FRED HUTCHINSON CANCER RESEARCH CENTER

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Title of Protocol:
Adaptation and Evaluation of an Online and eHealth Diet and Physical Activity Program to Improve Cardiometabolic Health in Rural Latino Adults "Mi Vida Saludable en el Valle"

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SPONSOR: CCSG Pilot Funds (May 1, 201 9 - December 31, 2021)

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PROTOCOL SYNOPSIS

Protocol Title	Adaptation and Evaluation of an In-person and eHealth Diet and Physical Activity Program to Improve Cardiometabolic Health in Rural Latino Adults "Mi Vida Saludable en el Valle"
Protocol Number	RG1005660
Protocol Sponsor	CCSG
Trial Phase	Phase 2
Trial Type	Pilot RCT
Clinical Indication	Latino adults with history of hypertension, diabetes, cardiovascular disease, cancer, or obesity
Study Objectives	Aim 1 Assess feasibility of a remotely delivered and remotely assessed online group sessions and eHealth communication intervention strategies as measured by quantitative (accrual rate, intervention adherence, study retention, percent data collection processes completed, duration of staff assistance to complete data collection) and qualitative (exit interviews) data. Feasibility of intervention delivery for staff within the rural community context will be assessed and necessary adaptations from the urban intervention delivery process will be documented. Aim 2 Examine changes from baseline to 3 months in nutrition and physical activity knowledge and preferences, and changes in physical activity patterns as assessed via Fitbit data.
Study Design	Feasibility study
Population	Latino residents of the Lower Yakima Valley with a history of hypertension, diabetes, cardiovascular disease, cancer, and/or obesity.
Primary Endpoints	Accrual rate, intervention adherence, study retention, data completion rates, assessability/acceptability (exit interview) and required intervention delivery adaptations.
Secondary Endpoints	Changes in nutrition and physical activity knowledge and preferences from baseline to 3 months. Changes in physical activity patterns as assessed via Fitbit data.
Type of control	N/A
Treatment Groups	Single-arm
Treatment Schedule	Participants will attend six 2-hour virtual nutrition and PA education sessions that include cooking and physical activity (i.e., dance class, walking in place). Participants will then receive 12 weeks of motivational text messages 4 times per week and link to access the nutrition cookforyourlife.org website. eHealth communication messaging will focus on increasing knowledge on the benefits of healthy nutrition, reducing intakes of energy dense and processed foods, and increasing physical activity.
Number of trial subjects	N=25
Estimated duration of trial	6 months
Duration of Participation	3-4 months

ABBREVIATIONS

CHE	Community Health Educator

CCHP	Center for Community Health Promotion
IPAQ	International Physical Activity Questionnaire

Contents

1.0 GENERAL INFORMATION

This document is a clinical research protocol and the described study will be conducted in compliance with the IRB approved protocol, associated Federal regulations and all applicable IRB requirements. Pilot data collected from this feasibility study will support a novel R21 application to assess the efficacy of an online group sessions and eHealth communication intervention in a rural population of Latino adults with hypertension, diabetes, cardiovascular disease, cancer, and/or obesity via a feasibility assessment. Importantly, through collaboration with community partners, the current and subsequent trials will build community capacity to deliver nutrition and PA resources to underserved rural Latino adults and to introduce innovative technology-based intervention strategies not often applied in rural Latino communities.

Testing scalable intervention strategies for uptake of nutrition and PA recommendations as a new treatment model to improve cardiometabolic health with potential for broad dissemination among Latinos living in a rural community. This feasibility study will generate preliminary data needed to design a novel R21 proposal for a larger trial with long-term outcomes in a broad population of Latino adults living in a rural setting. We will leverage the Fred Hutch capacity and resources to provide rural adult Latinos with tools beyond brochures and single visit referrals to clinicians to discuss lifestyle modifications. This work has the potential to identify a scalable and cost-effective intervention targeting multiple lifestyle behaviors to be disseminated in clinical and community settings.

Building collaborations and new research opportunities. The proposed project maximizes strengths of 2 Fred Hutch Public Health Sciences investigators, Drs. Rachel Ceballos and Heather Greenlee, in a new collaboration and new research directions. Dr. Ceballos brings to the collaboration experience in community-based participatory research (CBPR) in rural Latino communities and Dr. Greenlee provides her expertise in behavioral nutrition and PA interventions among cancer survivors. This new collaborative project provides an opportunity for Dr. Greenlee to expand her research into rural Latino communities and Dr. Ceballos to gain experience in the fields of nutrition and PA intervention delivery, which sets the stage for future grant applications. Through current request of applications (RFAs), the National Cancer Institute (NCI)'s Division of Cancer Control and Population Sciences is currently highlighting and prioritizing the needs of rural communities, racial/ethnic populations, and obesity-related cancer prevention and control. Achieving the proposed project's specific aims will provide important pilot data on intervention adaptation, feasibility assessment, and preliminary effectiveness data needed to support a larger R01 grant application.

Community partnerships and capacity building. This project will develop new community collaborations among Latinos in the Lower Yakima Valley by adapting and developing the Mi Vida Saludable en el Valle intervention through partner feedback and interaction. Based on participant input, the intervention will be tailored to the unique nature and needs of this rural population with the goal of achieving a more effective intervention. Community partners will contribute to the delivery of the intervention by providing space and resources. Community partners, along with our Community Action Board (CAB), will receive information about data collection, research methods, and contribute to data interpretation and next steps towards an R21 application. These community partnerships contribute to the community's ability to evaluate and build capacity for future behavioral programs. A local chef and local community health educator will receive rigorous training to deliver the online group class intervention, which will ensure education and skills specific to nutrition and PA for rural Latinos remain in the community.

eHealth communication as a new strategy for nutrition and PA change in rural Latinos. The use of technology in behavioral interventions is proving to be a cost-effective way to deliver targeted nutrition and PA education to promote behavior change. Electronic (e) technology has been effective in many types of health interventions,

including smoking cessation[1] and diabetes management[2], among others.[3-5] Studies suggest that when possible, participants should be offered multiple modes of theory-based e-communication to allow flexibility.[6,7] However, there are limited data on the use of eHealth communication to achieve and maintain behavior change among Latino adults.

As part of the eHealth communication intervention, participants will receive weekly educational and motivational text messaging, and links to electronic (e) newsletters and a nutritional website. Dr. Greenlee has collaborated with the non-profit Cook for Your Life for the past decade on NCI funded R21 and R01 trials. The study will make use of the bilingual Cookforyourlife.org website, now owned by Fred Hutch, which is tailored to cancer survivors and is available in English and Spanish.[7, 8] The website offers free nutrition and healthy cooking information, recipes, and cooking videos and disseminates scientifically supported information on nutrition and cancer survivorship. For the proposed trial, password-gated study specific pages will be created to provide resources addressing cancer, cardiovascular disease, diabetes and obesity.

Note about modifications due to the COVID-19 pandemic: On March 5, 2020, the Mi Vida Saludable en el Valle (My Healthy Life in the Valley) study among Latino cancer survivors was suspended due to the COVID-19 pandemic. Consenting for this study had not yet begun, but some recruitment activities had occurred, and interested individuals had provided their contact information to study staff. After consultation with IRO, these individuals were contacted and informed that the in-person intervention would be delayed due to public health related risk and that all consenting, and baseline data collection activities would be stopped immediately effective March 13, 2020. The intervention involved in-person group sessions with classroom education, cooking/eating, and exercise. Due to the foreseeable COVID-19-related risks of bringing immunosuppressed cancer survivors together for group activities, we have adapted our intervention and data collection activities to be delivered remotely. The trial has been a modified to test an intervention that is remotely delivered and remotely assessed so that no part of the study or data collection procedures occur in groups or onsite at the Fred Hutch Center for Community Health Promotion office in Sunnyside, WA.

Although recruitment activities were able to resume under the modified, remote protocol and many recruitment methods were used, our staff were unable to enroll a significant number of Latino cancer survivors. In February 2021, Drs Ceballos and Greenlee reviewed the study and decided to expand the eligibility criteria to include Latinos with other conditions and chronic illnesses for which nutrition and PA lifestyle changes are recommended.[35-36] This expanded the eligible population to include Latinos with hypertension, diabetes, cardiovascular disease, obesity, as well as Latino cancer survivors.

Modifications included modifications to the two arms of the study. The study was to use a high dose vs. low dose model for the study arms. The high dose arm would receive 6 virtual PA and nutrition classes every other week for 3 months. The low dose arm would receive 1 PA and nutrition class at the beginning of the intervention period. Both arms would have received the same set of eHealth materials including text message reminders and access to the Cook for Your Life website.

In October 2021, investigation into the reason for slow recruitment (n=22 to date) revealed a high burden of data collection for potential participants. In addition, preliminary analyses of data currently being collected by Dr. Greenlee in a similar intervention among a predominantly non-Hispanic white population of urban breast cancer survivors suggested a minimal effect of the low dose arm. As such, Drs. Greenlee and Ceballos decided to adapt the study as follows: change the design to be a single-arm feasibility study in which all participants receive the full “high-dose” intervention, decrease the target recruitment goal, and decrease participant burden by removing intensive data collection methods. These modifications will yield valuable information to determine how best to proceed with future diet and physical activity behavioral interventions in this rural population.

Overview of Study Design. The proposed pilot study will recruit 25 Latinos who are residents of the rural Lower Yakima Valley (LYV) with one or more of the following diagnoses based upon self-report: hypertension, diabetes, cardiovascular disease, obesity, or a history of cancer. Recruitment, retention, and data collection procedures will be carried out by Community Health Educator (CHE) study staff. Eligible participants will undergo online baseline assessments over a period of 1-2 weeks. Interested and eligible participants will be sent an online informed consent, HIPPA and medical records release form and baseline questionnaires to complete.

Following the completion of baseline data collection, participants will receive the intervention. All participants will receive a Fitbit device to self-monitor their PA. The intervention will include 6 biweekly 2-hour Zoom-based nutrition, culinary, and physical activity sessions. The sessions will be led by a local chef consultant and CHE, both trained by the study team. Participants will receive eHealth communication meant to motivate healthy diet and improved PA via educational and motivating text messages and using resources available as part of the study-related website over a 3-month period. Following completion of the 3-month intervention period, repeated baseline at-home assessments will take place and an exit intervention completed. The exit interview will include questions regarding acceptability and accessibility of the intervention for participants.

1.1 Protocol Title

Adaptation and Evaluation of an eHealth Diet and Physical Activity Program to Improve Cardiometabolic Health in Rural Latino Adults "Mi Vida Saludable en el Valle"

1.2 Sponsor Information

CCSG Pilot Funds (May 1, 2019 – December 31, 2021)

1.3 Investigator Information

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2.0 INTRODUCTION TO THE PROTOCOL

2.1 Introduction

The American Cancer Society and the American Institute for Cancer Research recommend cancer survivors to consume high-quality diets (i.e., diets high in fruits, vegetables, and whole gains, and low in energy-dense and processed foods) and to engage in ≥150 minutes per week of moderate-to-vigorous physical activity (MVPA).[1, 2] The American Heart Association and American Diabetes Association have similar recommendations to promote cardiovascular health and improve the prevention or management of diabetes.[35-36]

The rationale for these recommendations is to reduce disease recurrence risk, improve disease survival rates, and reduce comorbid conditions.[3] For Latinos living in rural medically underserved regions, meeting these recommendations is hindered due to limited resource availability and sociocultural barriers (linguistic, beliefs). These barriers contribute to poor diet quality, low physical activity (PA), disproportionately high risk of chronic diseases, and poor cancer-related outcomes, compared to non-Latino Whites.[4, 5] To address these disparities, innovative approaches utilizing effective technologies, culturally appropriate education, and skill building are needed to lay the groundwork for scalable and sustainable interventions.

2.2 Background

Dr. Heather Greenlee has developed and demonstrated feasibility and effectiveness of theory-based multi-strategy (in-person group and electronic e-health communication) interventions to improve nutrition and PA among urban Latino (primarily Dominican and Puerto Rican) cancer survivors (R21CA152903; R01CA186080).[6-8] In collaboration with Dr. Rachel Ceballos and her community partners in Yakima County, WA, the proposed pilot project will adapt Dr. Greenlee's existing *Mi Vida Saludable* (My Healthy Life) intervention to address the sociocultural (cultural, infrastructural, and logistical) needs of rural-dwelling, primarily Mexican-American, Latino adults with a history of hypertension, diabetes, cardiovascular disease, cancer, or obesity and test the feasibility of the adapted intervention. Latino adults with hypertension, diabetes, cardiovascular disease, obesity, and/or a history of cancer (n=25) who live in Yakima County's agricultural region known as the Lower Yakima Valley will be recruited. Participants will receive a high dose intervention delivery.

2.3 Risks/Benefits

There are few potential risks that may occur to participants. There may be some discomfort in completing questionnaires about cancer and other diseases, but staff are trained to be aware of such discomfort and are trained to be compassionate to individuals answering such questions. Research related injuries are highly unlikely due to the low risk nature of this study; however, there is a risk of unintentional injuries that may occur while cooking, dancing or participating in exercises as promoted via online sessions. Participants will be asked to increase their physical activity during the 3 months of the study. This increased physical activity may cause unintentional soreness, joint pain or exercise related injuries. Recommended dietary changes may include gas and bloating due to increased fiber consumption. The timing and frequency of the online sessions and data collection at baseline and 3 months may provide an inconvenience to participants' schedules.

Participants will receive up to $50 in compensation in the form of a gift card to a local vendor. Since the in-person session are to be delivered via online Zoom videos, we are also providing participants randomized to receiving the online sessions with a grocery bags with an estimated cost of $25 or less per sessions for total of $150 in groceries per participant to cover all six sessions or one session. Aside from the gift card and grocery bags and gaining new knowledge about ways in which participants can decrease their risk of cancer reoccurrence by being physically active and consuming a diet high in fruits and vegetables and low in fat and added sugar, there are no other direct benefits of this research to a given study participant. The data from the study will be used to direct future intervention efforts targeting similar populations.

3.0 OVERVIEW OF CLINICAL TRIAL

3.1 Study Objectives

This feasibility study aims to assess assessibility, acceptability, adherence, retention, data collection rates, and required adaptations of an online and eHealth intervention as well as to assess changes from baseline to 3 months in food knowledge and health-related physical activity.

3.1.1 Primary Objectives

Assess feasibility of online group sessions and eHealth intervention strategies.

3.1.2 Secondary Objectives

Assess changes from baseline to 3 months in nutrition and physical activity knowledge and preferences

Assess changes in physical activity patterns as assessed via Fitbit data

3.2 Study Population

Our aim is to enroll 25 adult Latinos in the Lower Yakima Valley. Participants must have one or more of the following: hypertension, diabetes, cardiovascular disease, past cancer diagnosis, or obesity. We will recruit with the assistance of our Community Health Educator (CHE) staff who work at the Fred Hutch satellite site, the Center for Community Health Promotion (CCHP) in Sunnyside, WA.

3.3 Study Design

This is a single arm feasibility study to assess a culturally tailored eHealth diet and physical activity program for rural Latino adults with a history of hypertension, diabetes, cardiovascular disease, cancer, and/or obesity in the Lower Yakima Valley.

3.3.1 Primary Endpoints

Accrual rate, adherence (online sessions attendance in intervention arm, text message responses, and use of website), retention (completion of all study assessments), and acceptability (exit interview). Feasibility of intervention delivery for staff within in the rural community context will also be assessed and necessary adaptations from the urban intervention delivery process will be documented.

3.3.2 Secondary Endpoints

Changes from baseline to 3 months in nutrition and physical activity knowledge and preferences

Changes from baseline to 3 months in physical activity patterns as assessed via Fitbit data

3.3.3 Exploratory Endpoints

Changes in self-reported weight, mediators of behavior change, and patient-reported psychosocial/quality of life outcomes.

3.4 Study Approach

Behavioral Framework. Intervention educational and motivational content for the study will be based on Social Cognitive Theory (SCT) and Self Determination Theory (SDT), which targets specific behavioral constructs (i.e., knowledge, self-efficacy, barriers and motivators).[14] These behavioral theories provide a comprehensive framework to identify behavioral strategies to increase patients' intrinsic motivation, confidence in their abilities, and expectations about improvements in their health. [8-11] This combined framework can provide relevant targets to build supportive environments to foster motivation, confidence, and outcome expectations in nutrition and PA behavioral interventions for Latino adults.[10,11]

SCT explains confidence in one's capability to change a behavior (i.e., self-efficacy) and expectations around engaging in a behavior.[12] A limitation of using SCT alone is that it does not fully address two key constructs: intrinsic motivation and the environment, which are important for initiating and sustaining behaviors.[10,11] Self-Determination Theory (SDT) incorporates these two constructs into a broad motivational theory to explain why and how individuals behave.[10,11] Intrinsic motivation is a desire to engage in an activity to achieve an internal sense of reward, satisfaction, or enjoyment. Individuals feel intrinsically motivated by being able to engage in challenging, achievable activities (i.e., competence) and being able to make their own choices about their behaviors (i.e., autonomy). To achieve this internal sense of satisfaction, improve confidence and achieve expectations, an autonomy-supportive environment provided by educators or eHealth communication can help an individual make better dietary and PA choices to improve health and reach their goals.

Behavioral Targets. All participants will be advised on nutrition and PA goals: 1) progressively adhering to high-quality diets by increasing intakes of fruits, vegetables and whole grains; and decreasing intake of energy-dense, nutrient-poor foods (i.e., processed foods, refined grains and added sugars), and 2) progressively reaching an optimal target of ≥150 minutes per week of MVPA.

Setting. The study will take place in the Lower Valley of Washington State's Yakima County. Yakima is the second largest county in the state by size and largely agricultural.[13] The Lower Valley region of the county includes the highest concentration of Latinos (69%) in Washington state, the majority of which are 1st and 2nd generation Mexican-Americans.[14] The region is characterized by high poverty levels, with 21% of the

population living below the poverty line, compared to 13% nationally.[15] The Community Need Index (CNI), which identifies the severity of health disparities for every U.S. zip code, ranks the LYV's zip codes from 4.2 to 5.0 where 5.0 is the highest level of severity of health disparities.[16] Our previous research shows up to 70% of adult Latinos in the Lower Valley have less than an 8th grade education.[17,18]

Community Health Educators (CHEs). Our CHEs (*promotores)* are male and female Latino bilingual and bi-cultural community members, trained to deliver health education, in qualitative and quantitative research methods, and have worked in the target community for 5-15 years.[19-22] For the purpose of this study, key functions of the CHEs include: participant recruitment, assisting during intervention activities, documenting implementation process, and/or coordinating and supporting data collection. As members of the community they serve, the CHEs are familiar and connected with their community thereby enhancing cultural competency of the research methods and the participants' level of comfort and trust with intervention delivery. They also serve as community stakeholders empowered to advocate for community health interests. All CHEs are required to complete and maintain human subjects, information privacy, and confidentiality certification.

Consultant. One community collaborator (trained local Chef) will participate in the delivery of the intervention. The collaborator has undergone 16 hours of training to ensure accurate delivery of the intervention content in the given timeframe. The training included human subjects' certification, orientation to the intervention content, and mock intervention delivery session prior to actual intervention delivery. He is known in the community through the creation of online recipe videos, and has the equipment and expertise needed to deliver nutrition content remotely.

3.5 Estimated Accrual

Based on previous studies with Latino cancer survivors in Yakima Valley, we expect target enrollment of up to 25 participants. The 25 participants will be recruited using methods successfully utilized by Dr. Ceballos to recruit Latino adults who meet the study eligibility criteria in the Lower Yakima Valley: 1) print and radio advertisements by bilingual/bicultural research staff at local retailers, community events, churches, and medical facilities, 2) through social media, and 3) mailing flyers to participants of previous studies that provided prior consent to contact.[10] For individuals who provided prior consent to contact, if there is no response from the potential participant within 1-week of mailing, the CHE will follow-up with 1 phone call to determine interest. CHEs will screen all interested participants via telephone. The eligibility screener is provided in **Appendix A**.

3.6 Name of Sponsor/Funding Source: CCSG Pilot Funds

4.0 SUBJECT ELIGIBLITY

4.1 Inclusion Criteria

4.1.1 Demographic Data

- Participants must self-identify as being at least 18 years of age or older.
- Participants must self-identify as Latino.
- Participants must be a resident of the Lower Yakima Valley (LYV) and anticipate remaining in the LYV for at least 1 year.
- Participants must speak Spanish or English and fully understand Spanish for online group sessions.

4.1.2 Disease Related Criteria

Participants must meet one of the following disease-related criteria:

Hypertension

- Participants must self-identify as having a medical history of hypertension

Diabetes

- Participants must self-identify as having a medical history of diabetes

Cardiovascular Disease

- Participants must self-identify as having a medical history of cardiovascular disease

Obesity

- Participants must self-identify as having a medical history of obesity, as defined by a BMI of >30 kg/m^2

Cancer

- Participants must self-identify as having a medical history of cancer (excluding non-melanoma skin cancer). All other cancer types will be included provided;
- there is no evidence of recurrent or metastatic disease; and
- the patient has not received a bone marrow, stem cell, or cord blood transplant

4.1.3 Prior/Current Therapy Criteria

- For cancer survivors, participants must self-identify as being at least 60 days post final chemotherapy, biologic therapy, or radiation therapy treatment and/or surgery. Current use of hormonal therapy is permitted (e.g., tamoxifen and aromatase inhibitors).

4.1.4 Accessibility Criteria

- Participants must be willing and able to receive text messages via cellphone for 3-6 months.
- Participants must be willing and able to attend six 120-minute online group sessions.
- Participants must be willing to complete the surveys, and diet/PA assessments.

4.1.5 Clinical/Laboratory Criteria

- Participants must not be active smokers within the past 30 days. Active smoking is defined as any smoking, even a puff. Participants who smoke are much less likely to engage in healthy lifestyle behaviors, and it is probably more important for participants to stop smoking than it is to change their dietary patterns. If identified as a smoker, the individual will be referred the CDC "Quit Now" phone line which supports smoking cessation, or the NIH quite support website "SmokeFree.gov which are both available in English and Spanish.
- Participants who report having been told by a health professional they have diabetes or cardiovascular disease must provide a clearance from their physician for participation **(See Appendix B for Medical Release Form).**
- Participants must consume <5 servings of fruits and vegetables per day and/or engage in <150 minutes per week of moderate to vigorous physical activity, as assessed by brief questionnaires.[23,24]
- Participants must have an ECOG Scale of Performance Status Score of 0 or 1 for performance status **(Appendix C).** These scales and criteria are commonly used by doctors and trained research staff to assess a person's daily living abilities. Scores of 0 and 1 corresponds to being fully active, able to carry on all pre-

disease performance without restriction; and restricted in physically strenuous activity but ambulatory and able to carry our work of a light or sedentary nature, respectively.

- Women must not be pregnant at time of enrollment.

4.1.6 Ability to understand and the willingness to sign an online informed consent document

- Depending on preference, the consent will be provided in English or Spanish.

5.0 SUBJECT REGISTRATION

Eligible participants will be identified by the Center for Community Health Promotion Study Staff who will register the patient by contacting the Fred Hutch Study Coordinator who will enter their information into the secure REDCap database. A complete, electronically signed, study consent and HIPAA consent are required for registration.

6.0 STUDY PROCEDURES AND INTERVENTION

Figure 1. Study Flow Chart

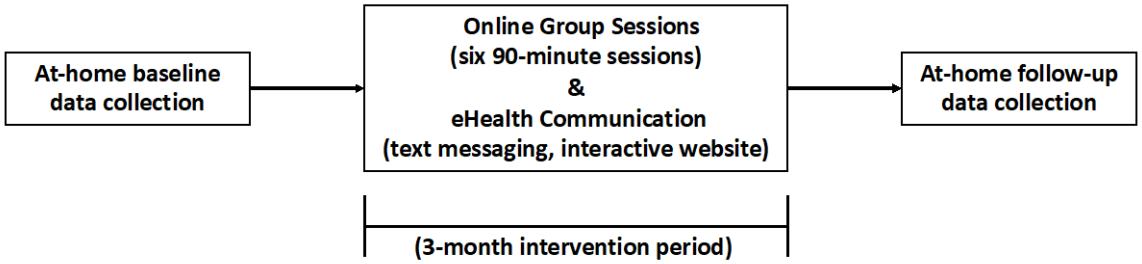

Table 1. Data Collection Overview

MEASURE	Screening	Baseline	Follow-up
		T1	T2
Eligibility criteria	X		
At-home assessments:			
Demographic and clinical characteristics		X	
Self-reported weight		X	X
Dietary Intake and PA measures:			
Social and Behavioral measures:			

Physical Activity Questionnaire		X	X
Psychosocial/Quality of Life Outcomes		X	X
Nutrition and physical activity knowledge and preferences		X	X
Exit Interviews on intervention acceptability			X

6.1 Informed Consent and Baseline Data Collection

Informed Consent. Prior to any baseline data collection, CHEs will orient participants to the study activities, rights and responsibilities and will provide electronic informed consent via a HIPPA-complaint and secured REDCap electronic form (eConsenting) for participation in the intervention program and data collection procedures, including the release of medical records regarding diagnosis and treatment for condition identified for study eligibility. Research staff will review the study in detail and outline participant involvement during the screening process over the phone. Research staff will discuss the consent process with the potential participant prior to providing consent online. All items in the informed consent will be discussed, including why the study is being conducted, the number of people participating, what is involved in the study, how long the participant will be in the study, the risks and benefits of the study, alternatives to participation, confidentiality, rights as a participant, and who to call with questions or concerns. Participants will be encouraged to contact research staff any time they have concerns or questions about the study. Each consent is implemented in REDCap using the survey functionality. The survey functionality presents the pages of the traditional paper consent, including the IRB stamp, to a potential research subject, then uses REDCap to present the questions and signature fields that appear on the paper consent. Once an individual agrees to participate, electronically signs the informed consent, then hits submit, a PDF of the completed consent can be automatically generated and saved to a REDCap form to preserve the exact consent text along with the research subject's responses. Informed consents will be provided in Spanish and English, depending on participant's preference. To make this less burdensome, we will collect their doctor/medical institution information as part of the medical release form and our staff can directly contact their doctors to acquire their clearance, when needed. See Appendix B for the consent and medical release form in English—provided in English for initial IRB approval and will be subsequently translated in Spanish.

Baseline Data Collection. Eligible participants will undergo remote baseline assessments that will include at-home, over the phone and web-based data collection and a "run-in" within an 8-week period prior to the start of the intervention (see Figure 1). Reasons for the run-in period include opportunities to: 1) assess participant's ability to complete trial assessments, 2) facilitate building of a rapport between the CHE and participant, and 3) ensure CHEs have the time needed to provide participants with proper orientation to the project and assistance completing surveys and study assessments. Because this pilot project will assess feasibility, this information is essential to determine acceptability of the project protocol.

All data collection materials will be provided to participants in Spanish or English based on the participants preferred language. For participants with low literacy, the CHEs are trained to assist in completing surveys without leading responses. Demographic, clinical characteristics, mediators of behavior change within domains framed within SCT and SDT, psychosocial and quality of life outcomes, stress, and acculturation will be assessed at T1. Details regarding data collection methods for these outcomes can be found in Table 4. Measurement Tools, Data Collection Timing, and Timing of Intervention Activities **(Appendix D).** Baseline survey materials are found in **Appendix E.**

The baseline data collection will include completion of an electronic (e) eConsent form via a secure HIPPA-complaint REDCap interphase and the following assessments: 1) online self-administered questionnaires

assessing demographics, medical history, clinical characteristics and self-reported height and weight; mediators of behavior change; and patient-reported psychosocial and quality of life (QOL) outcomes.

Intervention. The intervention includes six 120-minute online sessions. The participants will have access to text messages, electronic newsletters and access to interactive nutrition website. Participants will be notified of intervention start date via a phone call from the project coordinator. This will be followed by a mailed start-up study package that will include: 1) Fitbit device with detailed instructions on how to pair smartphone and sync data, 2) study activities schedule, 3) detailed instruction on how to set-up Zoom in their computers and access online sessions, and 4) study binder with written materials to be used during the online sessions. Study staff will call participants one week after receiving the start-up study package to review the materials together and answer any questions.

6.2 Intervention Overview

All participants will be assigned the goal of improving diet quality and engaging in ≥150 minutes per week of moderate-to-vigorous physical activity. The intervention will be based on an integrated social cognitive theory (SCT) and self-determination theory (SDT) theoretical framework to promote uptake of recommendations and target specific behavioral constructs (i.e., awareness, knowledge, self-efficacy, motivation, taste preferences, goal action planning, outcome expectations, autonomy-supportive environments).[25-27]

Remotely delivered online group sessions via Zoom video calls (Intervention Group). All online sessions will be held in Spanish. Resource materials and survey data will be available in both English and Spanish. The intervention will be delivered according to an intervention-specific curriculum that have been adapted to be delivered online[28], as we have done previously.

At least two days prior to each session CHEs will make reminder calls and send email or text messages to each study participant, depending on their preference, in order to keep attendance at sessions high and attrition low. Participants will also have the ability to contact the study coordinator via text, cell phone, office phone or email, whichever participants prefer, for any issues related to the study.

Class content: Each 120-minute session will include the following components: 1) classroom education on nutrition and PA, 2) exercise training/PA classes; 3) hands-on skills-building cooking; and 4) sharing a meal prepared by the group. *Behavioral framework*: Each activity will target specific behavioral constructs based on SCT and SDT theoretical framework: 1) classroom education (awareness, knowledge, autonomy-supportive environment); and 2) hands-on skills-building cooking and PA classes (self-efficacy, motivation, autonomy supportive environment); and 3) sharing a meal (taste preferences, goal action planning, and outcome expectations).

Timing and location: Classes will be held every other week via Zoom video calls. Participants will be provided with instructions on how to install Zoom and join Zoom video calls. Zoom video links will be sent to participants at least 24 hours prior each class via email or text, depending on participants preference. Zoom video calls will be recorded. Participants will receive a link to the recorded sessions. This will allow participants to watch it the session at a later and more convenient time.

Resources for cooking component of online sessions: All participants (n=25) will be provided with a grocery bag with the ingredients needed to participate in the hands-on cooking portion of the online sessions. Study staff will arrange the purchasing of the ingredients and will offer participants with the option to pick up the grocery bag at a convenient local grocery store or to have it delivery to participants homes either via Instacart or similar delivery service and/or by study staff, if needed. The total cost of each grocery bag is estimated at $25 or less per session for a recipe to serve 4 or more. The ingredients provided will be based on each menu to be demonstrated by the trained Chef so participants can prepare the meals themselves at home. Once the grocery

bags are ready for pick-up or delivery, depending on participants preference, study staff will send a friendly reminder to participants and will help coordinate as needed.

Fidelity of the online group-based intervention will be assessed by an objective process evaluator, who will attend all sessions and observe and take detailed notes on the timing of the activities and delivery according to protocol. This person will not have any interaction with study participants and will not participate in data collection or study activities implementation.

6.3 Intervention Details

- **Arm A (High Dose): Online Sessions 1 to 6**: The nutrition and physical activity educator leads the classroom education part of the session (refer to table 2 for detail on topics). Participants first receive nutrition education related to increasing intakes of fruits, vegetables and whole grains; and decreasing intake of energy-dense, nutrient-poor foods (i.e., processed foods, refined grains and added sugars) via PowerPoint slides. Physical Activity. Participants then discuss being physically active in the home, review the importance of using their Fitbit device as a self-monitoring tool (technical Fitbit issues are directed to study staff after class time), and are encouraged to engage in the exercises (stretching, Zumba dance class, aerobic exercises) during the presentation tracking steps. Cooking. Participants then receive hands-on cooking classes led by the Chef and get to participate in the preparation of a meal. Finally, all participants virtually share the meal they themselves prepared at their homes with the nutrition educator and other study participants while discussing lessons learned and setting goals for the next week as prompted by the nutrition and physical activity educator.

Table 2: Online group intervention schedule and topics for high dose

Class	Classroom Education Topic	Hands-on Skills-building Cooking and Physical Activity Classes & related activities	Sharing a Meal
1	Nutrition and Activity Guidelines, Increasing Fruits and Vegetables; Introduction to aerobic exercise, using the Fitbit	Cooking: Intro to a Healthy Kitchen Physical Activity: Intro to Aerobic Exercise + Using the Fitbit to Track Exercise	Share meal, discuss barriers and facilitators, goal setting activity
2	Reading Labels, Reducing Sugar and Finding Hidden Sugar; How to plan for Success	Cooking: Using Whole Ingredients and No Added Sugars Physical Activity: Planning exercise	
3	Healthy Fats & Proteins; Using the environment as your gym	Cooking: Cooking with Healthy Fats, Plant and Animal Protein Physical Activity: Outdoor physical activity	
4	Grocery Shopping; Learning When and How to Properly Stretch with Stretching Activity at End of Session	Cooking: Adapting Flavor to Preference Physical Activity: Optimal Stretching	
5	Carbohydrates, serving sizes, meal preparation and planning; ASCM New Guidelines, Tips and Tricks for exercising at home, injury prevention	Cooking: Healthy Carbohydrates Choices Physical Activity: Exercise for Injury Prevention	
6	Eating, Moving and Cooking for a Healthy Future; How to maintain physical activity as a lifestyle and community and online resources.	Cooking: Physical Activity: Community and Online Resources	

6.4 eHealth Communication

Electronic (e) Health (eHealth) communication materials are found in **Appendix G**, including sample text messages and sample newsletters content. Seattle-based study staff oversee the eHealth component. Participants in both arms will receive 12 weeks of motivational text messages 2-3 times per week and link to access the nutrition cookforyourlife.org website. eHealth communication messaging will focus on increasing fruits/vegetables intake and reducing intakes of energy dense and processed foods and increasing PA using constructs of the SCT and SDT. Participants will be prompted to respond on average to one of the weekly text messages (i.e., Think about yesterday. Did you eat 5 or more servings of fruits and vegetables?) Study staff will respond to participants as needed if any specific questions arise. The eHealth text topics and schedule are presented in Table 3.

Table 3: eHealth text topics and schedule (16 texts per month)

Target behavioral construct	Nutrition texts (50%)	Physical activity texts (50%)
Skill-building	2/month	2/month
Goal-setting	2/month	2/month
Motivation	1/month	1/month
Knowledge	1/month	1/month

6.5 Activity Monitoring

All participants will use both devices: participants will wear Fitbit Inspire on the wrist. Participants do not have to wear Fitbit during sleep. The wearing time of each device is outlined below.

Device	Duration
Fitbit Inspire	Baseline to 3 months follow-up data collection, on wrist

Participants will be trained to monitor their step count on smartphone and Fitbit. Participants should perform activity monitoring by checking the step counts by looking at the screen of their Fitbit Inspire and the Apple Health/Google Fit app. The purpose is to make participants aware of their activity level throughout the day. Participants are not required to change their usual activities according to the step count but are encouraged to progressively achieve ≥150 minutes per week of MVPA as displayed by the Fitbit physical activity tracker. Participants will receive monthly check-in calls, texts and/or emails to inquire about device usage and troubleshooting.

6.6 Retention

To improve retention CHEs will conduct a brief monthly follow-up telephone calls during month 2 of the 3 months intervention to all study participants. Staff will thank participants for their continued participation in the study, and will ask questions about (1) COVID-19 incidence, exposure, testing, related-symptoms and whether they have felt isolated during the pandemic, (2) Fitbit use, and (3) will help troubleshoot any issues associated with Fitbit devices. In month 3, participants will be encouraged to complete data assessments, as needed and even if participants do not completely adhere to the intervention.

In the event that a study participant's phone is disconnected, or if a participant stops responding to our calls or text messages after 4-6 attempts, study staff will mail a letter to study participants' home address and will send an email message indicating that we have had trouble reaching them. We will encourage study participants to get in touch with us and to provide us with a new phone number so that they can be contacted to answer study questions by phone, and if able, complete the in-person clinic visits.

6.7 Follow-up 3 Months Data Collection.
At 3 months, participants will repeat baseline measures (see Table 1) and complete a short exit interview to assess intervention acceptability.

7.0 SUBJECT EVALUATION

7.1 Evaluations

7.1.1 **Home-based Data Collection**

1) **Anthropometrics** will include self-reported height and weight.
2) **Nutrition and physical activity knowledge and preferences** will be measured using questions adapted from a battery of questions developed and validated by our team (The Preferences and Self-Efficay of Diet and Physical Activity Behaviors Questionnaires for Latinas) (preparing manuscript for submission).
3) **Patient-reported psychosocial/Quality of Life outcomes** will be measured via questionnaires assessing self- efficacy and motivation to make dietary and physical activity changes [16-19], stress (Hispanic Stress Inventory)[20], and quality of life (PROMIS 10).[21]

7.1.2 Retention calls and data collection

1) During monthly retention call participants will be asked about use of and technical issues with their study Fitbits. These data will be recorded to understand Fitbit usage patterns.
2) During monthly retention call, participants will be asked about COVID-19 symptoms, testing and isolation. These data will be used to examine the effects of the COVID-19 pandemic on intervention adherence patterns.

8.0 SUBJECT DISCONTINUATION OF ACTIVE TREATMENT- WITHDRAWL

Participants can discontinue participating at any time and for any reason.

9.0 CONCOMITANT MEDICATIONS

Participants will be asked during the Baseline 1 questionnaire about comorbidities and medication use.

10.0 ADVERSE EVENTS

10.1 Adverse Event
This is a low risk study with no intervention agent. We do encourage participants to be physically active to be able to capture, and compare, physical activity levels across devices. Any adverse events will be recorded in the Adverse Event Summary From **(Appendix I)** and reported as follows.

10.2 Serious Adverse Event

Adverse event grading scale:

0= No Adverse Event or within normal limits

1= Mild Severity: Transient laboratory test alterations; discomforts noted but no disruption of daily activities; no therapy, or only symptomatic therapy required

2= Moderate Severity: Laboratory test alterations indicating injury without long-term risk; discomfort sufficient to modify normal daily activity; specific therapy required (i.e., more than symptomatic)

3= Serious Severity: Laboratory test indicating a serious health threat or permanent injury; incapacity, inability to work, inability to perform normal daily activity; hospitalization required or prolonged; emergency treatment required; life-threatening events; death.

Plan for unanticipated AE reporting: All unanticipated AEs related to the study procedures that are severe or serious will be reported by Dr. Rachel Ceballos to the IRB within 7 days of notification of the investigator.

Plan for anticipated AE reporting: All serious anticipated AEs related to the study procedures will be reported by Dr. Rachel Ceballos to the IRB within 7 days of notification of the investigator.

Plan for ongoing review of results: The PIs will be notified within 24 hours by the research manager of any early terminations due to an adverse event.

Plan for safety review: The PI will perform a cumulative review of all adverse events and premature terminations review every 6 months after study initiation or after completion of 50% of participant visits, whichever occurs first.

Plan for annual reporting: A summary of the investigation including all adverse events and how they were handled, enrollment, drop-outs and reason for discontinuation and any protocol modifications will be provided to the IRB on an annual basis.

Annual Reports will contain:

a. The number of adverse events and an explanation of how each event was handled
b. The number of complaints and how each complaint was handled
c. The number of subject withdrawals and an explanation of why the subject withdrew or was withdrawn
d. The number of protocol deviations and how each was handled

The occurrence of any serious and unexpected event may prompt changes in study protocol. Any such change will be approved by the IRB before implementation.

11.0 DATA AND SAFETY MONITORING PLAN

A data safety and monitoring committee is not needed as this is not a Phase 3 clinical trial. Drs. Greenlee and Ceballos will oversee the data safety and monitoring for this project. They will meet with the study staff to discuss protocols and procedures to ensure participant safety and the validity and integrity of the study data. All staff members will attend trainings on these procedures and will be given information on the importance of reporting any adverse event immediately. Drs. Greenlee, Ceballos and the Institutional Review Office (IRO) will be alerted about any adverse events immediately. Drs. Greenlee and Ceballos will discuss any adverse effects and examine available data to assess whether safety is compromised. Action to resolve the adverse event will be discussed with IRO prior to implementation. The team will enact any actions recommended by the IRO.

12.0 DATA ENTRY AND MANAGEMENT/CONFIDENTIALITY

Collaborative Data Services (CDS) Shared Resource. CDS will use REDCap (Research Electronic Data Capture) to track, collect and maintain study data. REDCap is a web-based research-centric electronic data capture system supported through a federally-funded consortium led by Vanderbilt University. The system is fully supported by CDS, which maintains the REDCap installation and provides a secure system with high reliability and availability. CDS will design, build, and maintain the REDCap data forms that will be used for data capture, including

screening, participant questionnaires, and staff forms for participant tracking. CDS will provide programming extensions to REDCap when necessary to improve efficiency.

Specific to this study, CDS will build an automated bi-directional text message interface where participants will report their nutrition and physical activity goals and accomplishments, and the REDCap system will send automated motivational responses as provided by the study team. However, CDS will not monitor participant responses. All bidirectional communication with participants will take place with designated Spanish-speaking research staff only overseen by Dr. Greenlee. CDS will also build an integrated messaging system to send appointment reminders via email or text messaging (based on the participant's choice) that will be used to improve participant retention rates. CDS will also generate study tracking reports for staff to monitor day-to-day study activities. All staff have received Human Subject Research and HIPAA training. All data will be stored in a secure password protected computer folder, which only authorized research staff will have access to.

Fitbit Data

Fitbit PA data will be downloaded from Fitbit.com in weekly intervals up until their final follow-up visit. The data will reside on a server managed by the Fred Hutch IT group. Fred Hutch shared resource will develop a program to fetch and monitor PA data collected by Fitbit. Fitbit syncs user data through its smart phone application periodically and stores these data on their server. Fitbit Inc. offers an application-programming interface (API) for batch data access (https://dev.Fitbit .com/docs). The application is registered with Fitbit Inc., which grants a license to fetch data with the participants' consent. The program will collect the following data via the Fitbit API: steps, distance, calories and active times. The license allows the retrieval of both interday and intraday data (at one-minute level) on these activities. Participant data will be combined into a single data file for analyses. To monitor participant activity and Fitbit use, embedded within the program there are several visualizations of time-series activity history, and summary statistics for each participant. The program is written in R programming language and can run on a personal computer or a server. It is only on Fred Hutch's secure computing and networking environment where data collected by Fitbit, Inc. will be linked to the participants' questionnaire data responses. Neither questionnaire data will not be shared with Fitbit, Inc. nor will the link between the Fitbit.com username and subject name be shared anyone not authorized to work on this research study. Dr. Greenlee research team has successfully implemented this methodology in previous studies.

Text message management: The REDCap platform is a web-based software application that allows scientists to easily integrate and manage integration of SMS/text messaging into their research projects. Seattle-based study staff will manage and implement the REDCap platform. No personal health information will be transferred via the text-management system.

Participant ID's and personal telephone numbers are entered into a password protected web-based application (REDCap). REDCap requires strong passwords and will be accessed an encrypted (SSL) network connection only which is granted only to study personnel and software engineering staff that are trained in HIPAA compliance. Once participants are entered into the system, study personnel assign a start date and message suite to deliver to study participants. Participants then receive SMS messages according to the schedule defined for the message suite that they are assigned to (English or Spanish).

Participants can respond via SMS message to received messages. All SMS messages to participants will come from a single study phone number. This number is rented from Twilio, Inc. (see twilio.com). SMS messages originate from REDCap, which contacts Twilio's secure servers over an encrypted connection and then Twilio provides the gateway service to actually send the text messages. If participants reply to messages, they go to

Twilio and then Twilio's servers contact our servers to deliver the message back to our web application. Twilio does not store any of these text messages beyond the time it takes to pass them off to our web application. Twilio has access only to the phone number and the message.

REDCap includes functionality to notify study personnel of incoming SMS messages so that study personnel can then monitor and respond back to study participants via SMS message from within the web application. REDCap displays a conversation view of all messages per participant, both incoming and sent to the study team in a reverse time-based sorted order.

Using the Fitbit: The Fitbit device can be worn continuously for about 6 months before requiring a new battery. The Fitbit can be safely worn at all times, except when bathing or swimming. Participants will be required to sync data with the Fitbit web-based data repository at least once a week during the study period by simply opening the Fitbit app on their smartphone or signing onto their computer that has the program installed. Adherence to this requirement will be assessed each week by the study staff by logging into an online platform that tracks all Fitbit activity. The platform is described more thoroughly in the Data Management plan and Statistical Analysis.

Each participant will be assigned a de-identified anonymous user profile for Fitbit data collection. User profile emails will be an anonymous Gmail account that will be created for each participant by using the "+" tag in Gmail, in order to create multiple email accounts linked to one study account. User profile names will be participant's study IDs. *Note that the personal emails required for this study are only for emailing newsletters and not for the Fitbit user profiles*. The only personal information used to create the Fitbit accounts is a participant's height, weight, gender, and age. These data are essential in determining user-specific activity calculations, such as calories burned. Anyone who purchases the Fitbit for personal use, whether or not for research, would need to input this information to properly use the device.

During the course of the study participants will be instructed to wear the device while awake on their wrist and go about their normal daily routines and to remove when sleeping. Participants will be trained to sync their Fitbits using a computer or smartphone. The following types of data-points, in minute and per day units, will be collected daily and provided at the conclusion of the study by Fitbit:

- Number of steps walked
- Calories burned
- Distance walked
- Active minutes

Website: Text messages will direct study participants to the Spanish-language version of the Cook for Your Life website (www.cookforyourlife.org) (also available in English). Text messages will contain a unique de-identified URL tracking identifier and Google analytics will be used to track click through rates for each participant. The website will include study-specific web pages that participants will access via a unique login using their personal email address and a unique password. The study-specific web pages will include archived Zoom sessions, intervention materials, and community resources. These pages will be updated as the study progresses. Participants will have access to the study-specific web pages for 12 months following completion of the study. Participants randomized to the low dose study group will receive access to an archive of previously recorded sessions after completing 3-month follow-up.

In addition, Google analytics will be used to track overall usage of the website by study participants as a group by directing participants to enter the site with a private homepage that is available only to participants. Using

this method, it is not possible to track participants at an individual level, thus identifying information will not be collected, including IP addresses. The only extrapolation that can be made is whether or not a website user is a study participant based on their entry point to the site.

Google analytics provides the following information that can be used as measures of:

- Behavior (pages looked at, time on site, user pathways)
- Acquisition (where the audience is coming from social media, Google search, newsletters or otherwise)
- Conversions (goals to see if our users complete them, i.e., playing a video, downloading recipes or reading an article).
- Note: A HIPAA compliant server is not needed for the Cook for Your Life website because only participant IDs, and not PHI, will be used to track participants.

Post Intervention Data Collection. At 3 months, baseline data assessments will be repeated, including assessments at-home, web- and telephone-based. Participants Fitbit accounts will also be changed to participants own personal accounts and we will not maintain record of this account information and no longer have access to track Fitbit activity.

13.0 STATISTICAL CONSIDERATIONS

13.1 Study Design

This is a single-arm feasibility assessment.

13.2 Primary/Secondary Endpoints/Hypotheses and Analytical Methods

The endpoints for Aim 1, feasibility of intervention strategies, include accrual rate, adherence, retention, and acceptability (exit interview). Adherence will be measured by attendance to online sessions, text message responses, and use of the website. Retention will be measured by completion of all study assessments. Acceptability will be measured on a Likert scale in each of a series of questions regarding various aspects of the trial during the exit interview. All endpoints will be summarized using descriptive statistics. Statistical differences in retention rates for each study assessment between study arms will be assessed by Chi-square tests, and acceptability by t-test of median per-patient scores.

Exploratory endpoints include changes in anthropometrics, mediators of behavior change, and patient-reported psychosocial/quality of life outcomes. Descriptive analyses will be conducted to summarize exploratory outcomes.

13.3 Additional Outcome Measures and Statistical Methods

Demographic and clinical characteristics will be measured via an online questionnaire on demographics, comorbid conditions, medical history, and medication use (baseline only).

Intervention feasibility will be measured by accrual, adherence (attendance to online group sessions, response to text messages, and use of website), acceptability of the interventions (exit interview and motivation interviewing educator interaction, MIMSI), quantitative data collection processes (percent completed and duration of staff assistance to complete surveys), and qualitative (exit interviews) data, and retention at 3 months. MIMSI will be administered prior to the exit interview. Exit interviews will be conducted by *promotoras* and audio- recorded and later transcribed for analyses. Feasibility of intervention delivery for staff within in the

rural community context will also be assessed and necessary adaptations from the urban intervention delivery process will be documented.

13.4 Ethnic and Gender Distribution Chart

Projected Target Accrual
ETHNIC AND GENDER DISTRIBUTION CHART

TARGETED / PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex / Gender		
	Females	Males	Total
Hispanic or Latino	15	10	25
Not Hispanic or Latino	0	0	0
Ethnic Category Total of All Subjects*	15	10	25
Racial Categories			
American Indian / Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White	13	8	21
More Than One Race	2	2	4
Racial Categories: Total of All Subjects*	15	10	25

14.0 INVESTIGATOR OBLIGATIONS

The PI is responsible for the conduct of the clinical trial at the site and is responsible for personally overseeing the treatment of all study subjects. The PI must assure that all study site personnel, including sub-Investigators and other study staff members, adhere to the study protocol and to all applicable regulations and guidelines regarding clinical trials both during and after study completion.

All subjects are informed of the nature of the program, it's possible hazards, and their right to withdraw at any time, and each subject signs a form indicating their consent to participate prior to receiving any study-related procedures **(see Appendix B**).

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