Title: The HOMBRE Trial: Comparing Two Innovative Approaches to Reduce Chronic Disease Risk Among Latino Men

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1. Introduction

Obesity is a major contributor to the leading causes of death among all men in the United States (US) (e.g., type 2 diabetes, cardiovascular disease),[1-3] while rates are the highest among Latino men (39%).[4] Consequently, Latino men bear a disproportionate disease burden attributable to excess weight, namely higher incidence of type 2 diabetes and prevalence of major cardiovascular risk factors (e.g., metabolic syndrome, pre-diabetes) compared to non-Hispanic white men.[3,5-8] Latino men are part of the largest minority group in the US with Latinos representing 18% US population. Therefore, identifying effective and scalable interventions for prevention of obesity-related chronic disease is a critical public health priority.

Previous studies have proven behavioral lifestyle interventions are effective for promoting modest, yet clinically significant weight loss and can delay or prevent the onset of diabetes among high-risk adults in community and primary care settings.[9-12] For example, the Diabetes Prevention Program (DPP) trial demonstrated that an intensive lifestyle intervention targeting modest weight loss (7%) and increased moderate-intensity physical activity (150 minutes per week) lowered type 2 diabetes incidence by 58% among high-risk adults, including Latinos.[13] A critical gap in current evidence limiting widespread implementation and dissemination is that the majority of research has focused on non-Hispanic white women.[14] According to a 2012 systematic review, men represented only 22% of participants--and racial/ethnic minority men only 2%--in behavioral weight loss intervention trials in the US.[14] There have been no studies to date focused on how best to translate evidence-based DPP interventions among Latino men.[11,12,15-20] Pragmatic research on population-specific approaches is urgently needed to ensure that Latino men have equitable access to opportunities that enable them to manage obesity and prevent costly chronic diseases.

Compared to women, men experience less societal pressure for weight loss and are less likely to attempt weight loss.[21,22] Thus, while both men and women indicate a desire for flexible and individualized interventions,[23-26] this may be particularly important for men.[27-31] One strategy for individualizing evidence-based interventions is to offer participants choices for *how* to engage in the intervention. While we and others have tested the effectiveness of various delivery options for behavioral weight loss interventions including videos,[32-34] online,[33,35,36] and in-person group sessions,[32-34] few randomized controlled trials (RCTs) have tested an intervention that offers a package of delivery options from which participants can choose. Additionally, men's primary motivation for weight loss appears to be reducing chronic disease risk factors and avoiding adverse health outcomes.[14,21,37-39] Because their motivations for losing weight are related to health, the primary care setting may appeal to men.

This paper describes a new RCT comparing the effectiveness and potential for future implementation and dissemination of the HOMBRE (Hombres con Opciones para Mejorar su Bienestar y Reducir Enfermedades Crónicas; English translation: Men with options to improve well being and reduce chronic disease) intervention that offers a suite of delivery options and minimal intensity intervention. Findings from the trial will advance the understanding of weight management and diabetes prevention among Latino men, the largest racial/ethnic group in the US.

2. Methods

2.1 Study Design

In this comparative effectiveness trial (11/2016-10/2019), at-risk Latino adult men will be randomized to one of two arms: (1) HOMBRE, a behavioral lifestyle intervention tailored for Latino men, or (2) a minimal intensity intervention. The study utilizes the RE-AIM (Reach,

Effectiveness, Adoption, Implementation, and Maintenance) framework[40] to systematically assess the potential for implementation and dissemination over time. The specific aims are:

Aim 1: Compare the effectiveness of HOMBRE with a minimal intensity intervention for sustaining clinically significant weight loss among overweight and obese Latino men at 18 months.

Hypothesis: A significantly higher percentage of overweight and obese Latino men randomized to the HOMBRE intervention will maintain clinically significant weight loss (≥5% of baseline weight) compared with those randomized to the minimal intensity intervention. Research staff will objectively measure participant weights at baseline and 18 months.

Exploratory Aim 1: Compare weight trajectories of Latino men randomized to HOMBRE and the minimal intensity intervention over 18 months and 24 months. Although participants will be followed until 18 months in the study, longitudinal weight data from the electronic health record (EHR) will be abstracted through 24 months post randomization.

Aim 2: Compare the effectiveness of HOMBRE with a minimal intensity intervention for improving cardiometabolic risk factors, health behaviors, and psychosocial well-being among overweight and obese Latino men at 18 months.

Hypothesis: Compared with Latino men randomized to the minimal intensity intervention, HOMBRE participants will demonstrate statistically significant greater improvements in cardiometabolic indicators (blood pressure, waist circumference), health behaviors (diet, physical activity, sedentary behavior), and psychosocial well-being (quality of life and depressive symptoms) at 18 months.

Exploratory Aim 2: Examine potential moderators assessed at baseline (e.g., marital status, acculturation, health literacy) and theoretically-based mediators assessed at 6 and 12 months (e.g., self-efficacy, social support) of the effectiveness of HOMBRE compared to the minimal intensity intervention.

Aim 3: Examine the other attributes of RE-AIM (reach, adoption, implementation, and maintenance) of the two interventions using mixed methods to inform rapid dissemination and long-term sustainability among overweight and obese Latino men.

Exploratory Aim 3: Among those randomized to HOMBRE, examine socio-demographic determinants of modality choice and compare intervention engagement and effectiveness according to modality to inform future dissemination.

2.2. Patient and Stakeholder Engagement

This study features a patient-engaged approach leveraging a Latino Patient Advisory Board and physician advisors. The Latino Patient Advisory Board is a group of Latino patients that originally formed to help culturally adapt the DPP-Group Lifestyle Balance intervention that forms the basis of the HOMBRE approach. The Advisory Board met weekly for 12 weeks and then monthly for 4 months to complete the cultural adaptation. During subsequent meetings, contributions of the advisory board have included selection of a measure of acculturation appropriate for the local Latino population, pre-testing MyFitnessPal, a web/Smartphone application for dietary tracking as well as a fitness tracker selected for HOMBRE to ensure acceptability, and determining the language(s) for intervention delivery. As the study progresses, the Advisory board will meet at least quarterly to provide critical input into the design and implementation of the study. Stakeholders include medical directors and primary care physicians involved in Latino men's care. Stakeholders were engaged during the adaptation process through in-depth interviews and will be engaged during study implementation through research team presentations seeking approval for patient recruitment. .

2.2 Comparative Effectiveness Pragmatic RCT

2.2.1. Eligibility Criteria

The eligibility criteria are designed to yield a generalizable sample of at-risk men balanced with ensuring patient safety, intervention adherence, and study retention. We will enroll Latino men 18 years or older who are at risk for weight-related cardiometabolic conditions such as diabetes and heart disease. For this study, at-risk is defined as having a Body Mass Index (BMI) ≥27 kg/m^2 and one or more cardiometabolic risk factors (high waist circumference, high triglycerides, high blood pressure, high fasting plasma glucose, or low high-density lipoprotein cholesterol) (**Table 1**).[1,2] Patients with significant psychiatric (e.g., bipolar or psychotic disorder) or medical comorbidities (e.g., active cancer, organ failure) will be excluded. Additional exclusions are to protect participant safety, prevent loss to follow-up (e.g., planned relocation, limited lifespan), and prevent contamination of study arms (e.g., family/household member of another study participant).

Table 1. Inclusion and exclusion criteria

Inclusion criteria:

- Age (as of date of enrollment):
  - Lower age limit: 18 years
  - Upper age limit: NONE (only exclude for cause, e.g. disease and functional limitations, as detailed below)
- Race/ethnicity: Latino of any race
- Gender: male
- Body mass index: ≥27 kg/m^2
- At least one cardiometabolic risk factor:
  - Elevated waist circumference
  - Elevated triglycerides
  - Elevated blood pressure
  - Elevated fasting plasma glucose
  - Low high-density lipoprotein cholesterol
- Primary Care Provider approval of study contact
- Able and willing to enroll and provide informed consent, i.e., to meet the time and data collection requirements of the study, be randomized to one of two study arms, participate in follow-up for 24 months, and authorize extraction of relevant information from the EHR

Exclusion criteria:

- Medical exclusions:
  - Previous diagnosis of diabetes or diabetes diagnosed as a result of fasting blood glucose or hemoglobin A1c levels obtained through study screening;
  - Diagnosis of cancer (other than non-melanoma skin cancer) that is/was active or treated with radiation or chemotherapy within the past 2 years;
  - Inability to walk without the assistance of another person;
  - Severe medical co-morbidities that require aggressive treatment: e.g., stage 4 or greater renal disease, class III or greater heart failure, unstable coronary artery disease, liver or renal failure;
  - Diagnosis of a terminal illness and/or in hospice care;
  - Diagnosis of bipolar disorder or psychotic disorder within the last 2 years, or currently taking a mood stabilizer or antipsychotic medication
  - Initiation or change in type or dosing of antidepressant medications within 2 months prior to enrollment (The patient will be re-contacted for a later cohort once his/her regimen has been stable for at least 2 months unless the person declines to participate altogether.)
  - Have had or plan to undergo bariatric surgery during the study period
- Other exclusions:
  - Having no reliable telephone service
  - Plan to move out of the area during the study period
  - Family/household member of another study participant or of a study staff member
  - Investigator discretion for clinical safety or protocol adherence reasons

2.2.2. Recruitment and Screening

Patients will be recruited in four cohorts from internal medicine and family medicine departments at the Palo Alto Medical Foundation (PAMF), a large community-based multispecialty group practice in the San Francisco Bay Area. The recruitment and screening process will involve the following 5 steps; (1) leveraging the EHR to identify patients who are potentially eligible using the inclusion and exclusion criteria; (2) seeking approval from patients' primary care provider (PCP) who can exclude patients due to medical or psychiatric concerns; (3) sending PCP-approved patients a recruitment email or letter from the Principal Investigator introducing the study and inviting them to complete an initial brief screening online in Spanish or English with an option to opt out (patients can self-screen at this step); (4) contacting patients who do not opt via telephone to screen for eligibility; (5) scheduling eligible and interested patients for an in-person baseline assessment for final determination of eligibility. Bilingual and bicultural research assistants will be available to conduct screening in Spanish or English. Prior to the baseline assessment, patients will be provided the opportunity to complete a self-administered survey online in Spanish or English. Patients can also complete the survey at the baseline visit. The baseline visit will include the written informed consent, standardized measures of height, weight, waist circumference, and blood pressure, and interviewer-administered assessments of dietary intake and physical activity. At the conclusion of the baseline visit, all participants will receive a digital scales, wearable fitness tracker, and instructions for setting up Myfitnesspal, a web- or Smartphone-based application for tracking diet and physical activity.

2.2.3. Randomization and Blinding

Latino men deemed fully eligible will be randomized in a 1:1 ratio to receive the HOMBRE intervention or a minimal intensity intervention (controln =212/arm). Men will be informed of their treatment assignment and invited to an orientation visit. We will apply a covariate-adaptive biased coin method that we have published[41] and used successfully in several trials[42,43] to achieve good marginal balance between treatments across the following baseline characteristics: clinic, age, BMI, level of acculturation assessed by the Short Acculturation Scale for Hispanics, and number of cardiometabolic risk factors.[44,45] The dynamic block randomization algorithm of our method automatically ensures allocation concealment. By design, treatment will be identifiable to participants and the lifestyle coach, but masking of the investigators, safety officer, outcome assessors, and data analyst will be enforced. Regardless of random assignment, all participants will continue to receive usual medical care.

2.2.4. Orientation Visit

Following randomization, all participants will be scheduled for an orientation group session specific to their randomization arm. The orientation session will be led by a bilingual and bicultural lifestyle coach and a research assistant focused on the technology components (fitness tracker and Smartphone application). Participants in both arms will be encouraged to bring their partner and/or other family members to the orientation session with the purpose of increasing understanding and social support among family members as advocated by the Latino Patient Advisory Board in the cultural adaptation process. Group orientation sessions for both arms will feature a didactic component to provide information on the background and goals of the intervention and an interactive small group discussion component.

The small group component for the HOMBRE intervention will engage participants in a discussion on the advantages and disadvantages of the three delivery options: self-directed via online videos, coach-facilitated via in-person groups, and coach-facilitated via online videoconferencing groups. Following the small group discussion, men randomized to the HOMBRE arm will select their preferred option using a structured handout that guides them through important decision domains including preferred level of coach and peer support, comfort

with technology, and lifestyle factors (e.g., work and family schedule). Men will be encouraged to discuss their choice with their partner and family if appropriate. The small group discussion component for the minimal intensity intervention will focus on identifying challenges and potential solutions to intervention adherence. At the conclusion of the orientation session, men in both arms will receive their intervention materials and any needed technology support.

2.2.5 Interventions and Fidelity Assurance

2.2.5.1 Theoretical Basis

Both interventions are based on Social Cognitive Theory,[46] which emphasizes a triadic, reciprocally deterministic relationship between the individual, environment, and behavior. It recognizes that behavior change is a dynamic process that moves at variable speed through stages of readiness to change. Positive outcome expectancies through realistic goal setting and guided action planning are associated with initiation of behavior change. Self-efficacy developed for specific behaviors (e.g., physical activity) predict establishment and maintenance of behavior change. Social Cognitive Theory suggests that self-efficacy is enhanced through social support and gradual mastery of self-regulation skills (e.g., goal setting, self-monitoring).[47]

2.2.5.2 Self-monitoring

Participants in both arms will receive a digital scale to self-monitor weight, a wearable fitness tracker to self-monitor physical activity, and will be asked to use MyFitnessPal web or Smartphone application to track dietary intake. In pre-testing the Latino Patient Advisory Board concluded the application had high acceptability based on the language, ease of entering cultural foods, opportunities for social networking, and availability both on the phone and personal computer. We will help participants to set up the activity monitor at the baseline visit to ensure that these data are automatically and wirelessly synced with the self-monitoring application (MyFitnessPal) with minimal participant action needed except for wearing the device. MyFitnessPal is a free web- and mobile-based (Android, iOS, and Windows compatible) tracking application available in Spanish and English. Self-monitored data collected through the MyFitnessPal application will be used by the lifestyle coach to provide individualized feedback and guidance tailored for Latino men. In addition, self-monitoring data (e.g., self-monitoring frequency) will be used to assess intervention participants' engagement and adherence.

2.2.5.3 Minimal Intensity Intervention

Men randomized to the minimal intensity intervention group (control) will be offered a self-directed lifestyle program over a 12-month period. The program is based on the Group Lifestyle Balance (GLB) intervention, a group-based adaptation of the original DPP intervention.[15,16,48] The GLB program's feasibility and effectiveness in primary care, and other community settings, are well documented.[15-19,49,50] The GLB is an approved curricula for application of the CDC Diabetes Prevention Recognition Program, including electronically delivered modalities.[51] The goal of GLB is to promote 5-10% weight loss as recommended by obesity treatment guidelines [52] and a minimum of 150 minutes per week of moderate-intensity physical activity (e.g., brisk walking) as recommended by the 2008 Physical Activity Guidelines for Americans.[53] The GLB supports participants in making healthy lifestyle changes to improve weight and prevent diabetes using theoretically-based behavioral strategies such as self-monitoring, goal setting, action planning and problem solving. Participants receive access to 12 program videos, available online, and written information to use in completing home-based, independent activities designed to help them problem-solve challenges they may face in losing weight and increasing physical activity (**Table 2**). The videos are available in English, with Spanish subtitles. A trained PAMF health coach is available upon request to answer participants' questions by telephone, email, mobile text messaging or secure messaging through PAMF's secure patient portal known as My Health Online.

Table 2. Intervention features of the minimal intensity intervention and the HOMBRE intervention (by modality)				
	Options in HOMBRE			***Minimal intensity intervention control***
	Self-directed*	**In-Person***	**Videoconferencing***	
12 weekly core Sessions	Home, DVD or online (30 minutes/session)	Clinic, in-person, coach-led groups (45-60 minutes/session)	Remote, coach-led groups via video conferencing (45-60 minutes/session)	*Home, DVD or online*
Level of coach support	Medium: Standardized messages	High: Coach-led group, individualized feedback, standardized messages	High: Coach-led group, individualized feedback, standardized messages	*Low: Coach available to answer participant questions*
Type of peer support	None	Group: In-person groups	Group: Online groups	*None*
Use of technology	High: Videos online or DVD; messages via self-monitoring app	Medium: Messages via self-monitoring app	High: Video conferencing, messages via self-monitoring app	*Medium: Videos online or DVD, optional messages via self-monitoring app*
Convenience	High: Engage in intervention at self-determined time and place	Low: Come into clinic at a time determined by group (several times offered)	Medium: Join groups from any location at time determined by group (several times offered)	*High: Engage in intervention at self-determined time and place*
*self-directed: self-directed via online/DVD videos in-person: coach-facilitated via in-person groups videoconferencing: coach-facilitated via online groups				

2.2.5.4 HOMBRE Intervention

Men randomized to the HOMBRE intervention group will be offered three intervention delivery options from which they can choose one. All three options are based on the GLB program over a 12-month period. Similar to GLB, the HOMBRE intervention includes 12 weekly sessions during the intensive phase (Months 1-3) and 10 biweekly or monthly contacts during the maintenance phase (Months 4-12).

The three delivery options are: 1) self-directed via online videos or DVD (referred to as self-directed), 2) coach-facilitated via in-person groups (referred to as in-person), and 3) coach-facilitated via online groups (referred to as videoconferencing). The primary difference across delivery options is how men engage in the weekly sessions during the intensive phase (**Table 2**). In the self-directed option men will view 12 videos (15-30 minutes each) online or via DVD during the intensive phase. The in-person group option includes 12 coach-facilitated group sessions at the clinic for the intense intervention phase. The coach-facilitated via online group option is similar to the in-person option but the meetings will take place via cloud-based video conferencing called Bluejeans. Participants can join over the internet or with a free smartphone application. The only hardware required is a computer or smartphone with an internet connection and speaker/microphone functionality. Participants will attend the sessions at specified times, but can join from wherever is convenient. All three options deliver the GLB, and encourage web/mobile-based self-monitoring using Myfitnesspal and the wearable activity tracker. Men will choose their delivery option in the group orientation visit as described above. The lifestyle coach will reach out to men who have achieved less than 2% loss of their baseline weight by four weeks to see if a different delivery option is better. Changing options is possible because all three approaches offer the same content.

A secondary difference across delivery options is the level and type of coach feedback (**Table 3**) during the intensive (months 1-3) and maintenance (months 4-12) phases. The self-directed approach has the lowest level of coach involvement. Men in this option will receive standardized weekly messages in Months 1-3 with reminders to watch the videos, use written materials, self-monitor via the activity tracker and Myfitnesspal, and reach out to the coach with questions or requests for more individualized feedback. In Months 4-12, men in the self-directed option will receive biweekly, and then monthly, standardized messages that will include handouts on

maintenance topics, reminders to self-monitor, and contact information for the coach. The in-person and videoconferencing approaches have a higher level of coach involvement than the self-directed option. Using the tracking data from participants, the lifestyle coach will provide individualized feedback on diet and physical activity goals during the intensive phase. Individualized feedback will provide ample opportunity for tailoring based on culture and other individual differences. During the maintenance phase, men who choose the in-person and videoconferencing options will receive monthly phone calls from the coach that focus on supporting continued goal progress and problem solving for encountered barriers.

The language options (Spanish and English) will be communicated at the orientation session so men can base their choice on language availability. For the self-directed option, men can view the videos with or without Spanish subtitles (the videos are in English). The in-person and video-conferencing options are also offered in either Spanish or English. Finally, family members, especially spouses/partners, are incorporated into the intervention. In addition to encouraging men to bring family members to the orientation session, the coach will recommend that men include family members in the program. For the self-directed option, the coach will encourage men to view the videos with family members. For the in-person and videoconferencing options, men will be encouraged to bring a family member to session 6 and session 12.

Table 3. Level and type of coach feedback by modality

	Self-directed*	**In-Person***	**Videoconferencing***
Feedback on self-monitoring logs			
Intensive	Per participant request	Weekly review of diet, weight, physical activity, steps + comments via MyFitnessPal	
Maintenance	Per participant request	Monthly review of weight, physical activity, steps	
Email/text support			
Intensive	Standardized weekly reminders to complete sessions and self-monitoring	Standardized weekly reminders to attend sessions	Standardized weekly reminders to attend sessions
Maintenance	Standardized bi-monthly reminders for lifestyle change with handouts		
Individual support			
Intensive	Available as needed via phone, text, email, MyHealthOnline (MHO)		
Maintenance	Available as needed via phone, text, email, MHO	Available as needed via phone, text, email, MHO, monthly scheduled individual phone consults	Available as needed via phone, text, email, MHO, monthly scheduled individual phone consults

*self-directed: self-directed via online videos or DVD
in-person: coach-facilitated via in-person groups
videoconferencing: coach-facilitated via online groups

2.2.5.5 Fidelity Assurance

We will follow recommendations for quality assurance in behavioral interventions.[54] Use of standardized intervention materials, structured staff training and ongoing oversight are fundamental to ensuring high intervention fidelity. The lifestyle coach will undergo standardized training by a certified GLB master trainer with supplemental training on the cultural adaptations recommended by the Latino Patient Advisory Board. Per our standard practice, all group sessions will be audiotaped and a random 10% sample from the sessions by recruitment cohort will be audited and graded using a session-by-session rating scale from a previous trial.[34] The coach will complete a checklist of critical intervention behaviors and materials delivered during each session. Self-monitoring records and Smartphone application communication are readily retrievable and will be reviewed as part of routine quality control efforts. Falling below an a priori performance standard (e.g., 90% adherence to intervention protocol) will trigger more

frequent audit and feedback and, if needed, “booster” training for the coach. Participant engagement and adherence are also essential to intervention fidelity and must be monitored and supported. Participant progress on key intervention tracking parameters (e.g., date, format, duration of contact, most current weight, and physical activity level) will be routinely documented. The coach will review and give feedback on homework and self-monitoring records and document participant progress toward protocol-specific, achievement-based objectives. The coach will routinely inquire about barriers to intervention receipt and adherence, recommend personalized, actionable problem-solving strategies, and provide ongoing support via proactive follow-up.

2.2.6 Participant Safety

PCP approval will be required before potentially eligible patients are contacted by the study team. Participants will be carefully screened and individuals for whom the interventions would be medically inappropriate or unsafe will be excluded. Participants who develop any exclusionary condition (e.g., diabetes) following randomization may continue with the interventions and follow-up assessments with their PCP’s approval. To ensure unbiased ascertainment between the intervention and control group, outcome assessors will systematically screen all participants for adverse events during in-person assessments at baseline and 18 months using a standard interview and reporting form as done in our previous trials.[43,55-57] In addition, outcome assessors will call all participants at six and 12 months to screen for adverse events. Positive responses will trigger an adverse event record, which will be reviewed by the study clinician for seriousness, study relatedness, and expectedness. Similar information reported by participants at other times (e.g., during intervention encounters) will be duly noted and followed, as needed, to assure participant safety. Participants will be referred to their PCP for a medical evaluation as needed. We will report adverse events to the study safety officer.

A study safety officer will review the original protocol and any subsequent amendments, perform expedited monitoring of serious adverse events (SAEs) that are unexpected and related, perform ongoing monitoring of drop-outs, all other SAE’s, and non-SAEs, determine whether study procedures should be changed or the study halted due to serious safety concerns and/or major problems with conduct of the study, and perform periodic review of the completeness and validity of data to be used for analysis of safety and efficacy. The study safety officer also will monitor implementation of procedures to ensure research participant privacy and data confidentiality.

2.2.7 Study Measures and Data Collection Schedule

Assessments will occur at baseline, 6, 12, and 18 months on clinical, behavioral, and psychosocial outcome measures and potential effect modifiers and mediators at one of the PAMF clinics from which participants are recruited (**Table 4**). Trained bilingual and bicultural research assistants blinded to participants’ random assignment will conduct assessments using standardized measurement protocols and equipment and previously validated interviewer-questionnaires (in-person or by phone). For in-person data collection, participant’s preferred time and location will be accommodated whenever possible, including evenings and weekends. We will also utilize self-administered questionnaires online, which we have shown to be acceptable and feasible in previous trials with Latinos. We will use Spanish or English as indicated by the participant.

2.2.7.1 Primary and Secondary Outcomes

The primary outcome is proportion of participants who sustain at least 5% of baseline weight loss at 18 months. Research assistants will weigh participants in duplicate using a standard

calibrated scale at baseline and 18 months at local clinic sites as in previous and ongoing trials. The primary outcome was selected based on its clinical relevance for patients, providers, and health care systems, as well as patient and stakeholder input. Weight loss of ≥5% of baseline weight is known to confer a reduction in risk of diabetes and other chronic disease.[52] This outcome emphasizes chronic disease prevention by focusing on clinically relevant weight loss. Our patient advisors advocated for this primary outcome because their primary goal for the intervention is to reduce the risk for chronic disease. We will examine three types of secondary outcomes:

Health behaviors (dietary intake, physical activity, and sedentary behavior) and psychosocial well being will be collected via phone or online questionnaire at baseline, 6, 12, and 18 months (Aim 2). Dietary intake will be assessed using the gold-standard approach of multiple pass 24-hour recalls in Spanish or English by highly trained and experienced staff, over the phone, at baseline and 18 months.[58,59] Physical activity and sedentary behavior will be assessed using the interviewer-administered 7-day Physical Activity Recall[60,61] and a self-report measure of sedentary behavior[62] over the phone at all time points. Participants will complete online questionnaires that we have successfully used in prior trials[57,63] to assess psychosocial well-being (e.g., EuroQol EQ-5D,[64,65] PHQ-9 for depression[66,67]). If needed, a research assistant can help a participant fill out the online questionnaire at an office visit.

Cardiometabolic risk factors (blood pressure and waist circumference) measured at baseline and 18 months (Aim 2). Trained research assistants will conduct blood pressure and waist circumference measurement according to standard protocols.[68-70] Waist circumference will be measured in duplicate at the right iliac crest, in centimeters as per previously published protocols.[71,72]

Body Weight from the EHR up to 24 months post-randomization. We will abstract weight measurements from the EHR 3 months prior to randomization and up to 24 months post-randomization to examine trajectories of weight loss over time. We examined the feasibility of this approach by comparing data on researcher-measured weights and EHR-weights in two prior behavioral lifestyle intervention trials.[73] Using data from two prior trials we observed that participants had a sufficient number of weight measurements in the EHR and there was excellent agreement between researcher-measured weights and weight obtained in the EHR.

2.2.7.2 Potential effect modifiers and mediators

We will collect information on potential effect modifiers at baseline including demographic characteristics (e.g., race/ethnicity, marital status, education), technology utilization, and health literacy. For technology utilization, we adapted a survey from the Pew Hispanic Trust on technology access and usage.[74] For health literacy, we will use the newest vital sign, which uses a food nutrition label.[75] Additionally, at each time period, we will collect information on theoretically-based core constructs shown to predict weight loss and behavior change in diverse populations including outcome expectancy, self-efficacy, and social support.[47,76] These putative mediators are directly informed by Social Cognitive Theory, the theoretical base of HOMBRE and the GLB.

Table 4. Outcomes, potential effect modifiers and mediators measured at baseline visit (BV), 6, 12, and 18 months (M)						
Outcomes	**Measures**	**Mode**	**BV**	**6M**	**12M**	**18M**
Primary outcome:	Height	In-person	X			
Proportion losing ≥ 5% of baseline weight at 18 months	Weight - standardized methods[70,71]	In-person	X			X
Secondary outcomes: ***Clinical***: Weight change and cardiometabolic risk factors	Weight	EHR	Ongoing -> 24 months			
	Waist circumference	In-person	X			X
	Blood pressure- standardized methods[69,70]	In-person	X			X
***Behavior change*:** 1. Dietary intake 2. Physical activity **3.** Sedentary behavior	1. Multiple pass 24-hour diet recall[58,59]	Phone	X			X
	2. 7-day Physical Activity Recall;[60,61]		X	X	X	X
	3. Sedentary behavior questionnaire[62]		X	X	X	X
***Psychosocial well-being*:** 1. Health-related quality of life 2. Obesity-specific quality of life 3. Depressive symptoms 4. Sleep habits and quality	1. EuroQol EQ-5D[64,65]	Online	X			X
	2. Obesity-related Problem Scale[77,78]					
	3. Perceived Stress Scale & Nine-item Patient Health Questionnaire (PHQ-9)[66,67]					
	4. PROMIS™ sleep disturbance and Sleep-Related Impairment[79]					
Potential modifiers: 1. Demographics 2. Technology utilization 3. Health literacy	1. Age, race/ethnicity, education, employment, occupation, marital status, household size, income, acculturation	In-person	X			
	2. Adapted from the Pew Hispanic Trust technology use and access survey[74]	Online	X			
	3. The newest vital sign[75]	In-person	X			
Potential mediators: 1. Outcome expectancy 2. Self-efficacy 3. Social support	1. Goals and Relative Weights,[80] Stunkard silhouettes[81]	Online	X	X	X	X
	2. Weight Efficacy Life-Style Questionnaire;[82,83] Self-Efficacy for Dietary Change and Exercise[84]					
	3. Social Support for Diet Change & Exercise[85]					
Intervention engagement: 1. Session attendance 2. Interaction with coach 3. Self-tracking	1. Attendance at sessions (in-clinic or online) and tracking of online video viewing	Mobile app	Ongoing			
	2. Tracking of messages sent/received to coach					
	3. Self-tracking of physical activity, diet, and weight on app or web					

2.2.7.3 Evaluation for implementation and dissemination

To complement the focus on effectiveness in Aims 1 and 2, we will assess the potential for implementation and dissemination using the RE-AIM framework's reach, adoption, implementation, and maintenance domains (**Table 5**),[86-88] as we have done in other studies via interviews with study staff, coach, participant, and primary care and community stakeholders.[57,63] We will conduct a detailed evaluation of these RE-AIM domains with mixed methods to gain a nuanced understanding of why the intervention is (or is not) superior to the minimally intensity intervention control, whether high intervention fidelity is achieved, what barriers and enablers there are, how these may translate into future implementation and dissemination, and what modifications can maximize implementation success.[89] All interviews will be recorded and transcribed.[90,91] Transcriptions of interviews with Latino patients will be translated to English.

Table 5. Summary of quantitative and qualitative measures for the process evaluation		
	Example Questions, Data Sources, and Methods	
RE-AIM Domains	**Quantitative**	**Qualitative**
Reach of the intended target population	Patient survey & recruitment tracking data: percentage and characteristics (e.g., language preference, place of birth, years in the US) of participants compared with non-participants.	Interviews with study staff: Barriers enablers of recruitment, recruitment variability by demographics or other characteristics, strategies for addressing barriers, potential strategies to maximize reach.
Adoption by target staff or settings	Administrative data: Characteristics of participating clinics, percentage and characteristics of PCPs approached who participated (e.g., PCPs referring or approving patients for study screening).	Interviews with PCPs and clinic leadership: Barriers and enablers of clinic and provider participation, recommendations for reducing barriers and maximizing adoption.
Implementation success during intervention delivery (***staff perspective***)	Surveys of lifestyle coach: perceptions of (1) consistency of intervention procedures with available evidence, (2) intervention suitability for primary care, and (3) experience with the strategies facilitating intervention delivery based on the Promoting Action on Research Implementation in Health Services model.[92,93]	Interviews with lifestyle coach, PCPs, and clinic leadership: Barriers and enablers of delivering the intervention and differences across participating clinics, modifications to maximize implementation success?
Implementation success during intervention delivery (***patient perspective***)	We will assess intervention participants' engagement and adherence by monitoring the number of group sessions attended, reasons for missed sessions, secure messaging and self-monitoring frequency, and adherence across participant subgroups.	Interviews with a random sample of participants: Relevance and acceptability of knowledge and skills, frequency of practicing intervention strategies, perceived benefits, problems encountered, cultural congruence, satisfaction with program format, materials, and coach performance?
Maintenance of intervention effects in individuals and settings over time	We will assess attrition and adverse events by participant characteristics and treatment condition.	Interviews with lifestyle coach, PCPs, and clinic leadership: Potential for integration into regular care and sustained, resources, policies, and care process redesigns needed to maximize sustainability.

2.2.8 Retention

As we have done in our previous trials,[43,55-57] we will maximize adherence and retention by careful selection and training of staff, systematic quality control, and adhering to high-quality practices to maintain participation in the study. We will use a tracking database to facilitate coordination and monitoring of participant-level activities. No individuals will be randomized without eligibility verification or complete baseline data. Examples of processes that facilitate retention at follow-up include thorough and fully informed roles and responsibilities of staff and participants, conveying an appreciation of participation and study identification, nominal remuneration for study visits, reasonable accommodations to participant schedules, and prudent participant incentives (pedometer and cash incentives). We will contact participants who miss a visit to reschedule and re-engage them in subsequent follow-ups. Using a combination of these strategies, we have consistently achieved high retention in several RCTs of similar scope (82%-92%),[34,42,94] including those with Latino participants (85%).[95,96]

2.2.9 Statistical Analysis

2.2.9.1 Analytical Plan

Aim 1 and 2: The primary hypothesis that HOMBRE will lead to a greater percentage of Latino men who sustain ≥5% of baseline weight loss through 18 months than the minimal intensity intervention control group will be tested with a generalized linear mixed model.[97-99]

$$\mathbf{Y = \beta_0 + \beta_1 X + \beta_2 Y_0 + \Sigma\beta_{4+i} Z_i + \alpha + \gamma + e} \qquad \mathbf{(1)}$$

Let Y be the outcome of interest for a patient randomized to arm X (HOMBRE or control). Given the covariate-adaptive randomization, distributions of baseline values on the outcome variable (Y_0) and key characteristics (Z_i) should be similar between study arms and thus not bias the results. But to the extent they are associated with the outcome, their inclusion in the analysis will account for otherwise unexplained variation and hence increase efficiency.[100] α and γ are clinic and PCP nested within clinic random effects, and e is the random error term. Aim 2 examining secondary outcomes at 18 can be evaluated by adapting the same model. The outcome variables in Aim 2 (e.g., cardiometabolic, health behavior, and psychosocial well-being indicators) will be continuous. We will model the change from baseline in each indicator as the outcome Y and the fixed and random effects will remain the same as described in model (1).

Primary analyses will follow intent to treat principles. We will verify that mixed model-based results are not sensitive to violations of model assumptions with permutation and bootstrap resampling tests.[101,102] We will document the extent, pattern, and reasons for missing data, and will conduct sensitivity analyses of the impact of missing data on stability of the primary results. For example, we may use weight data up to the point when they are no longer available (e.g., dropouts) or should not be used, and then employ multiple imputation[103,104] based on a predictive distribution for future weights.

Exploratory Aim 1: Weight loss trajectories using weight data from the EHR will be examined using tests of group-by-time interactions in mixed-effects growth curve model.

$$\mathbf{Y_t = \beta_0 + \beta_1 X + \beta_2 Y_0 + (\beta_3 + \beta_4 X)\, T + \Sigma\beta_{4+i} Z_i + \alpha + \gamma + b_0 + b_1 T + \varepsilon} \qquad \mathbf{(2)}$$

Let Y_t be the outcome of interest at follow-up time T on a patient randomized to arm X (HOMBRE or control). Baseline values on the outcome variable (Y_0) and key characteristics (Z_i) will be included for efficiency as in model 1.[100] α and γ are clinic and PCP nested within clinic random effects as in model 1, b_0 and b_1 account for random intercepts and random slopes, and ε is the random error term. We will use a goodness-of-fit test to determine whether to include the quadratic or higher order of growth curves.

Exploratory Aim 2: We will also conduct exploratory subgroup analyses to evaluate potential effect modifiers for the primary outcomes by expanding equation 1 to include appropriate modifier-by-group interaction terms. In this context, testing whether the β coefficients of the interaction terms are equal to zero is equivalent to testing the null hypothesis that the variable of interest does not independently modify the intervention effect. Mediation (e.g., change in self-efficacy and its mediating effect on weight loss outcome) will be examined by MacKinnon's product of coefficients test (αβ).[106] Asymmetric confidence limits will be constructed based on the distribution of the product with the PRODCLIN program.[107] Because multicollinearity may be present in multiple mediator models, we first will test each mediator in single-mediator models. Multiple-mediator models including all variables that are at least marginally significant in the single-mediator models will test for independent and suppression effects. To determine the extent of mediated effect, the percentage of total effect mediated will be calculated for each significant mediator as $\alpha\beta/(\alpha\beta+\gamma)$, where γ is the direct intervention effect on outcome. The effect modification-mediation analyses are hypothesis-generating, but we pre-specify the variables to ensure a focus.

Aim 3: For quantitative data collected as part of the assessment testing the potential for future implementation and dissemination, we will use t-tests for continuous variables and chi-square tests for categorical variables. For qualitative data collected related to aim 3, we will use NVivo, a multifunctional software system, to help code and manage data from the interview transcripts. We will initially use the interview guide to organize and provide a starting list of codes related to the factors associated with participant's values and preferences related to weight, diet and physical activity which we will supplement with emergent codes to capture new factors that arise from the group discussion. Two project team members will independently code the transcripts. Discrepancies in initial coding will be solved by discussion between project team members. Based on these discussions, the raters will conduct a final code of the transcripts. The general categories of codes will relate to modality, presentation, messages or motivations for weight loss important to men. Intercoder agreement will be quantified and reported for each coding domain using Cohen's Kappa, which is calculated as follows: (Observed agreement – Chance) / (1 – Chance). If substantial intercoder disagreements exist, a third project team member will review the text in question to determine appropriate coding before finalizing the coding scheme.[108]

The purpose of the exploratory aim 2 & 3 analyses are to identify hypotheses for future rigorous studies. This study was not designed to have sufficient power to test the outcomes in exploratory analyses. In this case, multiple comparisons corrections will not be necessary.[109]

2.2.10 Sample Size and Data interpretation

This trial is powered on the primary outcome of percentage of participants achieving ≥5% weight loss at 18 months. A sample of 212 participants/arm has 80% power to detect a difference of 15 percentage points between the HOMBRE intervention and control at α=0.05 (2-sided), assuming at least 80% retention at 18 months based on our prior trial experiences. We estimated that the percentage of men randomized to the minimal intensity intervention who would maintain clinically significant weight loss at 18 months would be slightly lower than what we observed in a prior trial (39%).[34] Among racial/ethnic minorities, such as Latinos, lower proportions have maintained clinically significant weight loss in the intervention arms (e.g., 18%[110] to 26%[111]). Additionally, other low intensity interventions in primary care have also demonstrated a lower proportion maintaining clinically significant weight loss than what was observed in a prior trial.[9] We chose a 15-point difference in percentage of men achieving ≥5% weight loss at 18 months based on our prior studies and other available literature.[34,112,113] Among men randomized to the coach-led intervention in a prior trial, 51% maintained ≥5% weight loss at 24 months (12-point difference between groups). We anticipate a greater difference than observed in our prior trial, given that HOMBRE incorporates facilitated choice or delivery options and the control condition does not. The SHED-IT intervention tested a lower intensity intervention with a higher intensity intervention among Australian men over 12 months and found that 33% and 49% of men randomized to the respective arms maintained clinically significant weight loss (16 point difference).[112,113]

2.2.11 Data Management and Quality Control

All study data will be entered into computerized data files utilizing: (1) Microsoft ACCESS for data entry on recruitment, follow-up, and intervention tracking; (2) WorldApp hosted at PAMF for self- and interviewer-administered questionnaire data and physical measurements; (3) the Nutrition Data System for Research (NDS-R) (Minneapolis, MN) licensed for data collection and nutrient analysis based on multiple-pass 24-hour diet recalls;[58,59] and (4) a custom-designed web application for seven-day physical activity recall. WorldApp provides convenient multi-lingual functionality that allows participants to easily choose their preferred language for data collection. All data entry systems employ automatic, real-time range, logic, and missing value

checks. Also, the outcome assessors are trained on data collection protocols (e.g., multiple-pass 24-hour diet recall using NDS-R and 7-day physical activity recall), and their performance will be continuously monitored. Data sets will be cleaned, verified and archived, and then placed into SAS (version 9.2, SAS Institute, Cary, NC) data sets, which also will be archived. One official copy of all study data and a master data dictionary will be maintained and updated regularly by the study data analyst. All analytic and tracking databases will be stored in a password-protected, encrypted network drive with continuous backups. For the protection of participant confidentiality, unique anonymous study IDs will be used for data storing, tracking and reporting. Protected health information will be stored separately from all other study data, and used and disclosed in accordance with the Health Insurance Portability and Accountability Act regulations. Regular reports will be produced on (1) patient accrual and follow-up completion/retention in relation to goals and timeline; (2) the randomization process and group comparability on the balancing variables; (3) key baseline characteristics of the sample, by (blinded) group, related to the primary and secondary outcome variables and proposed effect modifiers and mediators; (4) intervention exposure and adherence; and (5) protocol violations. Any observed delays in these processes or data irregularities will be resolved in a timely manner.

4. Discussion

Together with patients and other key stakeholders, such as healthcare providers, we designed a study to address the gap in evidence on how best to deliver behavioral lifestyle interventions to overweight and obese Latino men in primary care. The HOMBRE study is unique in that it tests a flexible and individualized package of delivery options for an evidence-based behavioral lifestyle intervention compared to a minimal intensity intervention in primary care over 18 months.

Using national data, we and others have reported that men in general and specifically Latino men are less likely to attempt weight loss or join weight loss programs than women.[114-116] In a recent study, men were 60% less likely to attempt weight loss and 84% less likely to join a weight loss program compared to women.[116] Similarly, among obese Latino adults, 42% of men reported attempting to lose weight compared to 61% of women.[117] Diverse factors contribute to this disparity. Compared with women, men, including Latinos, more commonly misperceive themselves as normal weight when they are overweight/obese,[114-117] and they experience less societal pressure for weight control.[21,22] Rather, men's primary motivation for weight loss appears to be reducing chronic disease risk factors and avoiding adverse health outcomes - the emphasis of the GLB program.[14,21,37-39] This is particularly true for midlife and older men with identified risk factors[39] - the target population of the HOMBRE trial.

The primary care setting is ideal for capitalizing on this primary motivation for weight loss. However, there is limited research to inform primary care-based implementations. The participation of Latino men in behavioral lifestyle intervention trials based in primary care is difficult to quantify because ethnicity is not usually reported by sex.[9] A systematic review documented only 546 Latino men (4%) among 15,356 participants in behavioral lifestyle intervention trials (not limited to primary care) where race/ethnicity was reported by sex. It is possible that men have not been the focus of primary care-based interventions because they utilize healthcare less often than women.[118,119] While men may not use healthcare frequently, they still report a known usual place for medical care. Studies have shown that 86% of men age 45-64 years and 96% of men ≥65 years report a known usual place for medical care (excludes emergency room).[120] Benefits of the primary care setting include potential for scalability given policy support for lifestyle interventions. The US Preventive Services Task Force recommends

referral to behavioral lifestyle interventions for obese individuals and for overweight individuals with 1 or more risk factors (diabetes, pre-diabetes, hypertension, dyslipidemia, and elevated waist circumference) encountered in primary care. Additionally, the Center for Medicaid Services reimbursement policies support implementation of behavioral lifestyle interventions in the context of primary care. In addition to policy support, implementation in primary care offers the benefit of leveraging PCP support for adoption and maintenance of behavior change.

The utilization of rapidly expanding health information technology modes of communication (e.g., Smartphone applications, Web-based applications, secure e-messaging) to provide culturally and linguistically appropriate weight management for high-risk Latino men in primary care is an important addition in this study. First, offering the option of videoconferencing is an innovative feature of the intervention that has not been evaluated with Latino men. We previously tested delivering a behavioral weight loss intervention in primary care to men only using Bluejeans videoconferencing (Blue Jeans™, Mountain View, CA).[35] Obese men (BMI≥35 kg/m^2) randomized to the videoconferencing arm lost 3.5% (95% CI 2.1%, 4.9%) more weight than waitlisted controls. Second, HOMBRE incorporates technologies that enable self-monitoring including wearable activity monitors and Smartphone applications. Despite the evidence that internet and mobile phone interventions have shown promise for weight loss and maintenance in adults,[121-127] few studies of DPP translations in Latinos have incorporated technology. Although Latinos have historically experienced the 'digital divide,' their access to technology in general and Smartphones in particular make this a promising approach to maximize reach in this population.[128] The HOMBRE study will fill an important gap in the literature by integrating health information technology with traditional care models (e.g., group visits) to combat obesity among Latino men.

Testing a package of flexible delivery options as offered in HOMBRE presents a unique innovation in DPP translational research. It acknowledges a patients' desire for individualization and mirrors real-world applications where patients have choice in intervention programs. Very few studies have examined the potential benefits of this pragmatic approach. Kramer et al. showed that employees (n=89) randomized to an arm that offered 2 options for receiving the GLB (in-person groups or individual via videos) lost significantly more weight than those randomized to a non-choice, weight loss control arm (-10.4 lbs. or 5% vs. -2.3 lbs. or 1%, $p<0.01$) at 6-months.[32] Piatt et al. tested 3 lifestyle intervention modalities (face-to-face groups, DVD, and internet education) among 555 adults and included one arm where participants could choose the delivery modality.[33] Participants in the preference arm (n=101) lost 14.0 lbs. at 3 months and 8.7 lbs. at 6 months, which was significantly more than other groups at 3 months ($p<0.03$), but not at 6 months.[33] The HOMBRE trial will build on this limited evidence by testing a package of flexible delivery options compared to a minimal intensity intervention whose effectiveness has been previously established.[34]

Limitations of the HOMBRE trial relate to the pragmatic study design featuring in-person study visits at baseline and 18 months supplemented by follow-up data from the EHR over 24 months and a highly flexible intervention. Using the PRECIS (Pragmatic-Explanatory Continuum Indicator Summary) tool as a guide, the HOMBRE trial was designed to be pragmatic and yield evidence of the effectiveness of implementing an intensive lifestyle intervention in the context of routine primary care. As such, study design decisions favored pragmatic over explanatory methods. For example, while in-person follow-up visits extending to 24 months or longer is the gold standard for behavioral lifestyle trials, the HOMBRE trial aims to follow a large sample size (n=424) with lower patient burden, in part, by accessing weight data from the EHR. Other strategies to decrease patient burden include online self-administered questionnaires that can be completed at home and by phone between study visits. Additionally, the HOMBRE trial will

provide evidence of the effectiveness of a package of flexible delivery options and is not designed to compare the effectiveness of delivery options offered as part of the HOMBRE arm. The effectiveness of each delivery option compared to a usual care control has already been established.[34,35] These pragmatic features of the HOMBRE trial will result in robust evidence of the effectiveness of an intensive lifestyle intervention for a group that has been underrepresented in diabetes prevention translational research.

Pragmatic studies, such as HOMBRE, that focus exclusively on high risk groups are critical for translating the benefits observed in tightly controlled efficacy trials such as the DPP into population-wide impacts on health disparities. Specifically, this study focuses on the priority population of Latino men who have been left out of diabetes prevention translational efforts to date,[11,12,14,20] despite their high risk and significant population size. Furthering the benefit to address health disparities, the HOMBRE trial incorporates mixed methods to assess the potential for implementation and dissemination using the RE-AIM model. These data will supplement the comparative effectiveness trial outcomes by providing critical contextual information to inform implementation and dissemination in real world settings.

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