RESEARCH PROTOCOL
¡Vivir Mi Vida! Pilot Study

IRB Project Title: *¡Vivir Mi Vida!*: A pilot study of a lifestyle intervention to optimize health outcomes in Latino patients

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I. Specific Aims

1. Through a mixed-methods process evaluation, assess the feasibility and acceptability of the *¡VMV!* intervention and associated study procedures, as administered in a community-based health service system.
2. Preliminarily examine the efficacy of the *¡VMV!* intervention to improve patient-relevant outcomes pertaining to diabetes and CVD risk and general health promotion.
3. Based on data collected from Aims 1 and 2, refine and optimize the lifestyle intervention to prepare for a large-scale RCT.

II. Methods

A. Study Design

In the proposed study, 40 Latino adults aged 50-65 years old will be included. All participants will receive the intervention. Throughout the course of their study involvement, participants will continue to receive usual care at their regular primary care facilities or community health clinics or from community-based programs in which they are enrolled.

An assessment battery, consisting of both questionnaire and clinical outcome measures, will be administered at baseline, a subsequent four-month post-testing session, and a 12-month follow-up testing session. Each assessment period will include an in-person assessment to obtain clinical values and responses to questionnaires. Each in-person assessment period is expected to last about 1.5 to 2 hours. In addition to study-generated measures, we will collect electronic data on medical service utilization and clinical assessments from our collaborating healthcare partners. Finally, at the conclusion of the intervention and post-testing, we will collect information about implementation issues, including reach, patient and staff satisfaction, identification of intervention facilitators and barriers, and program sustainability.

Total length of enrollment will include one day for initial testing, four months for the intervention, one day for follow-up testing post-intervention, one day if the person participates in a post-intervention focus group, and one day if the person participates in the 12-month follow-up testing session.

B. Participants, Recruitment, and Consent

A convenience sample of 40 late middle-aged (50-65 years old) Latino adults will be recruited from direct personal contacts at recruitment tables, provider referrals, and postings at the Antelope Valley Community Clinic and local community centers. If a potential participant responds to a flyer and calls a study team member, the screening form will be utilized to describe the study and ensure his/her eligibility. For those individuals who participated in the study as a supervisor, intervener, or tester, research staff will directly approach them to solicit participation in a follow-up interview.

Potential participants for the intervention and follow-up focus group will be included if they:

1. Are male or female adults aged at least 50 years at the outset of the four-month intervention and will be no older than 65 years upon completion of the intervention
   Justification: This age group is at high risk for developing disease in older age and likely amenable to an intervention that may help prevent or delay chronic disease in later life
2. Self-identify as Latino/Hispanic
   Justification: The intervention was culturally tailored to and designed for Latino adults. Latino adults are at high risk for certain chronic diseases which could potentially be prevented or delayed through lifestyle intervention
3. Are fluent in Spanish
   Justification: Group sessions will be held in Spanish. Individual sessions may take place in either English or Spanish, depending on the participant's preference
4. Live in Antelope Valley and do not plan on moving within six months from the beginning of the study
5. Are enrolled as a patient in the Antelope Valley Community Clinic
6. Have visited his/her primary care healthcare facility within the past year
   Justification: This criterion ensures that patients are "active" in the health care system
7. Will be available by telephone for the duration of the intervention
   Justification: A portion of the intervention is delivered via telephone
8. Are oriented to person, place, and time as tested by asking the person's name, date, age, and place of residence
9. Self-report their ability to participate for the duration of the intervention

Individuals who participated as supervisors, interveners, or testers will be included for a follow-up interview if they:

1. Held the role of supervising occupational therapist or *promotor*, intervening *promotor*, or tester during study implementation.

After screening, informed consent materials will be sent or handed to prospective participants for pre-review. Only key personnel who are HIPAA and CITI certified, trained in consenting procedures, and do not have a conflict of interest will conduct the consent process. The consenter will explain the study procedures and describe in detail what will be expected of participants. Participants will have ample time to ask questions about the study and their role in it. If the individual is interested in participating, s/he will sign the consent form. If participants are not comfortable with the study, they may choose not to participate.

For the 12-month follow-up testing session, the project manager will mail the Consent Addendum with a cover letter, which will (a) invite existing participants to participate in this additional assessment session; (b) encourage them to read the enclosed consent document; and (c) inform them that the assessor (who is HIPAA and CITI certified) will contact them soon to schedule a time to go over the informed consent, enroll them in the study if they are willing, and complete the assessments if they are willing. The assessor and primary Spanish study contact will call each of the existing participants to schedule a time to go over the informed consent, enroll them in the study if they agree to participate, and complete the assessment battery.

C. Assessment Procedures

Following the informed consent process, participants will complete a battery of self-report questionnaires and clinical tests. The following data, with the exception of fixed background variables, will be assessed during each measurement point (baseline, four months, and 12 months). Participants may undertake assessment in Spanish or English, as preferred.

—*Background*. Information regarding participants' background and demographics (e.g., sex, race, smoking status, insurance coverage) will be collected using a study-specific questionnaire. Additionally, ongoing health problems will be documented (i.e., a checklist will include selected health conditions such as cancer, heart attack, heart failure, hypertension, high cholesterol, arthritis, asthma, alcohol abuse, drug abuse, mental/psychiatric problem, other).

—*Measure Your Medical Outcome Profile 2* (MYMOP2). The MYMOP2 is a simple patient-centered questionnaire that asks the participant to identify one or two symptoms that are bothersome. Patients rate the severity of the symptoms as well as how much they interfere with their daily activities. Upon retest, participants are asked about the symptoms that were initially identified, but are not told what their initial ratings were. The questionnaire has been shown to be sensitive to change,[90-92] and has demonstrated construct [90,92] and criterion validity.[90] Most importantly, this short item questionnaire gets to the heart of what is important to the patient and measures the personally relevant effect of changes that have taken place over the measurement interval. Therefore, the mean degree of change across the set of self-reported symptoms on the MYMOP2 will be used as the study's secondary outcome.

—*Block 2005 Food Frequency Questionnaire Spanish Version* (Block FFQ). The Block FFQ was designed to estimate usual and customary intake of a wide array of nutrients and food groups. It takes 30-40 minutes to complete and is intended for either self- or interviewer-administration (we intend to use interviewer-administration). The bilingual format, with text in both Spanish and English will be used. This version of the FFQ has additional food items typical of diets among Hispanics. The food list for this questionnaire was developed from NHANES 1999-2002 dietary recall data;[121] the nutrient database was developed from the USDA Food and Nutrient Database for Dietary Studies (FNDDS), version 1.0.[122] A series of "adjustment" questions provide greater accuracy in assessing fat and carbohydrate intake. Individual portion size is asked for each food, and pictures are provided to enhance accuracy of quantification.

—*International Physical Activity Questionnaire* (IPAQ). Exercise will be measured using the long version of the IPAQ.[96] This assessment includes 12 to 27 items, depending on the number of non-applicable questions that the respondent is allowed to skip. The questionnaire contains job-, transportation-, household-, and recreational-related physical activity, and time spent sitting. This questionnaire has been used extensively in varying cultures and has been validated with accelerometer data.[97-99]

—*Satisfaction with Participation in Discretionary Social Activities* and *Satisfaction with Participation in Social Roles* short forms. These two scales, contained on the Patient Reported Outcomes Measurement Information System (PROMIS), will be used to measure satisfaction with participation. Each covers the past seven days and contains 7 questions answered on a 5-point scale. These short forms, as well as the full Satisfaction with Participation bank, have been extensively tested and validated.[100]

— *PROMIS: Emotional Distress – Depression - Short Form 8a*. This instrument uses 8 items to assess depression over the past seven days. These 8 items have been calibrated and validated in both English and Spanish using Item Response Theory.[100-102] The short form has the advantage of providing almost as much precision as the full item bank (r=.977),[103] while substantially reducing the testing burden on the participant.

—*Pittsburgh Sleep Quality Index* (PSQI). Sleep quality within a one-month period will be measured using the l9-item PSQI. This assessment produces a global sleep quality score and seven subscores: sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleeping medications, and daytime dysfunction. This measure has been validated in adult and older adult populations.[123, 126]

—*Clinical Measures*. Non-fasting blood samples will be drawn using finger pricks and the Afinion (HBA1C) and Cholestech (Lipid Test) meters will be used to assess HbAlc and lipid profiles (total, HDL, and LDL cholesterol, and triglycerides). We have chosen to not require participants to fast at the time of blood draw. This will increase patient participation and decrease patient inconvenience. Recent studies have shown minimal difference between fasting and non-fasting values for total, HDL, and LDL cholesterol.[111] Blood pressure will be measured using an average of two readings taken from a digital blood pressure monitor. BMI (weight in kilograms divided by height in meters squared) will be obtained using a standard weight scale and stadiometer. Waist circumference will be measured via tape at the midpoint between the iliac crest and the lower rib. Hip circumference will be measured

via tape at the level of the trochanter and used in the calculation of waist to hip ratio. Elo et al.'s Single Item Stress Index will be used to assess level of stress using a 5-point Likert scale that captures general level of stress "these days."[104] It correlates well (r=0.20-0.75) with other validated measures of mental well-being.[104] Self-reported healthcare utilization will be collected including ER visits, hospitalizations, and clinic visits.

—*Disease Risk Scores*. In response to strong interest in the study population for overall risk scores for CHD and diabetes, we will use the Framingham Risk Score LDL Points Total[115] to measure CHD risk and the EPIC Diabetes Risk Score[116] to measure diabetes risk. Both risk scores are modifiable by lifestyle behaviors and calculable from data that are already being collected during the background and clinical assessment, and thus will not add to the participants' testing burden.

—*Healthcare Service Utilization*. We will extract data from each participant's electronic medical record for routine and preventive healthcare utilization (e.g., number of clinic, lab, and other preventive, diagnostic, or screening visits) and non-routine healthcare utilization (e.g., number of emergency department visits and hospitalizations) during the six months prior to baseline and at the end of the intervention. This extraction process will be conducted by the assessors on the study team.

—*Patient Activation Measure (PAM) 13*. The PAM 13 is a 13-item short form tool that assesses a patient's knowledge of, skills in, and confidence in health self-management.[127] Following assessment, a patient is classified in one of four progressively higher activation categories. This 13-item short form has been validated as a measure of a patient's level of engagement in his/her own healthcare.[127]

—*Brief Pain Inventory (BPI; short form) subscales: Pain Severity and Pain Interference.* The BPI Severity subscale measures the amount of pain a person experiences at its "worst," "least," and "average" severity as well as the pain he/she is in "now." The BPI Interference subscale assesses how much a person's pain interferes with everyday life including general activity, walking, work, mood, life enjoyment, relationships, and sleep. The BPI short-form and its subscales are considered valid and reliable.[128-130] The Spanish-translated tool has been validated in a Spanish-speaking population.[129]

—*Dietary Habits Questionnaire.* The My Habits questionnaire measures participants' heart-healthy behaviors, consisting of 3 subscales: salt intake, cholesterol and fat consumption, and weight control behaviors. The questionnaire has been shown to be reliable[131-132] in previous studies with Hispanic adults.

D. Intervention Procedures

—*Background*. The intervention is informed by Lifestyle Redesign (LR), a health promotion program which has produced beneficial effects in underserved, ethnically diverse, older minority populations.[60,68] LR enables patients to design, practice, and ultimately enact a personalized, sustainable health-promoting daily routine that is tailored to address CD risk factors as well as promote health and well-being more generally. *Promotores* – health workers in the Latino community who have completed specialized training to provide basic health education programs – will serve as the front line *¡VMV!* interveners. Typically well-respected in their communities, they are perceived as sharing commonly held values and predisposed to deliver interventions in a culturally sensitive manner.[75]

The American Occupational Therapy Association published the original LR manual in 1999.[76] A second edition was released in April 2015.[124] An investigative team from the United Kingdom has been studying the effectiveness of a LR spinoff adapted to the needs of British elders when implemented in the UK National Health Service system.[77] *¡VMV!* is the first version of the LR program that has been tailored for late middle-aged Latinos with or at risk for CDs.

—*Structural Overview*. The *¡VMV!* intervention is divided into five units representing different content areas and follows the general activity-based, culturally sensitive treatment strategies of other LR interventions.[60,61,68] The treatment protocol includes eight 1-hour individual sessions, three 1-hour group sessions, and two 15-minute telephone calls— all delivered over four consecutive months in a tapered design, as outlined in Table 1. Individual sessions, which will occur in patients' homes or in a public location of the patient's choosing, will allow patients to pursue their self-identified goals and to receive personalized health information. Group sessions, which will take place at the Antelope Valley Community Clinic, will be devoted to synthesizing individual session instruction, sharing experiences related to embracing a healthy lifestyle, and problem-solving as a means

of fostering peer support and advisement from other patients. Phone calls will be utilized to maintain contact with patients and to monitor their experience with lifestyle change.

Table 1: Intervention sequence for one participant

	Month 1	Month 2	Month 3	Month 4	Total
# Individual (in-home) Sessions (1 hour)	3	3	2	0	8
# Group Sessions (1 hour)	1	1	0	1	3
# Telephone Sessions (15 minutes)	0	0	1	1	2
Total contacts	4	4	3	2	13

—*Content*. The five educational units contained in the *¡VMV!* manual will be used to organize the presentation of principles and strategies to achieve a healthy and active lifestyle. These units are summarized in Table 2 and include: Healthy Eating and Physical Activity; Healthcare Navigation; Chronic Disease Management; Mental Well-being; and Wrap-up. To promote patient-centeredness, flexibility, and customization, the treatment plan includes standard content for all patients and discretionary content which will be presented to a given patient only when relevant. For example, as a part of the Healthy Eating and Physical Activity unit, all patients will be taught how to incorporate a balance of protein, fruits, vegetables, grains, and oils into meals. However, this unit will also contain discretionary content that pertains to specific diseases (e.g., self-care for diabetes) which will only be presented if appropriate.

Table 2: Intervention units and associated sessions

Unit	Month	Week	Type	Title
	1 (3/1/0)*	1	I	Session 1: Introduction
Healthy Eating & Physical Activity		2	I	Session 2: Transform Your Eating Habits Today
		3	I	Session 3: Making Healthy Food Choices in Real-Life Situations (Outing)
		4	G	Session 4: Healthy Eating in Social Situations
	2 (3/1/0)	5	I	Session 5: Healthy Physical Activity and You
Healthcare Navigation		6	I	Session 6: Getting the Most out of Your Healthcare
Chronic Disease Mgmt.		7	I	Session 7: Disease Specific Health Management (Flexible)
		8	G	Session 8: Gratitude and a Positive Outlook
Mental Well-Being	3 (2/0/1)	9	I	Session 9: Mental Well-Being
		10	I	Session 10: Stressors (Flexible Sessions) • Session 10a: Finances and Your Health • Session 10b Sleep • Session 10c: Effective Communication • Session 10d: Coping with Loss • Session 10e: Safety
		11	T	Session 11: Follow-Up
Wrap-Up	4 (0/1/1)*	12	G	Session 12: Graduation
			T	Session 13: Follow-Up

Notes: I=Individual; G=Group; T=Telephone

Although at the outset of the intervention patients will be assigned to groups of ten, the first session will be individualized and, in most cases, home-based. In this session, led by both the *promotor* assigned to the patient's group and an occupational therapist who will be present via teleconference using HIPAA compliant VSee software, the patient will be able to review a personalized Health Status Report, which contains a summary of the most recent information extracted from his or her health records, including health markers such as weight and blood pressure levels. After discussing this report, the patient, occupational therapist, and *promotor* will develop a Health Action Plan (HAP). The HAP will include three health-related goals that the patient wishes to achieve through the intervention and a list of four to five strategies or activities that can be implemented to achieve these goals. Additionally, each participant will be given a wrist-worn activity monitor to keep permanently even after the intervention concludes. Participants will be instructed in the features of the monitor and guided in how they

could use it to help achieve the goals delineated in the HAP, as appropriate. Through ongoing individual and group supervisory meetings, the occupational therapist will use the information from the HAP to guide the *promotor* in tailoring the intervention to meet individual patient's needs.

During the course of individual, group, and phone sessions, the HAP will be updated with topic-specific unit content. At the beginning of month three, the *promotor* will take note of the progress that the patient has made toward his or her goals and reassess various health indicators such as weight or blood pressure. These results will be forwarded to the patient's physician. Concurrently, patients will be encouraged to review these results to self-monitor any change in their health status. By the conclusion of the intervention, each patient will be helped to adopt his or her HAP to maximize the likelihood of lifelong implementation of health-enhancing activity and habits.

E. Feasibility and Acceptability Data Collection Procedures

Feasibility and acceptability data will be collected throughout the study. We will track (a) rates of recruitment, protocol adherence and engagement, and retention; (b) adverse events; (c) participants', interventionists', and testers' perceptions of the intervention and/or study procedures (e.g., perceived benefits, burden, satisfaction); and (d) facilitators and barriers to successful completion of study procedures.

A number of methods will be employed to collect these data. Detailed records will be kept throughout the duration of the study. Planned documentation ranges from specifics of the screening and intake process to *promotor* notes summarizing each intervention session. We will hold fidelity checks periodically which will require the *promotor* audio/video record selected patient sessions with permission of the participant or for the supervisory OT or *promotor* to sit in on patient sessions. Additionally, a brief exit interview at the end of the four-month and 12-month assessment sessions will be administered to all participants. After the close of the four-month data collection, semi-structured focus groups and interviews will be held with participants and research staff, respectively. We will conduct two 1.5 to 2-hour participant focus groups (approximately eight people per group) that will be video recorded to allow for verbatim transcription and analysis. Participants who join a focus group will have completed the intervention, as well as all other study requirements, within the past month, and will be selected so as to achieve variation in sex, ethnicity, education level, and number of chronic diseases. Furthermore, one-hour exit interviews will be conducted with the treating *promotores*, supervising occupational therapist and *promotor*, and assessment battery deliverers. Interviews will be audio recorded to allow for verbatim transcription and analysis by one of our bilingual research team members authorized to interact with participants. Due to the semi-structured nature of the focus groups and interviews, the focus group facilitator or interviewer may depart from facilitation guides in order to probe for pertinent details and follow up on information disclosed by the participants.

F. Data Management and Storage and Communication

Data collection during assessment sessions will primarily occur within REDCap—a secure, web-based application designed to support data collection for research—using a study-specific laptop. In rare circumstances (e.g., upon loss of internet access, participant request), assessment data will be captured through use of hardcopy questionnaires. REDCap will also serve as a secure, password protected storage database for data collected during assessment sessions (not including interview/focus group data). Data that are captured in hard copy form, will be transferred to REDCap by authorized, trained study personnel. Any hard copies of study documents when not in use will be maintained and stored in locked files at the Antelope Valley study office during the recruitment and intervention implementation phases of the study. Documents containing participants' names (e.g., informed consent documents) will be stored and locked separately from documents with participant codes. All hardcopy files will be permanently transferred to the USC study office (CHP-101) upon completion of the post-intervention assessments and focus groups. Data that are neither captured within REDCap nor in hardcopy format (i.e., audio/video recordings), will be stored on a secure, password protected data server of USC.

Research investigators and staff located at USC and Antelope Valley will remain in regular communication throughout the study. At the outset of the study and at subsequent one-month intervals, a project staff meeting will be held. We will discuss items such as the safety and proper treatment of the research participants. These meetings will be mandatory for all project personnel who have contact with participants or with data that result from the study. Additionally, an internal committee comprised of the principal investigator, Antelope Valley collaborator Ms. Michelle Kiefer, the co-investigator responsible for training and supervising the occupational therapist, and the project coordinator will meet monthly to assess participant recruitment; accrual and retention; data quality and timeliness; participant risk versus benefit; and the development of external conditions that could potentially affect

the study. Additionally, the primary investigator and collaborator Ms. Kiefer will remain in regular weekly contact via telephone or email to discuss any study-related issues that arise.

III. Statistical Considerations

A. Sample Size

We will enroll 40 participants in this pilot study. With this sample size we will have 80% power to detect a statistically significant change score effect size of 0.454 in any of our continuous outcome variables (two-sided alpha=0.05, paired sample t-test). This is considered a medium effect size. In the Well Elderly 2 study, effect sizes were generally small. Therefore, we expect this pilot study to have minimal statistical power. Nevertheless, this sample size is adequate for assessing the feasibility and acceptability of this intervention and to identify any obstacles that need to be addressed before a large-scale version of this study can be undertaken.

B. Data Analysis

Specific Aim 1: *Through a mixed-methods process evaluation, assess the feasibility and acceptability of the ¡VMV! intervention and associated study procedures, as administered in a community-based health service system.*

Feasibility and acceptability will be determined by (a) analyzing rates of recruitment, protocol adherence and engagement, and retention; (b) monitoring adverse events; (c) examining participants' and interventionists' perceptions of the intervention and study procedures (e.g., perceived benefits, burden, satisfaction) as collected during focus groups and interviews; and (d) identifying facilitators and barriers to successful completion of study procedures. Focus group and interview transcripts will be analyzed using a qualitative descriptive approach.[125] Two researchers will independently code translated transcripts. During this data analysis phase, they will meet bi-weekly for three months to review codes and discuss emerging themes. Each researcher will highlight significant transcript passages and their codes at analytic meetings, during which codes will be refined and preliminary themes identified. The review of relevant interview passages and thematic organization of findings will be an iterative process that will continue until consensus is achieved among the research team. Once the team agrees upon the primary themes expressed during the interviews and focus groups, one researcher will extract excerpts that support each theme. Data from the focus groups and interviews will be compared and contrasted to other data tracked throughout the study by the research team and interveners (e.g., adherence, participant engagement).

Specific Aim 2: *Preliminarily examine the efficacy of the ¡VMV! intervention to improve patient-relevant outcomes pertaining to diabetes and CVD risk and general health promotion.*

Efficacy of the intervention will be preliminarily evaluated based on comparison of baseline and post-intervention data collected on the following outcomes: perceived clinical outcomes related to symptoms, activity, and well-being (MYMOP2), pain (BPI Pain Severity and Pain Interference subscales), dietary intake (Block Food Frequency Questionnaire), dietary habits (My Habits Scale), self-reported exercise (IPAQ), sleep quality (PSQI), satisfaction with participation (PROMIS Satisfaction with Participation in Discretionary Social Activities and Satisfaction with Participation in Social Roles short forms), depression (PROMIS Emotional Distress - Depression – Short Form 8a), stress (Elo et al.'s Single Item Stress Index), patient activation (PAM-13), clinical outcomes (HbAlc, lipid profiles, waist and hip circumference, waist to hip ratio), CHD risk (Framingham Risk Score LDL Points Total), diabetes risk (EPIC Diabetes Risk Score), and healthcare service utilization.

Data will be directly entered into the Research Electronic Data Capture (REDCap) system. Data will be checked for completeness and reasonableness. Descriptive statistics will be presented and analyses will inform the appropriateness of our intended statistical plan. Changes in outcome variables will be assessed using paired-sample t-tests. Baseline covariates (e.g., age, gender), will be assessed for effect modification. Results will be stratified by any effect modifiers, and repeated measures ANOVA will be used to adjust for confounders. These preliminary estimations will inform refinement of the outcomes assessment battery and sample size calculations for a subsequent large-scale trial.

Specific Aim 3: *Based on data collected from Aims 1 and 2, refine and optimize the lifestyle intervention to prepare for a large-scale randomized controlled trial.*

Our multidisciplinary team will use the triangulated quantitative and qualitative data resultant from specific aims 1 and 2 to make important refinements necessary to improve the overall feasibility, acceptability, and efficacy of the intervention. We will fine tune data collection procedures as needed to ensure that participants can complete the assessment battery thoroughly and comfortably. Questions with excessive missing data will be re-evaluated. Questionnaires will be checked for internal consistency and ceiling and floor effects and will be revised accordingly. Aim 3 will be complete when: (a) there are no remaining questions/concerns from the investigative team about the *¡VMV!* intervention or study procedures; (b) modifications to the intervention and study procedures deemed necessary have been successfully integrated; and (c) a finalized research protocol has been produced.

IV. References

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