive medication.

c. Medical History

During screening, medical history of diabetes, cardiovascular disease and other medical conditions will be obtained to evaluate the inclusion and exclusion criteria. During follow-up, new diagnoses of diabetes, cardiovascular disease, hypertension and other chronic diseases, unexpected problems, serious adverse events will be tracked. Deaths will be identified by following up missed appointments with contacts to the participant's residence and informants.

d. Laboratory Measures

Phlebotomy will be performed by trained, certified phlebotomists. Specimen collection at baseline and follow-up visits will be performed following at least an 8 hour fast (typically over night) in accordance with American Diabetes Association guidelines. Blood samples for plasma glucose will be collected in vacutainers containing sodium fluoride in order to minimize post collection changes due to glycolysis and will be stored at room temperature until processed. Samples for HbA1c, glucose, insulin, and lipids will be collected and transported to the local LabCorp facility for analysis. Communications with LabCorp and requisitions for these assays will be facilitated through the CRU's existing contract with LabCorp. Plasma and serum samples will be retained for future analysis of CRP, IL-6, leptin, adiponectin, expression of IL-8 in circulating mononuclear cells, Omega 3 and 6 fatty acids, free fatty acids. We will also collect sufficient blood samples to isolate DNA and may perform genome-wide association studies (GWAS). These analyses are included in the specific aims, but samples with which to conduct these analyses will be stored in Dr. Chilton's laboratory until additional funding can be obtained.

e. Diet Assessment

Usual dietary intake will be assessed using a widely-used food frequency questionnaire (FFQ). The FFQ provides estimates of macronutrients, micronutrients, and servings of particular foods of interest, and has been validated against food records. Although the FFQ has shortcomings, such as potential underestimation of energy, it is the most practical instrument for large intervention studies and has become the most common method for measuring usual dietary intake. Its low cost and ease of administration are also important considerations.
In addition, diet will be monitored daily by the intervention participants through completion of their diet and physical activity logs. The precision of the FFQ is sufficient to enable us to evaluate intervention group differences in diet.

f. Physical Activity

Throughout the lifestyle intervention, physical activity will be monitored via logs that are collected by the LHAs and data entered by members of the research study team. These logs include a record of the frequency and duration of physical activity and daily steps that are self-monitored using pedometers. In addition, at assessment visits, we will use the International Physical Activity Questionnaire to evaluate between group differences in physical activity, an internationally reliable and valid instrument for assessing physical activity. The IPAQ short form is a 7-item index that asks respondents the number of days per week and the amount of time per day spent in vigorous- and moderate-intensity activities and walking, during the seven days prior to the interview. Different levels of physical activity are assigned metabolic

equivalent (MET) scores based on the Compendium of Physical Activity and, using MET-minutes, can be converted to both continuous and categorical values.

g. Self-Efficacy

There are a series of four brief measures based on social cognitive theory that address 1) barriers efficacy for physical activity and weight loss, 2) task efficacy related to specific physical capacities and weight loss, 3) satisfaction with physical function and body appearance and 4) the desire to be physically competent and to lose varying percentages of weight (converted to pounds on an individual basis). These measures will be collected at baseline and all follow-up visits for all participants and are included in Appendix B.

h. Health-Related Quality of Life

Two common HRQL instruments – the Short Form 36 items (SF-36) and Health Utilities Index - 3 (HUI 3) will be used in La Comunidad. The SF-36 is the most widely used general health status measure with extensive validation and population norms available. It allows comparison of the planned study population with those of other studies and other chronic diseases. Eight scale scores will be generated in the following domains: general health, physical function, role-physical, role-emotional, vitality, social function, mental health, and pain. It can also be scored in terms of physical health and mental health component scores. The Health Utilities Index Mark 3 (HUI3) system is a generic HRQL instrument which was developed not only for measuring health status but also for economic evaluation. HUI3 includes a health-status classification system and a preference-based scoring formula. The HUI3 has eight attributes (vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain) with five to six levels per attribute. The multiplicative multi-attribute utility function for the HUI3 system can be used to generate utility scores for use in economic analysis.

i. Cost

The cost of La Comunidad will be separated into research and intervention costs. Research costs will be excluded from the economic evaluation. The intervention costs will be classified into direct medical, direct nonmedical, and indirect costs. The identification and measurement of the cost of a health prevention program can be determined from four different perspectives: individual, health care provider, third party payer (including large health care systems, insurers, government, etc.), and society. In La Comunidad, we will adopt the perspectives of individuals, third party payers and society in three separate analyses, as all three perspectives will influence successful dissemination. From the individual's perspective, the total cost estimation will include participants' out of pocket expenses, and cost associated with travel time and missed working days due to illness. In the third party payer perspective, we will only include the direct medical costs (including the intervention) in the total cost estimation. The participants' out of pocket expenses and indirect cost such as missed working days will not be included. In the societal perspective, the total cost will constitute all direct and indirect costs incurred by participants and the third-party payers. In order to assure comparability to both DPP and HELP PD, we will apply similar criteria for determining costs. Direct medical costs

include the cost of implementation and maintenance of the intervention and the cost of utilization of medical services by study participants. We will assess the personnel resource use and cost in the comparison and lifestyle intervention groups, including personnel time, mailings and telephone calls using standardized questionnaires administered to the staff. Unit cost for personnel will be calculated as the median salaries of personnel employed by the study team with a fringe benefit rate. Unit costs of health education materials will be based on actual reproduction rates. Unit costs of laboratory tests will be based on the Center for Medicare and Medicaid Services (CMS) reimbursement rates. Overhead costs will be estimated by multiplying personnel costs related to the intervention by the institutional rate negotiated with NIH. The proposed intervention may have an impact on the use of medical services outside La Comunidad, including hospital, emergency department, outpatient clinic, physician office, and medications. A resource utilization questionnaire will be administered to participants semi-annually, inquiring about hospital admissions, length of stay, number of emergency department (ED) and physician office visits, and medications used. Unit costs of hospital admissions, hospital days, ED visits, and physician's office visits will be based on CMS average reimbursements, respectively. Unit costs of medications will be based on average wholesale prices available on the internet. This questionnaire will also inquire about purchases of equipment -and memberships in health facilities and other related direct nonmedical costs. These and other direct nonmedical costs including transportation to clinic, waiting and participation time will be estimated using the DPP direct nonmedical cost estimation methods[23]. Indirect costs include participants' productivity losses such as working days missed due to health reasons, and will be estimated based on the median hourly wage, as in DPP[23].

I. Documentation

La Comunidad will develop a Manual of Procedures (MOP), an LHA Intervention Manual (IM), and participant manuals. More comprehensive than this protocol, the MOP will include the protocol as its first chapter and will provide the specifics of study conduct. It will be modified during the study if any changes in the data forms and data collection techniques are necessary. The MOP will contain detailed information on the study's conduct, including comprehensive descriptions of recruitment, enrollment, randomization, data collection, monitoring and follow-up procedures. It is meant to be the "how-to" manual and the source of information regarding the day-to-day operation of the study. A separate manual, the IM, will be developed for LHA training, intervention conduct, and standardization purposes. Comprehensive detailed guidelines for the dietary, exercise and behavioral interventions will be in the IM and serve as the basis for the intervention monitoring system. Participant manuals will supplement the IM. The MOP and IM will be developed prior to the first training session.

J. Database Management System

To facilitate data transfer and preserve records that can be audited, we plan to use paper forms for data collection and remote data entry via an internet-based web browser interface. As in HELP PD, electronic data will be managed centrally, with a feedback mechanism through e-mail and web-based reporting. Data reside on the server in a Microsoft SQL Server relational database. Cold Fusion middleware, a web application development tool, will be used to link the web-based forms interface to the SQL Server database. SAS/Access is used to translate data from the SQL Server database to SAS datasets, which reside on a UNIX-based Sun

Microsystems server. Validation checks are applied during the data entry process. Insofar as possible, checks are programmed and made as the staff enter data from each form, so that errors on the forms are corrected on-site at this early stage. These include intra-form and inter-form checks for consistency of responses, range checking, and checks for required fields and skip patterns.

Our internet based data entry system will protect confidentiality and data security. A very high level of data encryption during transmission coupled with the use of acrostics and study ID numbers, rather than subject names, provides adequate data security. The use of text containing identifying information will be avoided. We will implement standard protection against computer hackers. Our site will offer neither special challenges nor sensational data for hackers. This lack of inducements may decrease the chance that it will be targeted.

K. Methods for Ensuring High Data Quality and Integrity

Quality control (QC) is a shared responsibility among all staff. The impact of La Comunidad on diabetes in the Latino population depends on the integrity of its implementation: maintaining randomization integrity, assessing participant eligibility accurately, recording dropouts and adherence, measuring outcome variables without bias, preventing premature leaks of results, monitoring and assessing protocol adherence, and avoiding biases in the analyses. In order to deal effectively with these important issues, adaptations of models for QC systems currently utilized in many of our ongoing studies will help us establish the QC system for La Comunidad. QC procedures will be devised to monitor screening, data collection, follow-up, clinical and biochemical measurements, forms control and data entry procedures, implementation of the intervention and overall operations.

IV. Analytical Plan

All statistical analyses will be conducted by the Research Core of the Maya Angelou Center for Health Equity. The main hypothesis being tested involves evaluating the mean differences in changes in HbA1c at one year. Secondary outcomes include changes in clinical characteristics and biochemical lab results and biomarkers of insulin sensitivity. Statistically, all of these analyses could be treated in a similar fashion after appropriate transformations are made to satisfy assumptions made about the distribution of residuals. We will apply a repeated measures analysis of variance to changes (collected across the planned visits at 6, 12, 18, and 24 months) to address intra-individual correlations, which accommodates interim testing and allows participants with incomplete patterns to contribute to the analysis and evaluation[24]. Our analysis adopts the intention-to-treat approach. Inference for primary comparisons will be two-sided, with significance level alpha = 0.05. We will use repeated measures analysis of covariance in which indicators for visit are included to control for systematic temporal differences that may occur that are common to both intervention conditions. We test differences from baseline (rather than using baseline levels as a covariate in analyses of post-randomization values), as it is these differences that are the focus of our intervention and to limit the bias associated with estimates from regression models that include fallible covariates. Random effects terms will be used to model differences as these have been shown to yield inferences of more appropriate size than fixed effect models. Compound symmetry models will be used to model intra-subject

longitudinal covariance and models will be fitted via maximum likelihood. The primary comparison will be based on a Wald statistic. We will not include additional covariates or stratification in the primary comparison, however, we will describe any chance differences between cohorts and, in supporting analyses, covary comparisons on any baseline factors that appear to be unbalanced. When we are developing the ANCOVA models, we will determine whether the assumptions of general linear models are satisfied. Diagnostics and residual plots will be reviewed to ensure that the assumptions are met. Should assumptions be violated, transformations of the outcome data will be considered: the order of the priority in choosing a transformation will be to satisfy the (1) linearity assumption, (2) homogeneity assumption (homoscedasticity), and (3) normality assumption. As mentioned above, secondary (supporting) analyses will assess the influence of covariates on the mean differences and to explore whether mean differences vary over follow-up time (using interaction terms). In addition, we will explore the homogeneity of LHAs with respect to outcome measures using hierarchical mixed models in which LHAs are coded as random effects and participant data are nested within LHAs. Such models will allow us to place confidence bounds on the contributions of LHA differences to overall variability.

Sample Size and Power

In this section we justify our plans to recruit and follow 225 participants who will be randomized with equal probability to either the intensive lifestyle intervention or individual education arm. Our goal is to provide greater than 80% statistical power to detect an average difference of .25 standard deviations from baseline in HbA1c between the two groups at one year. With a sample size of 225 participants, we will have 85-88% power to detect a net intervention effect of .25%. These estimates include allowance for a 5% loss to follow-up rate every 6 months. Although the DPP has not published any data that allow us to estimate the standard deviation and longitudinal correlation of HbA1c, similar studies conducted for a longer period of time have estimated the average change in A1c to be .74% with a standard deviation of 1.25% for an effect size of .59.

V. Human Subjects Protection

A. Potential Risks to Subjects

The risk to participants is modest, consisting primarily of the risk of increased moderate physical activity. Adoption of a vigorous activity regimen can increase the risk of cardiovascular events in sedentary individuals. The other minor risks include risks associated with phlebotomy and confidentiality concerns. Phlebotomy carries a small risk of vasovagal syncope (fainting), hematoma formation and phlebotomy site infection.

B. Protection against Risks

Approval to proceed with this project will be sought from the WFUHS Institutional Review Board (IRB). We will submit an informed consent document, including HIPAA authorization, as part of our application for approval. The risks inherent in the project consist mainly of the small risk of a cardiovascular event associated with adopting a moderate intensity physical activity regimen, the risk of phlebotomy and confidentiality concerns. The risk of the physical activity

program will be minimized by focusing on moderate, as opposed to vigorous, activity and by stressing a start slow and increase slowly approach. We will be encouraging participants to adopt brisk walking as the foundation of their activity program and we will educate participants about the potential risks of increased activity. Potential participants will also be screened using the Physical Activity Readiness Questionnaire. Persons who screen positive will be required to obtain medical clearance from a primary care provider prior to participation. All potential participants will be encouraged to discuss participation with their usual physician prior to enrolling in La Comunidad. An informational brochure will be developed so that potential participants can review and discuss the program with their physician, and if he/she does not have a physician, he/she will be referred to a source of care in the community. This brochure will be provided to the IRB for approval prior to use. The risk of phlebotomy will be minimized through the use of trained professional phlebotomists. The blood volume obtained at any phlebotomy will be no more than 20 mL. Risks related to inadvertent release of confidential information will be minimized through adherence to best practices for data collection and management. All research staff will be trained in methods for assuring participant confidentiality and safety. The information we are collecting is not of a particularly sensitive nature and we will follow exacting procedures to maintain confidentiality of the participant level data. Identifying information will be kept separate from research data and will be linked only by a participant ID, generated so as to be independent of any identifying information. The linking report and personal identifying data will be destroyed after completion of the study. No identifying information will be released in any published reports.

C. Potential Benefits and Importance of Knowledge to be Gained

The potential direct benefits to participants include the decreased risk of developing diabetes and cardiovascular disease. In the DPP, the risk of developing diabetes was 11% per year in the "usual care" group. This risk was decreased by over 50% in the intensive lifestyle intervention group. In the HELP PD study, the group-based intervention showed significant weight loss and improvements in glucose. La Comunidad is designed to move the intervention tested in HELP PD into the Latino community, improving diabetes prevention efforts. The development of diabetes carries with it significant morbidity and mortality risk. Persons with diabetes are at an increased risk of cardiovascular diseases, in addition to increased risk of blindness, kidney failure and lower extremity amputation. The small risks of an acute cardiovascular event triggered by moderate physical activity should be far offset by the substantial potential benefit of diabetes prevention. Other potential benefits to subjects may include improved quality of life and satisfaction with self-image. Little direct benefit is expected to others; however, as persons with diabetes may impose some care-giver burden on others due to their need for frequent medical attention, it is possible that there will be some benefit related to decreased care-giver burden.

The knowledge to be gained in the proposed trial relates to our ability to implement evidence-based lifestyle interventions in different populations. As discussed above, the risks of diabetes are substantial and the potential benefits for preventing diabetes are great at the societal level; hence, the risk that participants will assume by participating in this program should be offset by the potential for public health benefit that would occur following dissemination of a successful diabetes prevention program. Furthermore, this approach could also serve as a model for other

community-based health promotion programs in the Latino community, further enhancing the potential societal benefit of the proposed project.

VI. Subject Recruitment Methods

Participants will be recruited to La Comunidad using a mixture of advertising, community recruitment events, and provider referrals from healthcare sites. Given the unique role that churches play in the Latino community, we plan to initiate our recruitment efforts there. Currently, 5 local churches have agreed to serve as partners for this effort and we plan to identify additional churches in the future. We will also request a list of adult patients seen in outpatient primary care clinics at Wake Forest Baptist Medical Center who have no diagnosis of diabetes and for whom ethnicity is recorded as "Hispanic or Latino". This list will be requested from the Enterprise Data Warehouse through the Translational Science Institute and will be used to generate mailings to potential participants. As a part of this data request, we will also request a limited waiver of HIPAA authorization from the IRB and the list generated will only be used under this waiver. We will also plan to post flyers and posters in the Downtown Health Plaza space to supplement these efforts. All flyers, brochures, letters, and other recruitment materials will be submitted to the IRB of Wake Forest University Health Sciences for approval prior to use. Signed informed consent will be obtained from all participants prior to conducting any screening activities. Copies of the signed consent forms will be provided to all participants. The original signed forms will be kept in study files.

We plan to identify local adults who identify themselves as Latino who are at high risk for developing type 2 diabetes. Primary inclusion criteria include BMI of 25-45 kg/m^2 and evidence of pre-diabetes (based on HbA1c). Candidates will also be screened for co-morbid conditions that would make physical activity unsafe or limit participation in the study, including recent history of an acute cardiovascular disease event, clinical history of diabetes mellitus, cancer or other conditions limiting life expectancy, and major psychiatric or cognitive problems, including depression. For safety purposes, potential participants will also be screened using the Physical Activity Readiness Questionnaire (PAR-Q). Persons who screen positive on the PAR-Q will be required to obtain medical clearance from a physician prior to participation.

VII. Informed Consent

Signed informed consent will be obtained from each subject after pre-screening but prior to the collection of any blood samples or other physical measurements. Participants who speak Spanish as their primary language will be provided with Spanish-language consent forms and will be consented by a study data collector who is fluent in Spanish. All potential participants will be informed of the study design and interventions, the risks and benefits of participation, their rights and responsibilities as research participants, and alternatives to participation. Participants will be required to sign an informed consent document prior to screening and enrollment. HIPAA authorization to collect and share personal health information within the investigative group is included in the consent form and will be fully explained as part of the

consent process. For those participants who choose to allow us to store blood samples for future analysis of inflammatory markers, a separate sub-study consent will be administered during the baseline visit.

VIII. Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, two unique study identifiers will appear on the data collection forms. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. The linking report and personal identifying data will be destroyed within 3 years of completion of the study. This is consistent with accepted practices for data validation and study design, and will enable us to produce an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

IX. Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff and an independent safety officer (Kristen Hairston, MD) will be used to adjudicate adverse events and monitor study progress. As weight loss and weight fluctuation have been associated with increased morbidity and mortality, all hospitalizations will be monitored. In addition, potential adverse effects of the intervention specific to physical exercise, primarily injuries and orthopedic conditions, will be monitored. All serious adverse events and unexpected problems will be recorded on adverse event reporting forms, including action taken. A semi-annual report will be compiled and will include a list and summarization of any adverse events. In addition, these reports will address (1) whether adverse event rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely. These reports will be provided to both the study safety officer and the IRB.

A. Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and/or unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the safety officer, IRB and NIH if appropriate.

Reference List

(1) Centers for Disease Control and Prevention. National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2011.

(2) Dall TM, Zhang Y, Chen YJ, Quick WW, Yang WG, Fogli J. The economic burden of diabetes. *Health Aff (Millwood).* 2010;29:297-303.

(3) Centers for Disease Control and Prevention (CDC). Diabetes: Disabling, deadly, and on the rise 2003. National Center for Chronic Disease Prevention and Health Promotion . 2003. Atlanta, Georgia, Department of Health and Human Services.

(4) Knowler WC, Barrett-Connor E, Fowler SE et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002;346:393-403.

(5) Tuomilehto J, Lindstrom J, Eriksson JG et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med.* 2001;344:1343-1350.

(6) The Diabetes Prevention Program (DPP): description of lifestyle intervention. *Diabetes Care.* 2002;25:2165-2171.

(7) Klein S, Sheard NF, Pi-Sunyer X et al. Weight management through lifestyle modification for the prevention and management of type 2 diabetes: rationale and strategies. A statement of the American Diabetes Association, the North American Association for the Study of Obesity, and the American Society for Clinical Nutrition. *Am J Clin Nutr.* 2004;80:257-263.

(8) Absetz P, Valve R, Oldenburg B et al. Type 2 diabetes prevention in the "real world": one-year results of the GOAL Implementation Trial. *Diabetes Care.* 2007;30:2465-2470.

(9) Whittemore R, Melkus G, Wagner J, Dziura J, Northrup V, Grey M. Translating the diabetes prevention program to primary care: a pilot study. *Nurs Res.* 2009;58:2-12.

(10) McTigue KM, Conroy MB, Bigi L, Murphy C, McNeil M. Weight loss through living well: translating an effective lifestyle intervention into clinical practice. *Diabetes Educ.* 2009;35:199-204.

(11) McBride PE, Einerson JA, Grant H et al. Putting the Diabetes Prevention Program into practice: a program for weight loss and cardiovascular risk reduction for patients with metabolic syndrome or type 2 diabetes mellitus. *J Nutr Health Aging.* 2008;12:745S-749S.

(12) Boltri JM, Davis-Smith YM, Seale JP, Shellenberger S, Okosun IS, Cornelius ME. Diabetes prevention in a faith-based setting: results of translational research. *J Public Health Manag Pract.* 2008;14:29-32.

(13) Ackermann RT, Finch EA, Brizendine E, Zhou H, Marrero DG. Translating the Diabetes Prevention Program into the community. The DEPLOY Pilot Study. *Am J Prev Med.* 2008;35:357-363.

(14) Amundson HA, Butcher MK, Gohdes D et al. Translating the diabetes prevention program into practice in the general community: findings from the Montana Cardiovascular Disease and Diabetes Prevention Program. *Diabetes Educ.* 2009;35:209-4, 216.

(15) Kramer MK, Kriska AM, Venditti EM et al. Translating the Diabetes Prevention Program: a comprehensive model for prevention training and program delivery. *Am J Prev Med.* 2009;37:505-511.

(16) Katula JA, Vitolins MZ, Rosenberger EL et al. One-Year Results of a Community-Based Translation of the Diabetes Prevention Program: Healthy-Living Partnerships to Prevent Diabetes (HELP PD) Project. *Diabetes Care.* 2011;34:1451-1457.

(17) Ali MK, Echouffo-Tcheugui J, Williamson DF. How effective were lifestyle interventions in real-world settings that were modeled on the diabetes prevention program? *Health Aff (Millwood).* 2012;31:67-75.

(18) Blackwell CS, Foster KA, Isom S et al. Healthy Living Partnerships to Prevent Diabetes: recruitment and baseline characteristics. *Contemp Clin Trials.* 2011;32:40-49.

(19) Katula JA, Vitolins MZ, Rosenberger EL et al. Healthy Living Partnerships to Prevent Diabetes (HELP PD): design and methods. *Contemp Clin Trials.* 2010;31:71-81.

(20) Bandura A. *Social Foundations of Thought and Action: A Social Cognative Theory.* Englewood Cliffs, N.J.: Prentice-Hall; 1986.

(21) Cartwright DC. *Group dynamics: Research and theory.* New York, NY: Harper and Row; 1953.

(22) Bang H, Edwards AM, Bomback AS et al. Development and validation of a patient self-assessment score for diabetes risk. *Ann Intern Med.* 2009;151:775-783.

(23) Hernan WH, Brandle M, Zhang P et al. Costs associated with the primary prevention of type 2 diabetes mellitus in the diabetes prevention program. *Diabetes Care.* 2003;26:36-47.

(24) The Diabetes Prevention Program: baseline characteristics of the randomized cohort. The Diabetes Prevention Program Research Group. *Diabetes Care.* 2000;23:1619-1629.

Appendix A. La Comunidad Committee Membership

Lifestyle Intervention

- Pulgar (C)
- RD (TBN)
- Vitolins
- Katula
- LHAs

Data Management

- Divers (C)
- Vitolins
- Pulgar
- Chilton
- Davis
- Brown
- Ospino-Sanchez

Recruitment and Retention

- Pulgar (C)
- Vitolins
- Ospino-Sanchez
- Arias
- Del Valle-Fagan

Operations

- Blackwell (C)
- Vitolins
- Pulgar
- Ospino-Sanchez
- Arias
- Davis
- Brown
- Del Valle-Fagan

Steering

- Vitolins (C)
- Chilton
- Divers
- Katula
- Blackwell
- Pulgar

Appendix B. La Comunidad Baseline and Follow-Up Questionnaires

Physical Activity Readiness Questionnaire (PAR-Q)

Becoming more active is very safe for most people, but just to be certain, please complete the questionnaire below. Some people should check with their doctor before they start becoming much more physically active. Start by answering the seven questions below.

1. Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?
   ☐ YES ☐ NO
2. Do you feel pain in your chest when you do physical activity?
   ☐ YES ☐ NO
3. In the past month, have you had chest pain when you were not doing physical activity?
   ☐ YES ☐ NO
4. Do you lose your balance because of dizziness or do you ever lose consciousness?
   ☐ YES ☐ NO
5. Do you have a bone or joint problem that could be made worse by a change in your physical activity?
   ☐ YES ☐ NO
6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?
   ☐YES ☐ NO
7. Do you know of any other reason why you should not do physical activity?
   ☐ YES ☐ NO

If you answered YES to one or more questions, talk with your doctor before you start becoming much more physically active.

If you answered NO to all questions, you can be reasonably sure that you can start becoming more physically active right now. Be sure to start slowly and progress gradually- this is the safest and easiest way to go.

☐ Referred to primary care physician for medical clearance prior to participation

CURRENT PHYSICAL ACTIVITY LEVEL

VIGOROUS PHYSICAL ACTIVITY

First we are going to ask you some questions about your participation in vigorous or "hard" activities. These are activities that take hard physical effort, make you breathe much harder than normal, and cause heavy sweating.

1. In general how many days per week do you do vigorous activities like running, heavy lifting, aerobics, or fast bicycling for at least 10 minutes in a row? Do not count any vigorous activities you did for less than 10 minutes in a row. Assume that one week is seven (7) days.
CHECK ONLY <u>ONE</u> ANSWER

0 Days per week	4 Days per week
1 Day per week	5 Days per week
2 Days per week	6 Days per week
3 Days per week	7 Days per week

2. On the days that you do vigorous activities, how much time do you usually spend doing them? Only count the time that you spend doing vigorous activity *for at least 10 minutes in a row*. **CHECK ONLY <u>ONE</u> ANSWER**

I do not do vigorous activity for more than 10 minutes in a row

10-15 minutes per day

15-30 minutes per day

30-45 minutes per day

45-60 minutes per day

Over 60 minutes per day

DAILY WALKING

Next we are going to ask you about your daily walking.

3. In general, how many days per week do you walk *for at least 10 minutes in a row*? Think about all the walking you do during the day, including walking for exercise, walking to get to places (transportation), walking at work or home, or any other walking that you do during the day. Do not count any walking that you do for less than 10 minutes in a row. **CHECK ONLY <u>ONE</u> ANSWER**

0 Days per week	4 Days per week
1 Day per week	5 Days per week
2 Days per week	6 Days per week
3 Days per week	7 Days per week

4. On the days that you walk, how much time do you usually spend walking? Only count the time that you spend walking *for at least 10 minutes in a row*. **CHECK ONLY <u>ONE</u> ANSWER**

I do not walk for more than 10 minutes in a row

10-15 minutes per day

15-30 minutes per day

30-45 minutes per day

45-60 minutes per day

Over 60 minutes per day

5. Of the time you spend walking *for at least 10 minutes in a row*, how much of that time is spent in brisk walking that increases your heart rate and breathing faster than normal? **CHECK ONLY <u>ONE</u> ANSWER**

I do not do walk briskly for more than 10 minutes in a row

10-15 minutes per day

15-30 minutes per day

30-45 minutes per day

45-60 minutes per day

Over 60 minutes per day

OTHER MODERATE PHYSICAL ACTIVITY

Last, we are going to ask you about your participation in moderate activities other than walking. These are activities that take some physical effort, and increase your heart rate and breathing above resting levels, but is not as hard as vigorous activity. Please **do not include walking** in any of your answers about moderate activity.

6. In general, how many days per week do you do moderate activities like carrying light loads, playing doubles tennis, or regular bicycling, *for at least 10 minutes in a row*. Assume that one week is seven (7) days. **CHECK ONLY <u>ONE</u> ANSWER**

0 Days per week	4 Days per week
1 Day per week	5 Days per week
2 Days per week	6 Days per week
3 Days per week	7 Days per week

7. On the days that you do other moderate activities, how much time do you usually spend doing them? Only count the time that you spend doing moderate activity *for at least 10 minutes in a row*. **CHECK ONLY <u>ONE</u> ANSWER**

I do not do moderate activity for more than 10 minutes in a row

10-15 minutes per day

15-30 minutes per day

30-45 minutes per day

45-60 minutes per day

Over 60 minutes per day

ARE YOU AT RISK FOR

TYPE 2 DIABETES?

American Diabetes Association.

Diabetes Risk Test

1. **How old are you?**
   - Less than 40 years (0 points)
   - 40—49 years (1 point)
   - 50—59 years (2 points)
   - 60 years or older (3 points)

2. **Are you a man or a woman?**
   - Man (1 point)
   - Woman (0 points)

3. **If you are a woman, have you ever been diagnosed with gestational diabetes?**
   - Yes (1 point)
   - No (0 points)

4. **Do you have a mother, father, sister, or brother with diabetes?**
   - Yes (1 point)
   - No (0 points)

5. **Have you ever been diagnosed with high blood pressure?**
   - Yes (1 point)
   - No (0 points)

6. **Are you physically active?**
   - Yes (0 points)
   - No (1 point)

7. **What is your weight status?** *(see chart at right)*

Write your score in the box.

Add up your score.

Height	Weight (lbs.)		
4' 10"	119-142	143-190	191+
4' 11"	124-147	148-197	198+
5' 0"	128-152	153-203	204+
5' 1"	132-157	158-210	211+
5' 2"	136-163	164-217	218+
5' 3"	141-168	169-224	225+
5' 4"	145-173	174-231	232+
5' 5"	150-179	180-239	240+
5' 6"	155-185	186-246	247+
5' 7"	159-190	191-254	255+
5' 8"	164-196	197-261	262+
5' 9"	169-202	203-269	270+
5' 10"	174-208	209-277	278+
5' 11"	179-214	215-285	286+
6' 0"	184-220	221-293	294+
6' 1"	189-226	227-301	302+
6' 2"	194-232	233-310	311+
6' 3"	200-239	240-318	319+
6' 4"	205-245	246-327	328+
	(1 Point)	(2 Points)	(3 Points)

You weigh less than the amount in the left column (0 points)

Adapted from Bang et al., Ann Intern Med 151:775-783, 2009.
Original algorithm was validated without gestational diabetes as part of the model.

If you scored 5 or higher:
You are at increased risk for having type 2 diabetes. However, only your doctor can tell for sure if you do have type 2 diabetes or prediabetes (a condition that precedes type 2 diabetes in which blood glucose levels are higher than normal). Talk to your doctor to see if additional testing is needed.

Type 2 diabetes is more common in African Americans, Hispanics/Latinos, American Indians, and Asian Americans and Pacific Islanders.

For more information, visit us at www.diabetes.org or call 1-800-DIABETES

Visit us on Facebook
Facebook.com/AmericanDiabetesAssociation

Lower Your Risk

The good news is that you can manage your risk for type 2 diabetes. Small steps make a big difference and can help you live a longer, healthier life.

If you are at high risk, your first step is to see your doctor to see if additional testing is needed.

Visit diabetes.org or call 1-800-DIABETES for information, tips on getting started, and ideas for simple, small steps you can take to help lower your risk.

STOP DIABETES.

Barriers to Physical Activity

The items below reflect common reasons preventing people from participating in exercise sessions or, in some cases, for dropping out or quitting exercise altogether. Please indicate how confident you are that you could exercise in the event that any of the following circumstances were to occur.

1. How confident are you that you could maintain your physical activity if you were **tired**?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

2. How confident are you that you could maintain your physical activity **during or following a personal crisis?**

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

3. How confident are you that you could maintain your physical activity **during bad weather**?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

5. How confident are you that you could maintain your physical activity **when you are on vacation**?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

6. How confident are you that you could maintain your physical activity **when you have other competing interests** (like your favorite TV show)?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

7. How confident are you that you could maintain your physical activity when **you have a lot of work to do**?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

8. How confident are you that you could maintain your physical activity if you had to do it **by yourself**?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

9. How confident are you that you could maintain your physical activity if you were **recovering from an illness**?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

10. How confident are you that you could maintain your physical activity **when your schedule is hectic**?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

How confident are you that you could lose…

1. **5%** of your body weight (XX pounds) and keep it off ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 No Confidence — Moderate Confidence — Complete Confidence
2. **7½%** of your body weight (XX pounds) and keep it off ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 No Confidence — Moderate Confidence — Complete Confidence
3. **10%** of your body weight (XX pounds) and keep it off ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 No Confidence — Moderate Confidence — Complete Confidence
4. **12½%** of your body weight (XX pounds) and keep it off ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 No Confidence — Moderate Confidence — Complete Confidence
5. **15%** of your body weight (XX pounds) and keep it off ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 No Confidence — Moderate Confidence — Complete Confidence

Please tell your current *desire* to be able to perform each task. Please respond using a range of 0 (no desire whatsoever) to 4 (very strong desire). **It is very important to remember that we are not interested in whether you can do the tasks or not; rather, we are interested in your level of *desire* to be able to do each task.**

Please rate your level of desire to be able to…

1. Exercise at a moderate intensity for 10 minutes.				
☐ 0 No Desire Whatsoever	☐ 1 Low Desire	☐ 2 Moderate Desire	☐ 3 Strong Desire	☐ 4 Very Strong Desire
2. Exercise at a moderate intensity for 20 minutes.				
☐ 0 No Desire Whatsoever	☐ 1 Low Desire	☐ 2 Moderate Desire	☐ 3 Strong Desire	☐ 4 Very Strong Desire
3. Exercise at a moderate intensity for 30 minutes.				
☐ 0 No Desire Whatsoever	☐ 1 Low Desire	☐ 2 Moderate Desire	☐ 3 Strong Desire	☐ 4 Very Strong Desire
4. Exercise at a moderate intensity for 40 minutes.				
☐ 0 No Desire Whatsoever	☐ 1 Low Desire	☐ 2 Moderate Desire	☐ 3 Strong Desire	☐ 4 Very Strong Desire
5. Exercise at a moderate intensity for 50 minutes.				
☐ 0 No Desire Whatsoever	☐ 1 Low Desire	☐ 2 Moderate Desire	☐ 3 Strong Desire	☐ 4 Very Strong Desire
6. Exercise at a moderate intensity for 60 minutes.				
☐ 0 No Desire Whatsoever	☐ 1 Low Desire	☐ 2 Moderate Desire	☐ 3 Strong Desire	☐ 4 Very Strong Desire

Please indicate below how confident you are that you can successfully carry out each of the following activities.

"I BELIEVE THAT I COULD EXERCISE..."

1. For **10 minutes at a moderate intensity** without stopping?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

2. For **20 minutes at a moderate intensity** without stopping

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

3. For **30 minutes at a moderate intensity** without stopping

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

4. For **40 minutes at a moderate intensity** without stopping

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

5. For **50 minutes at a moderate intensity** without stopping

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

6. For **60 minutes at a moderate intensity** without stopping

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

This questionnaire relates to eating. Please respond to each statement by indicating how confident you are that you can resist or control your eating in the following situations by placing a check mark in the appropriate box.

1. I can resist eating when I am anxious (nervous).

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

2. I can control my eating on the weekends.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

3. I can resist eating even when I have to say “no” to others.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

4. I can resist eating when I feel physically run down.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

5. I can resist eating when I am watching TV.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

6. I can resist eating when I am depressed (or down).

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

7. I can resist eating when there are many different kinds of food available.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

8. I can resist eating even when I feel it's impolite to refuse a second helping.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

9. I can resist eating even when I have a headache.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

10. I can resist eating when I am reading.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

11. I can resist eating when I am angry (or irritable).

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

12. I can resist eating even when I am at a party.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

13. I can resist eating even when others are pressuring me to eat.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

14. I can resist eating when I am in pain.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

15. I can resist eating just before going to bed.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

16. I can resist eating when I have experienced failure.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

17. I can resist eating even when high-calorie foods are available.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

18. I can resist eating even when I think others will be upset if I don't eat.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

19. I can resist eating when I feel uncomfortable.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

20. I can resist eating when I am happy.

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — VERY CONFIDENT

MY HEALTH BEHAVIORS

Tobacco Use

1. Have you smoked at least 100 cigarettes during your entire life?

   1 ☐ Yes

   2 ☐ No ***go to Question 9, next page***

2. Do you smoke cigarettes now?

   1 ☐ Yes ⟶ About how old were you when you first started smoking cigarettes (fairly regu ☐☐
   Age

   2 ☐ No ***go to Question 7, below***

3. Do you now smoke cigarettes every day or some days?

   1 ☐ Every Day

   2 ☐ Some

4. On how many of the past 30 days did you smoke cigarettes?

   ☐☐ Number of days

5. On the days that you smoke, about how many cigarettes do you usually smoke per day?

   ☐☐ Number of cigarettes per day

6. For approximately how many years have you smoked this amount?

   ☐☐ Number of years **go to Question 9, next page**

7. About how old were you when you quit smoking cigarettes (fairly regularly)?

   ☐☐ Age

a. About how old were you when you first started smoking cigarettes (fairly regularly)?

☐☐ Age

8. About how many cigarettes per day did you usually smoke at that time?

☐☐ Number of cigarettes per day

9. Does anyone living with you now smoke cigarettes regularly inside your home?

1☐ Yes

2☐ No ***go to Section B, "Alcohol Use," below***

a. Please mark all the people who live with you who now smoke cigarettes regularly inside your home: Mark all that apply.

1☐ Spouse or partner 2☐ Son(s) or daughter(s) 3☐ Other person/people

Alcohol Use

1. Did you drink any alcoholic beverages in the past year?

1☐ Yes ***Go to Question 2, below***

2☐ No ***go to Section C, "Eating Patterns," next page***

2. How many drinks of wine do you usually have per week? By drink, we mean about a 5-ounce glass. ☐☐ Drinks per week

3. How many drinks of beer do you usually have per week? One beer is a 12-ounce glass, can, or bottle. ☐☐ Drinks per week

4. How many drinks of liquor do you usually have per week? Count each shot (1 ½ ounces) as one drink. ☐☐ Drinks per week

5. During the past 24 hours, how many drinks have you had?

☐☐ Drinks

6. In the past month, what is the largest number of drinks you had in one day?

☐☐ Drinks

7. Have you made any attempts to stop drinking in the past five years?

1☐ Yes

2☐ No

8. During the past 30 days, on how many days did you have five or more drinks on the same occasion?

By "occasion," we mean at the same time or within a couple of hours of each other.

☐☐ Days

Eating Patterns

1. How many days out of the 7-day week do you eat breakfast?

☐☐ Days per week

2. How many days out of the 7-day week do you eat lunch/brunch?

☐☐ Days per week

3. How many days out of the 7-day week do you eat dinner?

☐☐ Days per week

4. Counting all meals and any snacks you may have, how many times a day do you usually eat:

☐☐ Times per day

5. How many days a week do you eat out at...

	Breakfast	**Brunch/Lunch**	**Dinner**
a. Fast food restaurants for:	☐ days/wk	☐ days/wk	☐ days/wk
b. Other types of restaurants for:	☐ days/wk	☐ days/wk	☐ days/wk

6. In the past 6 months, have you experienced any food cravings (i.e., intense desires to eat a specific food)?

1 ☐ Yes

2 ☐ No

Weight Control Practices

1. How often do you weigh yourself? (check one answer only)

1 ☐ Never

2 ☐ About once a year or less

3 ☐ Every couple of months

4 ☐ Every month

5 ☐ Every week

6 ☐ Every day

7 ☐ More than once per day

Myself and My Family

MYSELF

1. Marital Status: (Choose one that is most appropriate)

1 ☐ Never married
2 ☐ Married
3 ☐ Divorced
4 ☐ Widowed
5 ☐ Separated
6 ☐ Living in a marriage-like relationship

2. What is the most education you have completed?

CHECK ONLY ONE BOX FOR THE HIGHEST LEVEL OF SCHOOLING YOU RECEIVED.

1 ☐ Less than high school
2 ☐ High-school diploma or equivalency (GED)
3 ☐ Some vocation school
4 ☐ Some college
5 ☐ Associate degree (junior college)
6 ☐ Bachelor's degree
7 ☐ Some graduate school
8 ☐ Master's degree
9 ☐ Doctorate
10 ☐ Professional (MD, JD, DDS, etc.)
11 ☐ Other, specify: _____

3. How many years of formal school did you attend?

☐☐ Years

4. Are you working full time for pay?

1☐ Yes → Which of the following best represent your full-time occupation? (choose only one)

2☐ No

1 ☐ Office/Professional	4 ☐ Office/Clerical
2 ☐ Technician	5 ☐ Skilled/Craftsman
3 ☐ Sales	6 ☐ Unskilled/semi-skilled

5. Are you working part-time for pay?

1☐ Yes → Which of the following best represent your full-time occupation? (choose only one)

2☐ No

1 ☐ Office/Professional	4 ☐ Office/Clerical
2 ☐ Technician	5 ☐ Skilled/Craftsman
3 ☐ Sales	6 ☐ Unskilled/semi-skilled

6. Are you unemployed or laid off?

1☐ Yes

2☐ No

7. Are you looking for work?

1☐ Yes

2☐ No

8. Are you keeping house or raising children full-time?

1☐ Yes

2☐ No

9. Are you a full or part-time student?

1☐ Yes

2☐ No

10. How many people are currently living in your household, including yourself?

☐☐ number of people

11. Do you have any children or stepchildren living with you now?

1 ☐ Yes → a. How many are 18 years of age or older? ☐☐

2 ☐ No b. How many are 18 years of age or younger? ☐☐

12. In the past twelve months, how much did you and others currently living in your household earn from all sources?

☐ *Preferred not to answer*

1 ☐ Under $10,000
2 ☐ $10,000-$19,999
3 ☐ $20,000-$29,999
4 ☐ $30,000-$39,999
5 ☐ $40,000-$49,999
6 ☐ $50,000-$59,999
7 ☐ $60,000-$69,999
8 ☐ $70,000-$79,999
9 ☐ $80,000 or more

13. How much money would you and others currently living in your household have if you cashed in all your checking and savings accounts, stocks and bonds, real estate, sold your home, your vehicles, and all your valuable possessions?

☐ *Preferred not to answer*

1 ☐ 0-$500
2 ☐ $501-$1,000
3 ☐ $1,001-$5,000
4 ☐ $5,001-$10,000
5 ☐ $10,001-$25,000
6 ☐ $25,001-$50,000
7 ☐ $50,001-$100,000
8 ☐ $100,001-$250,000
9 ☐ $250,001-$500,000
10 ☐ $500,001-$1,000,000
11 ☐ $1,000,001 or more

14. Which of the following categories describe your health insurance status?
Check all that apply.

1 ☐ Uninsured
2 ☐ Insurance from your or your partner's employer/ former employer/union
3 ☐ Individual Insurance
4 ☐ Medicare
5 ☐ Medicaid
6 ☐ Tricare/ VA/ other military insurance
7 ☐ Indian Health Service
8 ☐ Other

15. What type of health insurance do you have? Check all that apply.

1 ☐ Have to pay a co-payment for doctor's visits or emergency room visits.

2 ☐ Have to get a referral to see a specialist.

3 ☐ Neither. No co-payments or referral for specialist required.

4 ☐ Don't know.

16. Which one of the following health care facilities best describe your usual source of care? Check one.

1 ☐ Private doctor's office

2 ☐ Hospital clinic or outpatient department

3 ☐ Community health center

4 ☐ Other kind of health care facility

5 ☐ No usual source of care

MY FAMILY

1. Is your natural mother living? Check one box only: Yes, No, or I don't know.

1 ☐ Yes →

How old is she now?

☐☐ Years

☐ Don't know

Has your natural mother ever had any of the following?

Diabetes	1 ☐ Yes	2 ☐ No	9 ☐ I don't know
High blood pressure	1 ☐ Yes	2 ☐ No	9 ☐ I don't know
Stroke	1 ☐ Yes	2 ☐ No	9 ☐ I don't know
Heart Attack	1 ☐ Yes	2 ☐ No	9 ☐ I don't know

2 ☐ No →

Approximately how old was she when she died?

☐☐ Years

☐ Don't know

What was the cause of your natural mother's death?

1 ☐ Cancer

2 ☐ Heart Attack

3 ☐ Stroke

4 ☐ Diabetes

5 ☐ Other

9 ☐ Don't know

Did your natural mother ever have any of the following?

Diabetes	1 ☐ Yes	2 ☐ No	3 ☐ I don't know
High blood pressure	1 ☐ Yes	2 ☐ No	3 ☐ I don't know
Stroke	1 ☐ Yes	2 ☐ No	3 ☐ I don't know
Heart Attack	1 ☐ Yes	2 ☐ No	3 ☐ I don't know

3 ☐ I don't know if my natural mother is living.

2. Is your natural father living? Check one box only: Yes, No, or I don't know.

1 ☐ Yes →

How old is he now?

☐☐ Years

☐ Don't know

Has your natural father ever had any of the following?

Diabetes	1 ☐ Yes	2 ☐ No	9 ☐ I don't know
High blood pressure	1 ☐ Yes	2 ☐ No	9 ☐ I don't know
Stroke	1 ☐ Yes	2 ☐ No	9 ☐ I don't know
Heart Attack	1 ☐ Yes	2 ☐ No	9 ☐ I don't know

2 ☐ No →

Approximately how old was he when he died?

☐☐ Years

☐ Don't know

What was the cause of your natural father's death?

1 ☐ Cancer

2 ☐ Heart Attack

3 ☐ Stroke

4 ☐ Diabetes

5 ☐ Other

9 ☐ Don't know

Did your natural father ever have any of the following?

Diabetes	1 ☐ Yes	2 ☐ No	3 ☐ I don't know
High blood pressure	1 ☐ Yes	2 ☐ No	3 ☐ I don't know
Stroke	1 ☐ Yes	2 ☐ No	3 ☐ I don't know
Heart Attack	1 ☐ Yes	2 ☐ No	3 ☐ I don't know

3 ☐ I don't know if my natural father is living.

3. How many full brothers and sisters do you have? Include any brothers or sisters who may have died, but do not include any half or step brothers or sisters. Check the "don't know" box if you don't know.

☐☐ Number of brothers

☐ I don't know

☐☐ Number of sisters

☐ I don't know

4. How many of them have had:

(Check the "don't know" box if you don't know how many have had these conditions.)

	Number of brothers	**Number of sisters**
Diabetes	☐☐ **Number** ☐ Don't know	☐☐ **Number** ☐ Don't know
High blood pressure	☐☐ **Number** ☐ Don't know	☐☐ **Number** ☐ Don't know
Heart attack	☐☐ **Number** ☐ Don't know	☐☐ **Number** ☐ Don't know
Stroke	☐☐ **Number** ☐ Don't know	☐☐ **Number** ☐ Don't know

HEALTH UTILITIES INDEX III (HUI-3)

This questionnaire contains a set of questions which ask about various aspects of your health. When answering these questions please think about your health and your ability to do things on a day-to-day basis, during the past 4 weeks. To define the 4 week period, please think about what the date was 4 weeks ago and recall the major events that you have experienced during this period. Please focus your answers on your abilities, disabilities and how you have felt during the past 4 weeks.

You may feel that some of these questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar; please excuse the apparent overlap and answer each question independently.

Please read each question and consider your answers carefully. For each question, please select one answer that best describes your level of ability or disability during the past 4 weeks. Please indicate the selected answer by circling the letter (a, b, c, …) beside the answer.

All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities and feelings.

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1. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to read ordinary newsprint?

   a. Able to see well enough without glasses or contact lenses.

   b. Able to see well enough with glasses or contact lenses.

   c. Unable to see well enough even with glasses or contact lenses.

   d. Unable to see at all.

2. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to recognize a friend on the other side of the street?

   a. Able to see well enough without glasses or contact lenses.

   b. Able to see well enough with glasses or contact lenses.

   c. Unable to see well enough even with glasses or contact lenses.

   d. Unable to see at all.

3. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a group conversation with at least three other people?

   a. Able to hear what was said without a hearing aid.

   b. Able to hear what was said with a hearing aid.

   c. Unable to hear what was said even with a hearing aid.

   d. Unable to hear what was said, but did not wear a hearing aid.

   e. Unable to hear at all.

4. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a conversation with one other person in a quiet room?

   a. Able to hear what was said without a hearing aid.

   b. Able to hear what was said with a hearing aid.

   c. Unable to hear what was said even with a hearing aid.

   d. Unable to hear what was said, but did not wear a hearing aid.

   e. Unable to hear at all.

5. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking your own language with people who do not know you?

   a. Able to be understood completely.

   b. Able to be understood partially.

   c. Unable to be understood.

   d. Unable to speak at all.

6. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking with people who know you well?

   a. Able to be understood completely.

   b. Able to be understood partially.

   c. Unable to be understood.

   d. Unable to speak at all.

7. Which one of the following best describes how you have been feeling during the past 4 weeks?

   a. Happy and interested in life.
   b. Somewhat happy.
   c. Somewhat unhappy.
   d. Very unhappy.
   e. So unhappy that life was not worthwhile.

8. Which one of the following best describes the pain and discomfort you have experienced during the past 4 weeks?

   a. Free of pain and discomfort.
   b. Mild to moderate pain or discomfort that prevented no activities.
   c. Moderate pain or discomfort that prevented some activities.
   d. Moderate to severe pain or discomfort that prevented some activities.
   e. Severe pain or discomfort that prevented most activities.

9. Which one of the following best describes your ability, during the past 4 weeks, to walk?
   Note: Walking equipment refers to mechanical supports such as braces, a cane, crutches or a walker.

   a. Able to walk around the neighborhood without difficulty, and without walking equipment.
   b. Able to walk around the neighborhood with difficulty; but did not require walking equipment or the help of another person.
   c. Able to walk around the neighborhood with walking equipment, but without the help of another person.
   d. Able to walk only short distances with walking equipment, and required a wheelchair to get around the neighborhood.
   e. Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and required a wheelchair to get around the neighborhood.
   f. Unable to walk at all.

10. Which one of the following best describes your ability, during the past 4 weeks, to use your hands and fingers?

Note: Special tools refers to hooks for buttoning clothes, gripping devices for opening jars or lifting small items, and other devices to compensate for limitations of hands or fingers.

a. Full use of two hands and ten fingers.
b. Limitations in the use of hands or fingers, but did not require special tools or the help of another person.
c. Limitations in the use of hands or fingers, independent with use of special tools (did not require the help of another person).
d. Limitations in the use of hands or fingers, required the help of another person for some tasks (not independent even with use of special tools).
e. Limitations in the use of hands or fingers, required the help of another person for most tasks (not independent even with use of special tools).
f. Limitations in the use of hands or fingers, required the help of another person for all tasks (not independent even with use of special tools).

11. Which one of the following best describes your ability, during the past 4 weeks, to remember things?

a. Able to remember most things.
b. Somewhat forgetful.
c. Very forgetful.
d. Unable to remember anything at all.

12. Which one of the following best describes your ability, during the past 4 weeks, to think and solve day to day problems?

a. Able to think clearly and solve day to day problems.
b. Had a little difficulty when trying to think and solve day to day problems.
c. Had some difficulty when trying to think and solve day to day problems.
d. Had great difficulty when trying to think and solve day to day problems.
e. Unable to think or solve day to day problems.

13. Which one of the following best describes your ability, during the past 4 weeks, to perform basic activities?

a. Eat, bathe, dress and use the toilet normally.

b. Eat, bathe, dress or use the toilet independently with difficulty.

c. Required mechanical equipment to eat, bathe, dress or use the toilet independently.

d. Required the help of another person to eat, bathe, dress or use the toilet.

14. Which one of the following best describes how you have been feeling during the past 4 weeks?

a. Generally happy and free from worry.

b. Occasionally fretful, angry, irritable, anxious or depressed.

c. Often fretful, angry, irritable, anxious or depressed.

d. Almost always fretful, angry, irritable, anxious or depressed.

e. Extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help.

15. Which one of the following best describes the pain or discomfort you have experienced during the past 4 weeks?

a. Free of pain and discomfort.

b. Occasional pain or discomfort. Discomfort relieved by non-prescription drugs or self-control activity without disruption of normal activities.

c. Frequent pain or discomfort. Discomfort relieved by oral medicines with occasional disruption of normal activities.

d. Frequent pain or discomfort; frequent disruption of normal activities. Discomfort required prescription narcotics for relief.

e. Severe pain or discomfort. Pain not relieved by drugs and constantly disrupted normal activities.

16. Overall, how would you rate your health during the past 4 weeks?

a. Excellent.

b. Very good.

c. Good.

d. Fair.

e. Poor.

17. How did you complete the questionnaire? Please select the one answer that best describes your situation.

a. By myself, without any help from anyone else.

b. By myself, except someone else circled the answers on the questionnaire form for me.

c. With the help of someone else.

d. This questionnaire was completed by a family member, without help from the subject or patient.

e. This questionnaire was completed by a nurse or other health professional, without help from the subject or patient.

Please specify type of health professional: _____

f. This questionnaire was completed by another person, without help from the subject or patient.

Please specify relationship to subject or patient: _____

INDIRECT COST OF MEDICAL CARE

Date of last cost ascertainment:

MONTH	DAY	YEAR
☐☐	☐☐	☐☐☐☐

Refer to this date when inquiring below about events that have occurred or procedures that were performed since the last time cost data were collected.

Treatments or Procedures

1. **Have there been any major changes in your health since (date above)?**

   1 ☐ Yes (complete AE forms as needed)

   2 ☐ No (go to question 2)

2. **Have you been admitted to the hospital since (date above)?**

   1 ☐ Yes (complete AE form for each)

   MONTH ☐☐ DAY ☐☐ YEAR ☐☐☐☐ REASON ☐

   MONTH ☐☐ DAY ☐☐ YEAR ☐☐☐☐ REASON ☐

   2 ☐ No (go to question 3)

3. **How many times did you visit your physician or receive outpatient treatment (including emergency room visits) since (date above)?**

   ☐☐☐ Times

4. **Have you had any diagnostic tests as an outpatient since (date above)?**

   1 ☐ Yes ☐ Heart test *(ECG, echo, stress test)* ☐ X-ray ☐ CT/MRI

   ☐ Other (specify) ☐

   2 ☐ No (go to question 5)

Insurance Status

5. Which of the following best describes your current type of insurance coverage?

1 ☐ Medicare

2 ☐ Medicaid

3 ☐ Tricare/CHAMP VA

4 ☐ Private/Commercial

5 ☐ HMO

6 ☐ Don't Know

7 ☐ Uninsured

6. Do you have full or partial drug benefits under your insurance?

1 ☐ Yes

2 ☐ No

3 ☐ Don't Know

4 ☐ Uninsured

INFORMANT CONTACT INFORMATION

When you come in for your clinic visit, we will ask you for the names and addresses of three people outside your immediate household and one person within your household. These will help us to reach you, only in the case of an emergency, in the future. We will also ask you for the name of a physician whom you consider to be your usual source of medical care. Please complete this worksheet and bring it with you to your clinic visit.

Contact Information

A. Please list the names and addresses of three people <u>outside</u> your immediate household who will always know how to contact you.

1.

First Name | MI | Last Name

Street Address

City | State | Zip Code

Phone Number | Relationship

2.

First Name | MI | Last Name

Street Address

City | State | Zip Code

Phone Number | Relationship

3.

First Name | MI | Last Name

Street Address

City | State | Zip Code

Phone Number | Relationship

B. Please list the name and telephone number of a person within your household.

First Name | MI | Last Name

Phone Number | Relationship

Cell Phone Number

☐ Lives Alone

C. What is the name and address of a physician whom you consider to be your regular source of medical care?

First Name | MI | Last Name

Name of Practice or Office

Street Address

City | State | Zip Code

Phone Number

MEDICATIONS

We are interested in the prescription medications you are using. We are particularly interested in medications your doctor prescribed for you and were filled by a pharmacist. These include pills, skin patches, eye drops, creams, salves, inhalers, and injections. The letter you received about this appointment asked you to bring them to the clinic. Have you brought them with you? Are these all medications that you took in the last two weeks?

☐ Yes → May I see them?

☐ No → Make arrangement to obtain.

☐ Took no meds

☐ Refused

1.
2.
3.
4.
5.
6.
7.
8.
9.
10.
11.
12.
13.
14.
15.

SHORT FORM 36

The followings items ask you about your health.

INSTRUCTIONS: Please read each question carefully and mark the box next to the appropriate answer.

1. In general, would you say your health is:

☐	☐	☐	☐	☐
Excellent	*Very good*	*Good*	*Fair*	*Poor*

2. Compared to one year ago, how would you rate your health in general <u>now</u>?

☐	☐	☐	☐	☐
Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago

3. THE FOLLOWING ITEMS ARE ABOUT ACTIVITIES YOU MIGHT DO DURING A TYPICAL DAY. DOES YOUR HEALTH NOW LIMIT YOU IN THESE ACTIVITIES? IF SO, HOW MUCH?

a) Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports

☐	☐	☐
Yes, limited a lot	*Yes, limited a little*	*No, not limited at all*

b) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

☐	☐	☐
Yes, limited a lot	*Yes, limited a little*	*No, not limited at all*

c) Lifting or carrying groceries

☐	☐	☐
Yes, limited a lot	*Yes, limited a little*	*No, not limited at all*

d) Climbing several flights of stairs

☐	☐	☐
Yes, limited a lot	*Yes, limited a little*	*No, not limited at all*

DOES YOUR HEALTH NOW LIMIT YOU IN THESE ACTIVITIES? IF SO, HOW MUCH?

e) Climbing one flight of stairs

☐	☐	☐
Yes, limited a lot	*Yes, limited a little*	*No, not limited at all*

f) Bending, kneeling or stooping

☐	☐	☐
Yes, limited a lot	*Yes, limited a little*	*No, not limited at all*

g) Walking more than a mile

☐	☐	☐
Yes, limited a lot	*Yes, limited a little*	*No, not limited at all*

h) Walking several blocks

☐	☐	☐
Yes, limited a lot	*Yes, limited a little*	*No, not limited at all*

i) Walking one block

☐	☐	☐
Yes, limited a lot	*Yes, limited a little*	*No, not limited at all*

j) Bathing or dressing yourself

☐	☐	☐
Yes, limited a lot	*Yes, limited a little*	*No, not limited at all*

4. DURING THE PAST 4 WEEKS, HAVE YOU HAD ANY OF THE FOLLOWING PROBLEMS WITH YOUR WORK OR OTHER REGULAR DAILY ACTIVITIES AS A RESULT OF YOUR PHYSICAL HEALTH?

a) Cut down on the amount of time you spent on work or other activities?

- ☐ YES
- ☐ NO

b) Accomplished less than you would like

- ☐ YES
- ☐ NO

c) Were limited in the kind of work or other activities?

- ☐ YES
- ☐ NO

d) Had difficulty performing the work or other activities (for example, it took extra time/effort)

- ☐ YES
- ☐ NO

5. DURING THE PAST 4 WEEKS, HAVE YOU HAD ANY OF THE FOLLOWING PROBLEMS WITH YOUR WORK OR OTHER REGULAR DAILY ACTIVITIES AS A RESULT OF ANY EMOTIONAL PROBLEMS (SUCH AS FEELING DEPRESSED OR ANXIOUS?

a) Cut down on the amount of time you spent on work or other activities

- ☐ YES
- ☐ NO

b) Accomplished less than you would like

- ☐ YES
- ☐ NO

c) Didn't do work or other activities as carefully as usual

- ☐ YES
- ☐ NO

6. DURING THE PAST 4 WEEKS, TO WHAT EXTENT HAS YOUR PHYSICAL HEALTH OR EMOTIONAL PROBLEMS INTERFERED WITH YOUR NORMAL SOCIAL ACTIVITIES WITH FAMILY, FRIENDS NEIGHBORS, OR GROUPS?

☐ *Not at all* ☐ *Slightly* ☐ *Moderately* ☐ *Quite a bit* ☐ *Extremely*

7. How much bodily pain have you had during the past 4 weeks?

☐ *None* ☐ *Very Mild* ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Very Severe*

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐ *Not at all* ☐ *Slightly* ☐ *Moderately* ☐ *Quite a bit* ☐ *Extremely*

9. The following questions ask you about how you have felt during the past 4 weeks. Please choose the one answer that comes closest to the way you have been feeling.

HOW MUCH OF THE TIME DURING THE PAST 4 WEEKS...

a) did you feel full of pep?

☐ *All of the time* ☐ *Most of the time* ☐ *A good bit of the time* ☐ *Some of the time* ☐ *A little of the time* ☐ *None of the time*

b) have you been a very nervous person?

☐ *All of the time* ☐ *Most of the time* ☐ *A good bit of the time* ☐ *Some of the time* ☐ *A little of the time* ☐ *None of the time*

c) have you felt so down in the dumps nothing could cheer you up?

☐ *All of the time* ☐ *Most of the time* ☐ *A good bit of the time* ☐ *Some of the time* ☐ *A little of the time* ☐ *None of the time*

d) have you felt calm and peaceful?

☐ *All of the time* ☐ *Most of the time* ☐ *A good bit of the time* ☐ *Some of the time* ☐ *A little of the time* ☐ *None of the time*

e) did you have a lot of energy?

☐	☐	☐	☐	☐	☐
All of the time	*Most of the time*	*A good bit of the time*	*Some of the time*	*A little of the time*	*None of the time*

f) have you felt downhearted and blue?

☐	☐	☐	☐	☐	☐
All of the time	*Most of the time*	*A good bit of the time*	*Some of the time*	*A little of the time*	*None of the time*

g) did you feel worn out?

☐	☐	☐	☐	☐	☐
All of the time	*Most of the time*	*A good bit of the time*	*Some of the time*	*A little of the time*	*None of the time*

h) have you been a happy person?

☐	☐	☐	☐	☐	☐
All of the time	*Most of the time*	*A good bit of the time*	*Some of the time*	*A little of the time*	*None of the time*

i) did you feel tired?

☐	☐	☐	☐	☐	☐
All of the time	*Most of the time*	*A good bit of the time*	*Some of the time*	*A little of the time*	*None of the time*

10. During the past 4 weeks, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?

☐	☐	☐	☐	☐
All of the time	*Most of the time*	*Some of the time*	*A little of the time*	*None of the time*

11. HOW TRUE OR FALSE IS EACH OF THE FOLLOWING STATEMENTS FOR YOU?

a) I seem to get sick a little easier than other people

☐	☐	☐	☐	☐
Definitely true	*Mostly true*	*Don't know*	*Mostly false*	*Definitely false*

b) I am as healthy as anybody I know

☐	☐	☐	☐	☐
Definitely true	*Mostly true*	*Don't know*	*Mostly false*	*Definitely false*

c) I expect my health to get worse

☐	☐	☐	☐	☐
Definitely true	*Mostly true*	*Don't know*	*Mostly false*	*Definitely false*

d) My health is excellent

☐	☐	☐	☐	☐
Definitely true	*Mostly true*	*Don't know*	*Mostly false*	*Definitely false*

SOCIAL SUPPORT

Instructions: This questionnaire requires you to think about current relationships with other participants and/or group leaders in this study. Please read each item and then indicate the extent to which you agree with it by checking one box next to each item with an X.

Some items may seem similar to others, but it is very important that you provide an answer for each item.

1. There are people in this program I can depend on to help me if I really need it.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
2. I feel that I do not have close personal relationships with other people in this program.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
3. There is no one in this program I can turn to for guidance in times of stress.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
4. There are people in this program who depend on me for help.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
5. There are people in this program who enjoy the same social activities that I do.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
6. Other people in this program do not view me as competent.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
7. I feel personally responsible for the well-being of other people in this program.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
8. I feel part of a group of people in this program who share my attitudes and beliefs.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
9. I do not think other people in this program respect my skills and abilities.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
10. If something went wrong, no one in this program would come to my assistance.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
11. I have close relationships in this program that provide me with a sense of emotional security and well-being.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree

12. There is someone in this program I could talk to about important decisions in my life.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
13. In this program, people recognize my competencies and skills.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
14. There is no one in this program who shares my interests and concerns.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
15. There is no one in this program who really relies on me for their well-being.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
16. There is a trustworthy person in this program I could turn to for advice if I were having problems.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
17. I feel a strong emotional bond with at least one other person in this program.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
18. There is no one in this program I can depend on for aid if I really need it.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
19. There is no one in this program I feel comfortable talking about problems with.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
20. There are people in this program who admire my talents and abilities.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
21. I lack a feeling of intimacy with another person in this program.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
22. There is no one in this program who likes to do the things I do.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
23. There are people in this program I can count on in an emergency.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree
24. No one in the program needs for me to care for them.	☐ Strongly Disagree	☐ Disagree	☐ Agree	☐ Strongly Agree

CLINIC ASSESSMENT FORM

1. Is the participant fasting?

   1 ☐ Yes

   2 ☐ No

2. Was the fasting blood sample drawn?

   1 ☐ Yes

   2 ☐ No

3. Was blood collected for storage and future analysis?

   1 ☐ Yes

   2 ☐ No

Blood Pressure

4. Blood Pressure (after sitting 5 minutes)

1	☐☐☐ **systolic**	☐☐☐ **diastolic**	mm/Hg
2	☐☐☐ **systolic**	☐☐☐ **diastolic**	mm/Hg
AVG	☐☐☐ **systolic**	☐☐☐ **diastolic**	mm/Hg

Body Size

5. Weight ☐☐☐.☐ kg

6. Height ☐☐☐.☐ cm

7. BMI ☐☐☐.☐ kg/m^2

8. Waist Circumference ☐☐☐.☐ cm

ENCOUNTER AND DISPOSITION

1. Was information collected during this visit for a previously missed visit?

☐ Yes → Code for Missed Visit: ☐☐☐

☐ No

2. Was this visit completed in the clinic as described in the protocol/MOP?

☐ Yes (stop here)

☐ No (complete question 3)

3. Was partial information collected?

☐ Yes →

Indicate below the items that were scheduled to be collected but are missing:

☐ Blood draw	☐ HUI-3	☐ FFQ
☐ Physical Exam	☐ SF-36	☐ Self-Efficacy Qs
☐ Blood Pressure	☐ Medications	☐ Events Assessment
☐ Economic Evaluations	☐ IPAQ	☐ Health Behaviors

Why were these not completed as planned?

☐ Phone Contact

☐ Other (specify) _____

☐ No →

Why was this visit missed?

☐ Participant cannot be located
☐ Participant located but refused clinic visit
☐ Participant is hospitalized
☐ Participant died
☐ Scheduling conflict
☐ Visit scheduled, but participant did not show

☐ Other (specify) _____

PRE-SCREENING INTERVIEW

First I would like to collect some general information from you.

What is your name?

Prefix or title preffered: ☐Mr. ☐Mrs. ☐Ms. ☐Dr. ☐Other:_____

First Name _____ Middle Initial _____ Last Name _____ Suffix _____

Preferred Name _____ **Prefered Languague:** English$_1$ Spanish$_2$

How did you hear about this study? (check all that apply)

Church Event	1 ☐	Newspaper or Magazine Article	7 ☐
Community Event	2 ☐	Newspaper or Magazine Ad	8 ☐
Flyer or Poster	3 ☐	Radio Ad	9 ☐
Doctor/Doctor's office	4 ☐	Television Ad	10 ☐
Letter in Mail	5 ☐	Don't Know	11 ☐
Referral	6 ☐	Refused	12 ☐
Other (please specify):	13 ☐		

1. Has anyone interviewed you or given you information about this study before?

[1] ☐ Yes → When? ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR
What was the outcome? _____

[2] ☐ No

[3] ☐ Don't Know

2. What is your date of birth?

☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

3. What is your sex?
   [1] ☐ male
   [2] ☐ female

4. Which of the following best describes your race?
   - [1] ☐ African American/ Black
   - [2] ☐ American Indian/ Native American/ Alaskan Native
   - [3] ☐ Asian/ Pacific Islander
   - [4] ☐ White
   - [5] ☐ Other specify:_____

5. Are you Latino, Hispanic, or of Spanish origin?
   - [1] ☐ Yes
   - [2] ☐ No → ☐ **PARTICIPANT EXCLUDED** Not Latino, Hispanic, or of Spanish Origin

6. Do you have diabetes?
   - [1] ☐ Yes → Are you taking any oral medications or insulin to control your diabetes?
     - [1] ☐ Yes → ☐ **PARTICIPANT EXCLUDED**
     - [2] ☐ No
     - [3] ☐ Don't Know

     Are you following a special diet or exercise program to manage your diabetes?
     - [1] ☐ Yes ☐ **PARTICIPANT EXCLUDED**
     - [2] ☐ No
   - [2] ☐ No
   - [4] ☐ Borderline → Are you taking any oral medications?
     - [1] ☐ Yes → ☐ **PARTICIPANT EXCLUDED**
     - [2] ☐ No
     - [3] ☐ Don't Know
     - [4] ☐ Don't Know

7. What is your height?

   ☐☐ ☐☐
   Feet Inches

8. What is your weight?

   ☐☐☐ lbs.

***BMI _____kg/m^2

☐ **PARTICIPANT EXCLUDED**
BMI is not between 23 and 50 kg/m^2

9. Have you been diagnosed with or treated for any cancer except (non-melanoma) skin cancer in the last 5 years?

[1] ☐ Yes → ☐ **PARTICIPANT EXCLUDED**
Recent diagnosis and/or treatment of cancer

[2] ☐ No

[3] ☐ Don't Know

10. Have you ever had any of the following?

your heart stopped and doctors had to restart it with an electric shock or defibrillator	[1] ☐ Yes	[2] ☐ No	[3] ☐ Don't Know
kidney dialysis	[1] ☐ Yes	[2] ☐ No	[3] ☐ Don't Know
implanted defibrillator	[1] ☐ Yes	[2] ☐ No	[3] ☐ Don't Know
major organ transplant	[1] ☐ Yes	[2] ☐ No	[3] ☐ Don't Know

If participant answered yes to any of the above: ☐ **PARTICIPANT EXCLUDED**
History of major condition/chronic disease

11. Can you walk two blocks (about ¼ mile) without stopping without the aid of a cane, crutches, walker or other such device?

[1] ☐ Yes

[2] ☐ No → ☐ **PARTICIPANT EXCLUDED**
Unable to perform moderate intensity exercise

[3] ☐ Don't Know

12. (If female) Are you currently pregnant or nursing or planning to become pregnant?

[1] ☐ Yes → ☐ **PARTICIPANT EXCLUDED**
☐ Pregnant
☐ Nursing
☐ Planning pregnancy

[2] ☐ No

[3] ☐ Male, not applicable

13. Have you had any of the following?

Heart Attack	[1] ☐ Yes	[2] ☐ No	[3] ☐ Don't Know
Stroke, mini stroke, or TIA	[1] ☐ Yes	[2] ☐ No	[3] ☐ Don't Know

Heart bypass surgery	1☐Yes	2☐No	3☐Don't Know
Heart angioplasty, balloon surgery of the heart, or a stent	1☐Yes	2☐No	3☐Don't Know
Participated in cardiac rehabilitation	1☐Yes	2☐No	3☐Don't Know

If participant answered yes to any of the above, did it occur in the past six months?

1☐Yes →

2☐No

☐**PARTICIPANT EXCLUDED**
Recent history of cardiovascular disease
When was your most recent event?

☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

☐ *Re-screen 6 months from above date*

14. Are you currently taking medications for weight loss or participating in a weight loss program?

1☐Yes →

2☐No

Are you willing to stop taking these medications or participating in the other weight loss program for the time that you are participating in HELP?
1☐Yes
2☐ No → **PARTICIPANT EXCLUDED**

15. Are you currently taking steroid pills or shots such as prednisone or cortisone? (This does not include hormone replacement)

1☐Yes →

2☐No

3☐Don't Know

Which ones?
_____
Contact study doctor for consult before participant can continue screening process.

16. Are you currently being treated for drug or alcohol abuse?

1☐Yes →
2☐No

☐**PARTICIPANT EXCLUDED**
Self-Reported substance abuse

17. Have you ever been hospitalized for a major mental disorder or psychiatric problem?

1☐Yes →

2☐No

If "**yes**", contact study doctor for consult before participant can continue screening process.

18. Are you or any members of your household currently participating in any other medical research trials?

[1] ☐ Yes → Study: _____ *Contact study coordinator for more information before participant can continue screening process.*

[2] ☐ No

19. Are you planning to move from the area in the next 2 years?

[1] ☐ Yes → ☐ **PARTICIPANT EXCLUDED** Unable to make time commitment for length of the study

[2] ☐ No

[3] ☐ Don't Know

20. Are there times when you might be away for more than 2 weeks at a time that might limit participation in the intervention?

[1] ☐ Yes → ☐ **PARTICIPANT EXCLUDED** Travel may limit participation in intervention

[2] ☐ No

21. Do you know of any reasons, health related or otherwise, that you would not be able to participate completely in a 2 year research study?

[1] ☐ Yes → **Reason:** _____ _____ _____ *Evaluate ability to participate before continuing*

[2] ☐ No

If eligible:

Based on these questions, you may be eligible to participate in La Comunidad. We would like to invite you to watch a brief video to learn more about the study. Are you interested in continuing the screening process?

☐ Yes ☐ No

If ineligible:

Based on these questions, it looks like you are not eligible to participate in La Comunidad. We really appreciate your interest in the study and hope that we can contact you in the future for other studies related to diabetes or weight loss. Would it be okay for us to keep your information on file for future studies?

☐ Yes ☐ No

For staff use only

Eligibility status:

☐ Eligible

☐ Ineligible

☐ Refused

☐ Pending: Explain

Call back: ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

ELIGIBILITY SCREENING FORM

1. Informed Consent
Was informed consent obtained?

☐ Yes Date signed: ☐☐ (MONTH) ☐☐ (DAY) ☐☐☐☐ (YEAR)

☐ No

2. Confirmation of Prediabetes

☐ Diabetes Risk Test completed

Score: ☐☐

3. Blood Pressure

1. ☐☐☐ **Systolic** ☐☐☐ **diastolic** mm/Hg

2. ☐☐☐ **systolic** ☐☐☐ **diastolic** mm/Hg

AVG ☐☐☐ **systolic** ☐☐☐ **diastolic** mm/Hg

Is average SBP >160 or average DBP>100?
☐ Yes
☐ No

☐ **PARTICIPANT EXCLUDED**
Average BP > 160/100 mm/Hg; referred to PCP

4. Body Size

Weight ☐☐☐.☐ lb

Height ☐☐☐.☐ in

**BMI ☐☐.☐ kg/m^2

Is BMI < 25 kg/m^2 or ≥45 kg/m^2?
☐ Yes
☐ No

☐ **PARTICIPANT EXCLUDED**
BMI < 25 kg/m^2 or ≥45 kg/m^2

5. Was the PAR-Q completed?

☐ Yes

☐ No

☐ Check here if medical clearance is required prior to participation.

6. Measurement of HbA1c

☐ Blood sample collected

☐☐ . ☐ %

Was the HbA1c less than 5.7% or more than 6.5%?

☐ Yes
☐ No

☐ **PARTICIPANT EXCLUDED**
HbA1c < 5.7% or >6.5%

If ineligible:
Based on the blood that we collected at the screening event, you are not eligible to participate in La Comunidad. This is because your blood sugar was *above/below* the range to qualify for the study. If you would like, please feel free to contact us in the future if you would like to be screened again. We really appreciate your interest in the study and hope that we hear from you again.

☐Yes ☐No

Date Participant is scheduled to return: ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

Time: ☐☐ : ☐☐ ☐AM ☐PM

Nature of Next Visit:
☐ Additional Screening
☐ Randomization

Current Status:
☐ Eligible
☐ Ineligible
☐ Refused

Contact Information

Complete Legal Name

First | Middle

Last | Suffix | Mother's Name

Address

Address 1

Address 2

City | State | Zip

Telephone

Home | Work

Cell | Other

Email

☐ I do not have access to email

What is your preferred contact number?

☐ Home ☐ Work ☐ Cell ☐ Other

What is the best time of day to reach you?

☐ Morning (8 AM-12 PM) ☐ Afternoon (12-5 PM) ☐ Evening (5-8 PM)