



A gender- and culturally-sensitive weight loss intervention for Hispanic males: The ANIMO randomized controlled trial pilot study protocol and recruitment methods



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ABSTRACT

Hispanic men have the highest rates of overweight and obesity when compared to men of other racial/ethnic groups, placing them at increased risk for obesity-related disease. Yet, Hispanic men are grossly under-represented in weight loss research. Tailored intervention strategies to improve obesity treatment programs for this vulnerable racial/ethnic subgroup are needed. This manuscript describes recruitment strategies, methodology, and participant characteristics of the ANIMO study, a 24-week randomized controlled pilot trial testing the effects of a gender- and culturally-sensitive weight loss intervention (GCSWLI) on body weight in Hispanic men compared to a wait-list control condition. The ANIMO study included two phases. The first phase was a 12-week GCSWLI. Participants attended weekly in-person individual sessions guided by a trained bilingual Hispanic male lifestyle coach, were prescribed a daily reduced calorie goal, and 225 min of moderate-intensity physical activity per week. In the second phase, GCSWLI participants received bi-weekly phone calls across a 12-week follow-up. Wait-list control (WLC) participants from phase 1 received the GCSWLI plus mobile health technology support. Recruitment strategies included face-to-face efforts at a swap meet (outdoor marketplace), family/friend referrals, printed advertisements and social media. Recruitment, screening, and participant enrollment occurred over three months. Overall, 143 men expressed interest in participation. Of these, 115 were screened and 78% (n = 90) were eligible to participate; 45% of enrolled participants (n = 52) completed baseline assessments and 43% (n = 50) were randomized (mean age of 43.3 ± 11.4 years; BMI: 34.1 ± 5.3 kg/m²; 58% Spanish monolingual). Parameter estimates from ANIMO will support future adequately powered trials for this health disparate population.

Trial registration: ClinicalTrials.gov: NCT02783521

1. Introduction

Hispanic males have the highest prevalence of overweight and obesity among racial/ethnic groups in the U.S. [1]. Obesity is strongly linked to cardiovascular disease, metabolic syndrome, type 2 diabetes, hypertension, non-alcoholic fatty liver disease (NAFLD), and certain types of cancers such as colorectal and liver [2–4]. Consequently, Hispanic males have the highest prevalence of obesity-related comorbidities relative to other racial/ethnic subgroups. For example, estimates suggest that Hispanic men are 1.4 times more likely than non-Hispanic

white (NHW) men to have been diagnosed with diabetes by a physician despite lower healthcare access [5]. Cardiometabolic abnormalities such as abdominal obesity, hypertension, high cholesterol and triglycerides, and high blood glucose levels are also significantly higher in this population subgroup overall [6,7].

Current evidence-based guidelines for the management of overweight and obesity in adults recommend weight loss treatment for individuals with a body mass index (BMI) ≥ 30 kg/m² or with a BMI ≥ 25 kg/m² coupled with weight-related comorbidities [8]. While behavioral weight loss interventions, delivered on-site in academic

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research settings, are capable of producing approximately an 8–10% weight loss over the course of 6 months [8,9], approximately 73% of study samples are comprised of women [10,11]. Further, Hispanic participants tend to lose less weight and are more likely to regain weight at follow-up compared to other racial/ethnic groups [12–18]. It has been suggested that culturally-specific gender roles may contribute to this differential effect; however, there is limited evidence of effectiveness of behavioral weight loss interventions for Hispanics long-term [17]. The Diabetes Prevention Program (DPP) is one of few randomized controlled studies with long-term weight loss data among Hispanic men. Data specific to the intensive lifestyle intervention demonstrated weight loss achieved by Hispanic men (−6.8 kg) and non-Hispanic White men (−7.1 kg) at 24 months were not significantly different [19]. While these data are promising, the DPP enrolled only 58 Hispanic men in the intensive lifestyle intervention, comprising only 6.0% of the total intervention arm population [19]. Identifying intervention strategies to engage and promote successful weight management in Hispanic males is critical to reducing morbidity and mortality among this large and growing population [20,21].

Using existing practice guidelines and evidence from our recently completed in-depth qualitative interviews in overweight/obese Hispanic males [22,23], we developed and tested a novel intervention to address this gap in knowledge. We proposed to 1) assess the feasibility, acceptability and preliminary efficacy of a gender- and culturally-sensitive weight loss intervention in 48 overweight/obese Hispanic males ages 18–64 over 12-weeks; 2) assess participant characteristics and process measures related to the uptake of mobile-health (mHealth) technology in overweight/obese Hispanic males over 12-weeks; and 3) evaluate pathologic changes in the liver in Hispanic men enrolled in a 12-week weight loss intervention using non-invasive magnetic resonance imaging (MRI) as a therapeutic response biomarker. This manuscript describes the study's recruitment strategies, methodology, and participant characteristics.

2. Methods

2.1. Experimental study design

The ANIMO (Spanish term for encouragement or motivation) pilot study was a 24-week randomized controlled trial testing the effects of a gender- and culturally-sensitive weight loss intervention (GCSWLI) on body weight in Hispanic men compared to a wait-list control condition (Fig. 1). Phase 1 of the GCSWLI consisted of 12-weeks of individual counseling, while in the second phase, GCSWLI participants received bi-weekly phone calls for another 12-weeks. Wait-list control (WLC) participants received the GCSWLI plus mobile healthmHealth technology support after 12-weeks of no intervention. Qualitative inquiry of weight loss experiences, for both groups, was conducted with participants shortly after their 24-week intervention process.

2.2. Setting of the human research

Research activities took place at the University of Arizona (UA) Collaboratory for Metabolic Disease Prevention and Treatment. The

Collaboratory is located in a high need, underserved area of Tucson, Arizona whose residents suffer a disproportionate burden of chronic disease. All research activities were approved by the University of Arizona Institutional Review Board (IRB approval # 604536275).

2.3. Randomization

Participants were randomized to intervention arm using stratified block randomization with variable block sizes, where BMI category (overweight or obese) and diabetes status (yes/no) were used as strata. A computer randomization system was used to complete the randomization assignment by a statistician who had no contact with participants.

2.4. Study population

Individuals were considered eligible if they self-reported meeting all of the following criteria: 1) self-identified as Hispanic; 2) 18–64 years of age; 3) BMI between 25 and 50 kg/m² (we elected to cap this at 50.0 kg/m² to minimize potential risks and reduce the potential for obesity to limit exercise participation); 4) ability to provide informed consent and complete health risk assessment prior to participation in the pilot study; and 5) speak, read, and write English and/or Spanish.

Individuals were excluded if they self-reported meeting any of the following criteria: 1) Uncontrolled diabetes mellitus; 2) history of bariatric surgery; 3) reported medical condition or treatment for a medical condition that could affect body weight or ability to engage in structured physical activity that is consistent with the intervention for this pilot study; 4) currently treated for congestive heart failure, angina, uncontrolled arrhythmia, or other symptoms indicative of an increased acute risk for a cardiovascular event; 5) resting systolic blood pressure of ≥ 150 mmHg or resting diastolic blood pressure of ≥ 100 mmHg; 6) eating disorder that would contraindicate weight loss or physical activity; 7) alcohol or substance abuse; 8) currently treated for psychological issues (e.g., depression, bipolar disorder, etc.), taking psychotropic medications within the previous 12 months, or hospitalized for depression within the previous 5 years; 9) reported exercise on ≥ 3 days per week for ≥ 20 min per day over the past 3 months; 10) reported weight loss of ≥ 5% or participation in a weight reduction diet program in the past 3 months; or 11) reported plans to relocate to a location that limited their access to the study site or having employment, personal, or travel commitments that prohibit attendance to all of the scheduled assessments.

2.5. Recruitment and screening process

Face-to-face recruitment efforts primarily occurred at a swap meet (outdoor marketplace) frequented by the Hispanic community in Tucson. Family and friend referrals, printed advertisements, and social media posts comprised additional recruitment efforts. We also contacted individuals who had previously expressed interest in weight loss treatment and signed consent to be contacted for future intervention studies. Interested men were instructed to call study staff and a telephone screening was conducted to determine initial eligibility. Those

		Phase 1 12-weeks	Phase 2 12-weeks
Recruitment and Baseline Assessments	Randomization (n=50)	Gender- and culturally-sensitive weight loss intervention (GCSWLI; n=25)	Bi-weekly phone calls
		Wait-list Control (WLC; n=25)	GCSWLI plus mHealth technology

Fig. 1. Study phases and participant randomization for the ANIMO Pilot Study.

engaged at face-to-face recruitment events were given the option of being screened on-site or during a future phone call with study staff. Telephone and on-site screenings included a detailed description of the study and its potential risks and benefits. Upon the participants' verbal agreement, study staff initiated the screening process by asking questions regarding medical history and other pertinent questions related to exclusion/inclusion criteria.

2.6. Informed consent

All eligible participants were invited to the Collaboratory where complete details of the study were given in the participant's preferred language (English or Spanish). During this time, participants were encouraged to ask questions about the study's procedures. Consent forms were available in the participant's preferred language.

2.7. Certificate of Confidentiality

Due to ethical considerations of our population (e.g., U.S. citizenship status) and sensitive research information collected, we obtained a Certificate of Confidentiality (CC-DK-16-021) from the National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The researchers could use this Certificate to protect the participants' privacy and legally refuse to disclose information that may identify the participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena.

2.8. Intervention development

The first step in developing effective culturally-tailored weight loss interventions is to identify a target population, learn about their views on weight and body shape, and understand their preferences, customs, and beliefs [20]. Consequently, we conducted semi-structured interviews with overweight/obese Hispanic men ($n = 14$) to examine their perspectives on health behaviors related to weight management. In brief, our findings revealed that while our participants had a rich understanding of how obesity-related disease affects health, they struggled with access to affordable foods, safe spaces for physical activity, strenuous work schedules, and familial influences that hindered their weight management efforts [22]. Thus, individual, cultural, familial, and environmental influences required the future programs to be tailored to meet the needs of this population. However, these data were from a sample of men who were primarily U.S. born, English speaking, and well-educated. These factors influence acculturation, which is the adoption of practices, social values, and behaviors (e.g., diet) of the majority culture [24]. As a result, we focused latter efforts on recruiting a less-acculturated sample (e.g., Spanish-speaking; foreign-born, low educational attainment) for parallel inquiry. We completed a second qualitative assessment with 15 Spanish-speaking Mexican-origin men who were interested in engaging in behavior changes to improve diet and physical activity habits for weight management [23]. The men identified additional barriers to weight management-related behaviors; specifically, that healthful eating habits were hindered by lack of knowledge, sociocultural norms, and conceptualizations of masculinity [23]. Participants also recommended viable strategies for weight management including expanding knowledge of obesity-related risks, promotion of traditional Mexican foods, and increasing participant-interventionist accountability.

2.9. Gender- and cultural-tailoring

We considered a variety of frameworks for the gender and cultural tailoring of our intervention. We chose a framework formulated by Bernal & Saez-Santiago [25] for its comprehensive consideration of a variety of fundamentals of adaptation. Bernal and Saez-Santiago's

framework is composed of eight elements that are used to “culturally center” an intervention including; (1) language, (2) persons, (3) metaphors, (4) content, (5) concepts, (6) goals, (7) methods, and (8) context [25]. The use of these elements in practice was as follows: (1) *Language* is a carrier of culture; therefore, we delivered our intervention in the participants preferred language (English or Spanish). (2) *Persons* highlights the importance of the cultural and linguistic matching of participant and interventionist as such, we employed the use of Hispanic male interventionists who were from the local community and had a broad understanding of the complex sociocultural and socioeconomic barriers to weight management that our participants may face. (3) *Metaphors* encompassed the inclusion of objects and symbols of the target population in the space where the intervention was delivered. Therefore, this intervention took place at a location that was highly accessible to our study population. The research team ensured that the visible décor and any passive information that was hanging on the walls was culturally and linguistically appropriate. (4) *Content* adaptations call for the inclusion of values, customs, and traditions shared by the intervention sample within all verbal communication (e.g., recruitment communication) and/or any distributed materials (e.g., flyers, informational pamphlets etc.). Consequently, all participant communication from recruitment to intervention, whether verbal or otherwise, was tailored to be culturally- and regionally-responsive. (5) *Concepts* considered the distinct ways in which different cultures and genders can define, manifest, and treat health concerns. As such, using our formative findings, we considered the opinions and perspectives of weight management of Hispanic males to better frame attainable bilateral communication with our participants. (6) *Goals* entailed that participant objectives of the intervention should be created with attention to the specific values, customs, and traditions of a client's gender- and culturally-bound definitions of success. Our preliminary work [22,23] suggested that prescribed dietary and physical activity changes should take into consideration cultural gender norms as well as strenuous work schedules. For instance, prescribed dietary changes were based on alterations to participants' current diets (e.g., consumption of 2 flour tortillas versus 4 tortillas per meal) or the inclusion of culturally appropriate alternatives (e.g., substitution of corn tortillas for flour tortillas every other meal). (7) *Methods* referred to procedures implemented to simplify the achievement of intervention goals and their consideration of cultural and/or gender norms, which in this case could include our culturally- and/or gender-adapted recruitment sites that were chosen (e.g., Swap Meet). (8) *Context* referred to the consideration of a participant's broader social, economic, and political reality, encompassing the effects of social and cultural processes such as socio-economic status, acculturative stress, immigration status, and neighborhood effects on their adherence to intervention-related prescribed behavior change. Cultural adaptation elements, their application, and examples of operationalization are summarized in Table 1.

2.10. Phase 1: intervention components

Individual counseling sessions were identified as a preferred intervention delivery mode in our preliminary work [22,23]. Therefore, intervention participants attended 12 weekly 30–45-min individual counseling sessions guided by a trained bilingual Hispanic male lifestyle coach. Participants were weighed in each week prior to their session to assist interventionists with weight counseling and goal-setting. Counseling sessions were tailored to the needs of the participants (e.g., language preference, evening/weekend sessions, waiting/childcare area). The lifestyle coach provided expertise, goal setting support, and self-monitoring reminders for participants. Participants also received tailored lesson materials focused on behavioral strategies for adopting and maintaining healthy eating and physical activity behaviors based on Social Cognitive Theory (SCT) [26] and Problem Solving Theory [27]. For instance, the lessons included information necessary for participants to possess the skills and knowledge to perform behaviors. Self-

Table 1
Cultural adaptation elements, their application, and examples of operationalization based on the framework by Bernal & Saez-Santiago [25].

Cultural Adaptation Element	Application	Example of Intervention Adaptation
Language	Treatment delivered in the native language of a target population assumes at least a superficial integration of culture.	Study recruitment, informed consent, and all intervention materials were delivered in participant's preferred language.
Persons	Ethnic and gender matching of service providers enhances provider positionality in client-therapist relationships.	All intervention sessions were delivered by bicultural and bilingual Hispanic males.
Metaphors	Inclusion of objects and symbols of the target population in the space where programs were delivered or the delivery of treatment out of a culturally driven space (church, cultural center, neighborhood/community center, etc.).	All recruitment materials were designed to be culturally and gender appropriate. Recruitment strategies were tested and qualitatively triangulated with target population to ensure congruency. In addition, the intervention was delivered in a space well-recognized and accessible to our study population.
Content	Inclusion of values, customs, and traditions shared by the populations receiving treatment within communication (recruitment communication) and any materials (flyers, informational pamphlets etc.) received.	All communication with participants was centralized around <i>personalismo</i> , <i>simpatia</i> , and <i>respeto</i> .
Concepts	Consideration of how different cultures and genders define, manifest, and treat physical, behavioral, and social problems may be very different.	Health-related information was presented to participants in a manner that would promote understanding. Risk-based communication was used when providing feedback on cardiometabolic lab values, because fear-appeal communication was identified as a motivator for behavior change in our formative work.
Goals	Goals of treatment should be created with attention to the specific values, customs and traditions of a client's gender- and culturally-bound definitions of success.	Interventionists ensured that dietary changes considered culturally-bound food choice preferences so that behavior changes were attainable. For instance, instead of replacing tortillas with an alternative food or eliminating all together, portion control was suggested. Gender- and culturally-bound norms related to strenuous work schedules and its impact on health were discussed at counseling sessions to encourage participants to achieve physical activity recommendations.
Methods	All program procedures should facilitate achievement of treatment goals and their consideration of cultural and or gender norms.	The intervention provided the participant and their family a free three-month gym membership to facilitate achieving physical activity recommendations.
Context	Consideration of a participant's broader social, economic, and political reality.	Participant's boarder context was considered in every aspect of intervention delivery. For example, discussions related to gender role strains (the role of the man in the household) took place within intervention sessions. In addition, issues related to access of healthy foods or safe spaces for physical activity were discussed within the context of socio-economic status.

regulation was reinforced through the promotion of self-monitoring behaviors, goal setting, and self-instruction. In addition, problem solving exercises were used to improve adherence to study goals and improve self-efficacy [28]. Lesson material content was modeled after the publicly available evidence-based DPP lifestyle intervention [29,30]. However, we recognized that cultural, ethnic, and gender differences impact weight loss behaviors (eating and physical activity). Therefore, we incorporated tailored content for Hispanic men obtained from our preliminary work [22,23] to address these factors during counseling sessions and in the written materials that were provided to all participants (Table 2). Participants self-monitored their body weight eating, and physical activity behaviors in a weekly journal. The information provided in these journals was used to generate discussion points for the lifestyle coach. Further, as family social support was identified as an important intervention component, spouses/significant others were invited to attend weeks 1 and 12 of counseling sessions. The duration of the counseling sessions was recorded to determine how much time participants spent in intervention sessions.

2.11. Diet and physical activity prescriptions

Participants were prescribed a calorie and fat gram goal to reduce total energy intake to approximately 1200–1800 calories per day dependent on their initial body weight [8]. To facilitate the adoption of the dietary recommendation, participants were provided with culturally-tailored meal plans and grocery lists that allowed them to make small, practical dietary changes of ~100 calories/meal each day [31]. Specific focus areas included reducing the amount of foods consumed, modifying the types of food they eat, making small changes when eating out, and reducing liquid calories (e.g., alcohol and sugar-sweetened beverages). We also addressed specific eating behavior issues identified in our formative work [22,23] including: access to healthy food, cost of food, meal preparation, portion control, and family/social

events that may prohibit optimal change [32]. Participants were prescribed weekly exercise goals with the duration increasing from 15 to 40 min, 5 days a week, over the 12-week program [33]. Aerobic physical activity, similar to a brisk walk, was recommended as the primary mode of physical activity. However, participants could engage in any physical activity modes based on their preference. Additional issues related to physical activity were addressed including: neighborhood safety, childcare to allow time for physical activity, and acceptance from other family members [34]. We provided strategies to overcome these barriers (e.g., providing a list of neighborhood resources for physical activity). In addition, we provided a 12-week membership to the YMCA. Participants were reminded of individual appointments and other study-related activities via their preferred contact method (e.g., telephone, email, SMS text messaging, etc.).

2.12. Phase 2: intervention components

During phase 2, GCSWLI participants received bi-weekly phone calls across a 12-week follow-up. Phone calls lasted approximately 10 minutes, and study staff followed a script to review current body weight, eating and activity behaviors, and specific barriers for weight loss and maintenance of loss and diet and physical activity behaviors. After 12-weeks of receiving no intervention, WLC participants received the GCSWLI plus mHealth technology support. The integration of mHealth technology, in combination with face-to-face counseling, was due to our formative work suggesting it may improve participation and assist participants with behavior change, particularly for physical activity [22]. This included tailored text messaging from study staff and real-time self-monitoring support through the use of the Fitbit Charge 2, a consumer-wearable physical activity tracker, and a Fitbit Aria Wi-Fi Smart Scale for body weight. Participants were encouraged to use the Fitbit during all waking hours and weigh themselves daily using the Aria smart scale. In addition, two weekly text messages were tailored to

Table 2
Summary of lesson material content and intervention tailoring for Hispanic men.

Lesson Topic	Material Content for Individual Counseling Sessions	Tailoring for Hispanic men
Week 1: The Behavioral Approach to Changing Your Eating and Exercise Habits	<ul style="list-style-type: none"> ● Welcomed to the ANIMO study ● Discussed motivation for weight loss ● Introduced the concept of self-monitoring <ul style="list-style-type: none"> ○ Review ANIMO study diet and exercise journals ● Reviewed calorie/fat intake and exercise goals ● Reviewed the calorie and fat gram goals for the upcoming week ● Reviewed the exercise goal for the upcoming week 	<ul style="list-style-type: none"> ● Reviewed cardiometabolic lab values for understanding of personal risks of disease (fear appeal/arousal) ● Reviewed gender role strain and its impact on health behaviors and outcomes (gender role strain) ● Reviewed social and cultural norms of health behaviors and health outcomes (fatalism, familism)
Week 2: Using Food Labels	<ul style="list-style-type: none"> ● Discussed ANIMO study food and exercise journal from previous week <ul style="list-style-type: none"> ○ Review progress towards diet and exercise goals ● Introduced and demonstrate how to read food labels ● Reviewed the calorie and fat gram goals for the upcoming week ● Reviewed the exercise goal for the upcoming week 	<ul style="list-style-type: none"> ● Discussed social and cultural norms related to diet behaviors (e.g., traditional foods, familial influence, convenience) ● Discussed caloric value of commonly consumed traditional foods ● Used visual aids to demonstrate how sugar is in commonly consumed beverages (fear appeal/arousal)
Week 3: Developing and Implementing Your Exercise Program	<ul style="list-style-type: none"> ● Discussed ANIMO study food and exercise journal from previous week <ul style="list-style-type: none"> ○ Review progress towards diet and exercise goals ● Reviewed the importance of exercise and its health benefits ● Reviewed the role of exercise for weight loss and weight maintenance ● Made a plan to exercise <ul style="list-style-type: none"> ○ Chose a type of exercise ○ Chose the time in the day that works best to exercise ○ Brainstormed any strategies to fit in exercise during the work week ● Introduced the Rating of Perceived Exertion (RPE) scale ● Reviewed the calorie and fat gram goals for the upcoming week ● Reviewed the exercise goal for the upcoming week 	<ul style="list-style-type: none"> ● Reviewed body composition scans and discuss the importance of maintaining lean muscle tissue during weight loss (fear appeal/arousal) ● Discussed strenuous work schedules and occupation type (e.g., construction work) influence on exercise adherence ● Discussed environmental influences (e.g., neighborhood safety, access to exercise facilities) impact on exercise behaviors
Week 4: Problem Solving	<ul style="list-style-type: none"> ● Discussed ANIMO study food and exercise journal from previous week <ul style="list-style-type: none"> ○ Reviewed progress towards diet and exercise goals ● Reviewed the five general stages involved in the process of problem solving <ul style="list-style-type: none"> ○ Recognition that problems are normal ○ Problem definition ○ Developed possible solutions or alternatives ○ Decision making ○ Carrying out the solution ● Highlighted the importance of: <ul style="list-style-type: none"> ○ Avoiding criticism ○ Generating multiple ideas ○ Combining ideas ● Discussed a problem related to diet or exercise <ul style="list-style-type: none"> ○ Practice problem solving ● Reviewed the calorie and fat gram goals for the upcoming week ● Reviewed the exercise goal for the upcoming week 	<ul style="list-style-type: none"> ● Discussed social and cultural processes (e.g., socio-economic status, acculturative stress, immigration status, and neighborhood effects) influencing diet and physical activity behaviors
Week 5: Stimulus Control Cues in Your Physical Environment for Eating & Exercise	<ul style="list-style-type: none"> ● Discussed ANIMO study food and exercise journal from previous week <ul style="list-style-type: none"> ○ Review progress towards diet and exercise goals ● Introduced the concept of food cues ● Discussed and choose techniques to limit activities while eating ● Discussed and choose techniques to change kitchen or room cues 	<ul style="list-style-type: none"> ● Discussed environmental influences (e.g., neighborhood safety and access to healthy foods) impact on behaviors ● Discussed the role of significant others (primary caretakers of the home), family, and friends on behavior change (role strain)

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Table 2 (continued)

Lesson Topic	Material Content for Individual Counseling Sessions	Tailoring for Hispanic men
Week 6: The Role of Thoughts in Weight Management Taking Responsibility for Your Weight Loss Behaviors	<ul style="list-style-type: none"> ◦ Introduce the concept of a Designated Eating Place (DEP) ● Introduced change cues for exercise <ul style="list-style-type: none"> ◦ Discuss and choose techniques to remove cues for inactivity ● Reviewed the calorie and fat gram goals for the upcoming week ● Reviewed the exercise goal for the upcoming week ● Discussed ANIMO study food and exercise journal from previous week <ul style="list-style-type: none"> ◦ Review progress towards diet and exercise goals ● Reviewed tips for handling any obstacles faced during behavior change <ul style="list-style-type: none"> ◦ Avoid extreme thinking and perfectionism ◦ Avoid unrealistic expectations and negative expectations ◦ Avoid excuses/rationalizations ◦ Avoid negative attitude ● Reviewed the role of negative thoughts ● Reviewed how to combat negative thoughts ● Reviewed tips to build self-efficacy <ul style="list-style-type: none"> ◦ Start small ◦ Set goals for behaviors, not weight loss ◦ Look for a good role model ◦ Learn from past experiences ◦ Get support ◦ Reward yourself ● Reviewed the calorie and fat gram goals for the upcoming week ● Reviewed the exercise goal for the upcoming week 	<ul style="list-style-type: none"> ● Reviewed gender role strain and its impact on psychological health
Week 7: Eating Out in Restaurants	<ul style="list-style-type: none"> ● Introduced tips to manage eating out in restaurants ● Reviewed the role of planning ahead to improve success ● Reviewed tips on selecting and ordering a meal <ul style="list-style-type: none"> ◦ Be cognitive of extra calories and fats ◦ Avoid being intimidated to ask for special request ◦ Always ask how foods are prepared ◦ Don't be afraid to leave food on plate ◦ Avoid “get your money’s worth” mentality ● Reviewed tips when eating at buffets or fast food restaurants ● Introduced healthy beverage guidelines ● Reviewed alcoholic beverages calorie and fat gram levels ● Reviewed the calorie and fat gram goals for the upcoming week ● Reviewed the exercise goal for the upcoming week 	<ul style="list-style-type: none"> ● Discussed social and cultural processes influencing diet behaviors ● Discussed strenuous work schedules and occupation type (e.g., construction work) influence on eating food away from home ● Discussed the role of convenience, family, friends, and significant others, in decisions to eat food away from home (role strain)
Week 8: More Volume, Fewer Calories	<ul style="list-style-type: none"> ● Discussed ANIMO study food and exercise journal from previous week <ul style="list-style-type: none"> ◦ Review progress towards diet and exercise goals ● Introduced the concept of increasing the volume of food, while consuming fewer calories ● Reviewed tips with participants on how to add volume of food <ul style="list-style-type: none"> ◦ Add water to dishes cooked ◦ Add fruit to increase water and fiber ◦ Add vegetables to increase water and fiber ◦ Add soups and salads to diet ◦ Add legumes, nuts, seeds, and whole grains to diet ● Reviewed how to evaluate the impact of calorie and fat intake on satiety ● Reviewed the calorie and fat gram goals for the upcoming week 	<ul style="list-style-type: none"> ● Discussed social and cultural processes influencing diet behaviors ● Reviewed the concept of diet quality (e.g., food as fuel)

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Table 2 (continued)

Lesson Topic	Material Content for Individual Counseling Sessions	Tailoring for Hispanic men
Week 9: Smart Snacking	<ul style="list-style-type: none"> ● Reviewed the exercise goal for the upcoming week ● Discussed ANIMO study food and exercise journal from previous week <ul style="list-style-type: none"> ○ Review progress towards diet and exercise goals ● Highlighted smart snacking versus unhealthy snacking ● Reviewed timing of snacks, particularly during the work day ● Reviewed tips how to snack healthy <ul style="list-style-type: none"> ○ Being prepared ○ Controlling snack portions ● Reviewed how to snack, but continue to stay within calorie and fat gram goals ● Reviewed the calorie and fat gram goals for the upcoming week ● Reviewed the exercise goal for the upcoming week 	<ul style="list-style-type: none"> ● Discussed social and cultural processes influencing diet behaviors ● Reviewed the concept of diet quality (e.g., food as fuel)
Week 10: Learning to Manage Food Cravings and Urges	<ul style="list-style-type: none"> ● Discussed ANIMO study food and exercise journal from previous week <ul style="list-style-type: none"> ○ Review progress towards diet and exercise goals ● Reviewed the concept of food cravings ● Introduced how to handle psychological factors associated with food cravings <ul style="list-style-type: none"> ○ Recognize if food cravings are habitual ○ Recognize if food cravings are a result of emotions ● Introduced participants to the “5 D’s” strategy when a craving arises: <ul style="list-style-type: none"> ○ Delay ○ Distract ○ Distance ○ Determine ○ Decide ● Introduced the concept of surfing the urge <ul style="list-style-type: none"> ○ Halting before eating to decide if it is an emotional response ○ Delaying eating until the urge comes down ● Reviewed the calorie and fat gram goals for the upcoming week ● Reviewed the exercise goal for the upcoming week 	<ul style="list-style-type: none"> ● Discussed social, cultural, and environmental influences impact on food cravings ● Discussed the role of family, friends, significant others on eating behaviors (role strain)
Week 11: Slippery Slope and Relapse Prevention	<ul style="list-style-type: none"> ● Discussed ANIMO study food and exercise journal from previous week <ul style="list-style-type: none"> ○ Review progress towards diet and exercise goals ● Explained that relapses may occur but can be stopped and rebounded from ● Introduced participants to the idea of slip versus slide <ul style="list-style-type: none"> ○ Slips are a normal part of lifestyle change, to be expected, and inevitable ● Reviewed ways to avoid slips from becoming slides and slides from becoming falls ● Reviewed with participants on how to set up a relapse prevention plan ● Reviewed with participants on how to develop a “comeback” plan ● Reviewed the calorie and fat gram goals for the upcoming week ● Reviewed the exercise goal for the upcoming week 	<ul style="list-style-type: none"> ● Discussed social and cultural processes influencing behavior change
Week 12: Looking Forward	<ul style="list-style-type: none"> ● Discussed ANIMO study food and exercise journal from previous week <ul style="list-style-type: none"> ○ Review progress towards diet and exercise goals ● Highlighted struggles and successes during the program ● Discussed the role of progress, not perfection in behavior change ● Reviewed behaviors of successful weight loss and weight maintenance ● Reviewed next steps 	<ul style="list-style-type: none"> ● Reviewed how perception of gender role strains has changed over the course of the intervention ● Reviewed overall progress and re-evaluated personal risks ● Reassessed motivation to continue weight loss behaviors

their self-reported barriers and observed from their Fitbit tools. Intervention strategies of Phase 1 were maintained during this delivery, thereby ensuring all participants had the appropriate tools to continue weight loss efforts regardless of mHealth use. To address potential barriers related to the uptake of mHealth support, participants were instructed on how to use all components during their first in-person session.

2.13. Retention of participants

We used common strategies to enhance participant retention, including collecting contact information of participants and at least two family members; program reminders (e.g., phone calls and text messages); activities and events to engage family members (e.g., barbeque); “mini-assessments” at weeks 6 and 18; and incentives to complete assessments. Participant incentives in the amount of \$25 were awarded for the completion of the baseline assessment and \$50 for the completion of assessments at week 12 and 24. The participants received \$25 for the completion of mini-assessments. In total, a participant could receive up to \$175 cash if all assessments were completed.

2.14. Measures

Full clinical assessments were conducted at baseline, 12, and 24 weeks. Mini-assessments were conducted at weeks 6 and 18. Table 3 displays an assessment schedule for data collection. Outcomes were assessed by two clinical assessment coordinators blinded to the treatment arm assignment. To ensure data quality control and assurance, the Principal Investigator held training sessions with the coordinators prior to data collection.

Table 3
Assessment data collection schedule for the ANIMO pilot study.

	Baseline	6 weeks	12 weeks	18 weeks	24 weeks
Informed Consent	X				
Physical Activity Readiness Questionnaire	X				
Medical History Form	X				
Alcohol Use Disorders Identification Test	X				
Drug Abuse Screening Test	X				
Demographics Questionnaire	X				
Height	X				
Weight	X	X	X	X	X
Date of Birth/Age	X		X		X
Heart Rate	X		X		X
Blood Pressure	X		X		X
Waist Circumference	X		X		X
Dual energy X-ray absorptiometry	X		X		X
Magnetic Resonance Imaging (GCSWLI only)	X		X		
Buccal Swab	X				
Blood Collection	X		X		X
Global Physical Activity Questionnaire	X	X	X	X	X
Self-Efficacy and Diet Questionnaire	X	X	X	X	X
Self-Efficacy and Physical Activity Questionnaire	X	X	X	X	X
Self-Efficacy and Weight Loss Questionnaire	X	X	X	X	X
Social Support and Diet Questionnaire	X		X		X
Social Support and Physical Activity Questionnaire	X		X		X
Eating Behavior Inventory	X	X	X	X	X
Pittsburgh Sleep Quality Index	X	X	X	X	X
Food Choice Questionnaire	X		X		X
Goal Setting Assessment	X		X		X
Acculturation Rating For Mexican Americans-II	X		X		X
Conformity to Masculinity Inventory	X		X		X
Southwestern Food Frequency Questionnaire	X		X		X
Motivators for Physical Activity	X		X		X
Perceived Stress Scale	X		X		X
Lewis and Rook Partner Influence Scale	X		X		X
Adverse Childhood Experiences Scale	X		X		X
Dyadic Coping Inventory	X		X		X
Participant Satisfaction Questionnaire	X		X		X
Qualitative Inquiry					X
Participant Incentives	\$25.00	\$25.00	\$50.00	\$25.00	\$50.00

3. Methods for assessing pilot study outcomes

3.1. Anthropometry

Height was measured to the nearest 0.1 cm (cm) using a ShorrBoard® wall-mounted stadiometer with participants removing their shoes prior to the measurement. Two measurements were taken. A third measurement was taken if the first two measurements differed by more than 0.5 cm. The average of the two measurements which met the criteria above was recorded for data collection. Body weight was measured to the nearest 0.1 kg (kg) using a Seca 876 digital scale with the participant in street clothes without shoes. Two measurements were taken. A third measurement was taken if the first two measurements differed by more than 0.2 kg. The average of the two measurements which met the criteria above was recorded for data collection. BMI was calculated using body weight in kg divided by squared height in meters (kg/m²).

Waist circumference was obtained using a Gulick measuring tape recorded to the nearest 0.1 cm. Waist circumference was measured in the horizontal plane directly at the umbilicus. Two measurements were taken at each site. A third measurement was taken if the first two measurements differed by more than 2.0 cm. The average of the two measurements closest to each other was recorded for data collection.

Resting blood pressure and heart rate were measured on the participant's left arm using an Omron Digital Blood Pressure Monitor HEM-907XL automated blood pressure system. Using a Gulick measuring tape, an arm measurement was performed on the lateral aspect of the left arm at the midpoint between the acromion process to the olecranon process to determine the appropriate cuff size. Upon a 5-min resting

period with the participant in an upright position with feet flat on the floor, two blood pressure measurements were taken with a 1-min time period between each measurement. A third blood pressure was taken if the mean difference between the systolic blood pressure measurements differed by 10 mmHg or greater and/or the diastolic blood pressure measurements differed by 6 mmHg or greater. The average of the two measurements which met the criteria above was recorded for data collection. If the measurements did not meet the criteria, the average of all three was recorded for data collection. In addition, if the mean resting systolic blood pressure was ≥ 150 mmHg or average diastolic blood pressure was ≥ 100 mmHg at baseline, the participant was excluded from participation and referred back to their physician.

3.2. Body composition

It is recommended that body fat percentage be measured as an additional outcome in weight loss interventions due to limitations of body weight and BMI informing only on total change, not the types of tissue mass lost [35]. Therefore, body composition including bone mass, body fat percentage, and muscle mass was measured using the whole-body dual-energy X-ray absorptiometry (DXA, Lunar Prodigy; Lunar, Madison, WI, USA). Direct measures of regional (trunk, abdomen, and thigh), whole body soft tissue composition (lean and fat masses), and whole-body mineral mass also were obtained. All DXA scans were undertaken by a certified bone densitometry technologist (CBDT).

3.3. Magnetic resonance imaging (MRI)

The prevalence of NAFLD and the accelerated incidence of hepatocellular carcinoma (HCC) and mortality in Hispanic men [36] underscores the need to develop therapeutic interventions for this high-risk, understudied population. Non-invasive MRI was used as a therapeutic response biomarker to measure abdominal subcutaneous, visceral adipose tissue (VAT) volumes, and liver fat fraction content in men enrolled in the GCSWLI at baseline and week 12. All images were acquired by a trained MRI technologist using an 8-channel phased array, dual breast coil on a 1.5 T MRI scanner (GE Signa NV-CV/i, Milwaukee, WI, USA).

3.4. Cardiometabolic measures

Fasting blood samples (venipuncture), 25 ml, were collected by a trained phlebotomist using a specific approved protocol for the purpose of examining cardiometabolic measures including:

- A comprehensive metabolic liver/kidney panel (albumin, globulin, A/G ratio, total protein, alkaline phosphatase, alanine transaminase (ALT), aspartate transaminase (AST), total bilirubin, blood urea nitrogen (BUN), calcium, creatinine, BUN/creatinine ratio, GFR-glomerular filtration rate/estimated, electrolytes (sodium, potassium, chloride, carbon dioxide)).
- Total cholesterol, triglycerides, high-density lipoprotein (HDL), low-density lipoprotein (LDL), very low-density lipoprotein (VLDL), high-sensitive CRP, fasting glucose, and hemoglobin A1c (HbA1C). In the event elevated HbA1c values were observed, which may indicate undiagnosed or uncontrolled diabetes, participants with insurance were advised to seek care from their primary care physician (PCP) or referred to an endocrinologist at the Diabetes Program at the University of Arizona Medical Center. If they did not have insurance, they were advised to seek care from a list of health care providers which provided free/low cost/or services on a sliding scale.

Participants also had the option of allowing the study investigators to store some of the blood obtained but not used for other tests. This

will allow the researchers to derive metabolomics and molecular data that are complementary in obesity research and provide value for enhancing precision care in this health disparate population.

3.5. Physical activity

Physical activity was assessed using the validated Global Physical Activity Questionnaire (GPAQ) [37,38]. The GPAQ was available in both English and Spanish and provided minutes/week of physical activity of varying intensity and type.

3.6. Diet

We assessed diet using the Southwestern Food Frequency Questionnaire (SWFFQ) [39–41], a bilingual FFQ that includes food items commonly consumed by Mexican Americans and uses Mexican names for food items commonly given different names by other Spanish speakers (e.g., “naranja”, not “china”, for “orange”). Output data from the SWFFQ allowed for the calculation of daily total sugar, saturated fat, sodium, fiber, whole grain, and fruits/vegetables. Internal validity of the SWFFQ compares favorably with 24-h recall ($r = 0.822$) [41].

3.7. Sleep

We assessed sleep using the Pittsburgh Sleep Quality Index (PSQI) [42] which provides a retrospective measurement of sleep disturbances and asks the subject to consider their sleep for the past month. The PSQI differentiates between good and poor sleepers by providing a brief assessment of various sleep disturbances that may be clinically useful. It includes 19 items grouped into 7 equally-weighted component scores. In addition, there are 5 questions rated by the bed partner/roommate which are not included in the total score but are clinically informative.

3.8. Psychosocial measures

The following self-reported questionnaires were used to assess psychosocial measures which may influence diet and physical activity behaviors. All measures that were not available in Spanish were translated and back translated by native Spanish speaking staff to ensure accuracy of the translation. All Spanish language measures were then pilot tested with other Spanish-speaking staff to ensure accuracy of the translation and a direct comparison with English measures was made for content validity. There was no formal psychometric testing conducted for reliability and validity.

- Self-efficacy [43] and social support for diet and physical activity [44].
- Motives for Physical Activity Questionnaire [45] and Food Choice Questionnaire [46] to assess motivation for engaging in healthy diet and physical activity.
- Goal Setting and Relapse Prevention and Maintenance scales to assess the ability to set, monitor, and achieve goals (self-regulation), and avoid and respond to relapse [47].
- The Acculturation Rating Scale for Mexican Americans–II (ARSMA-II) [48] to measure acculturation related to language, ethnic identity, and ethnic interaction. The reliability and validity of the ARSMA-II are well established in English and Spanish [48].
- The Conformity to Masculinity Inventory to assess an array of dominant cultural norms of masculinity (e.g., winning, risk-taking, dominance, pursuit of status, and self-reliance [49].
- The Adverse Childhood Experiences Scale (ACEs) was used to assess developmental environment including past adverse childhood experiences such as abuse and neglect as well as family dysfunction that could be impactful to weight management [50].
- The Perceived Stress Scale (PSS) was used to assess levels of perceived stress over the last month [51]. The Dyadic Coping Inventory

(DCI) was used as a measure of perceived communication and dyadic coping that occurs in close relationship when one or both partners are stressed [52]. The Lewis and Rook Partner Influences Scales assesses the level of health-related support perceived to be given by one's partner [53].

3.9. Biological samples

Emerging evidence indicates that genetic variation may impact the efficacy of behavioral weight loss interventions [54]. Therefore, we performed an optional buccal cell collection for the extraction of DNA and subsequent genetic analyses. Interested participants were asked to spit approximately 2 ml of saliva into a specialized collection cup (i.e. Oragene-DISCOVER or similar cup or alternatively by cheek swab). This non-invasive, self-collection of buccal cells was needed only one time and performed at either the baseline (preferable) or follow-up visits. This work holds high potential to identify genetic predictors of obesity treatment responses for Hispanic males.

4. Monitoring for participant safety

As mentioned above, the risks associated with this pilot study were minimal. All participants provided self-reported body weight and height information, a detailed health history questionnaire, a Physical Activity Readiness Questionnaire (PAR-Q), as well as screening questionnaires related to alcohol [55] and substance abuse [56]. Based on these screening procedures, individuals for whom regular exercise or a reduced calorie and fat diet were contraindicated were not permitted to participate in this pilot study. During the intervention, participants also completed exercise and food records that were reviewed by the intervention team. Individuals found to be participating in inappropriate exercise and/or diet behaviors were counseled accordingly. The dietary component of this pilot study conformed to the dietary recommendations proposed by the clinical guidelines for obesity management [8]. In addition, the exercise protocols conformed to the minimal public recommendations and reflected the documented amount of exercise performed by individuals successful at weight loss and weight maintenance [57].

4.1. Serious adverse events (SAEs) and adverse events (AE)

Since this was a pilot feasibility study, there was no formal data safety and monitoring committee. An AE was any reaction or undesirable event that occurred while a subject was on the research protocol whether or not it was considered related to any study interventions. Such events included illness, signs, symptoms, or clinically significant laboratory test abnormality that appeared worsened during the course of the research study regardless of casual relationship to the study. A SAE is an AE that results in one of the following: 1) Death: death due to any cause; 2) Life-threatening condition: the subject was at potential risk of dying at the time of the AE or it is suspected that the use of continued use of the study interventions would result in the subject's death; 3) Hospitalization: this indicates initial admission to the hospital or prolongation of a hospital stay that results from the AE; or 4) Disability: the AE results in a significant, persistent, or permanent change, impairment, damage or disruptions in the participant's body function/structure, physical activities, or quality of life. An AE form was completed and documented at each clinical evaluation. AE assessments were done by measurement staff and these staff members also were responsible for collecting all relevant source documentation to ensure accurate assessment and grading of adverse events is achieved. The Principal Investigator was responsible for reviewing, confirming, and signing off on all AE forms. AE/SAE data also were used to assess whether there was any change in the risk-to-benefit ratio of this study. If potential safety concerns were identified that changed the benefit-to-risk ratio for participants, the UA IRB was notified to

determine the proper course of action to address these safety concerns.

5. Statistical analysis plan

5.1. Feasibility outcomes

The primary feasibility outcomes were recruitment and retention. Effectiveness of recruitment was determined by the number of Hispanic men who contacted the researchers and expressed interest in participation; numbers screened for eligibility; numbers eligible/ineligible for study inclusion and reason for ineligibility; and numbers enrolled in the study. Having assumed that recruitment would be carried out over 12-months, we aimed to recruit, on average, approximately 2 participants per week. A recruitment rate of less than this would have indicated a lack of feasibility. Retention was measured as the number of participants who remained in the pilot study at 12 and 24 weeks, divided by the number enrolled. Retention rates in weight loss trials have been shown to be between 60 and 80% [58,59]. A retention rate less than 60% would indicate a lack of feasibility. Descriptive analyses were conducted to examine process measures which included attendance at weekly counseling sessions, self-monitoring of dietary intake, physical activity, self-weighing, treatment satisfaction, and intervention delivery time. Descriptive analyses were also used to examine the use of mHealth technology (e.g., receipt of text messages, use of wearable activity monitors, and smart scale).

5.2. Treatment satisfaction and acceptability

Participants were asked to rate their overall satisfaction with the intervention at 12 and 24-weeks and if they would recommend the program to others [60]. Participants were also asked questions regarding satisfaction with their overall progress and for changing dietary and physical activity habits, and weight [61]. Each item was rated on a Likert scale with higher scores indicating greater program favorability. Open-ended questions and personal interviews were used to seek participant input on modifications that could be made to improve acceptability and effectiveness of the intervention. This helped identify which recruitment and intervention components were well-received, which could be improved, and which were not acceptable.

5.3. Efficacy outcomes

The primary efficacy outcome was weight loss. Weight was assessed at 0, 6, 12, 18, and 24-weeks and was modeled with a linear mixed model using an unstructured mean and covariance to guard against misspecification. Fixed effect terms include intervention group (GCSWLI, WLC), time, and their interaction. Linear mixed models account for the non-independence due to repeated measures on the same participant, and yield unbiased estimates for certain types of missing data [62]. Weight loss at 6, 12, 18, and 24-weeks for each group will be estimated using contrasts within this model and will be reported with 95% confidence intervals, as will the differences between groups. Similar models will be used to analyze the secondary outcomes of eating behaviors, physical activity patterns, psychological measures, and metabolic biomarkers.

5.4. Sample size justification

Since this was a pilot study and our objective was to assess feasibility, we did not undertake formal sample size calculations. However, this sample size will give us a 95% confidence interval of width no more than 0.32 (± 0.16) for proportion feasibility outcomes, and will be adequate to estimate variance components for a future definitive trial [63].

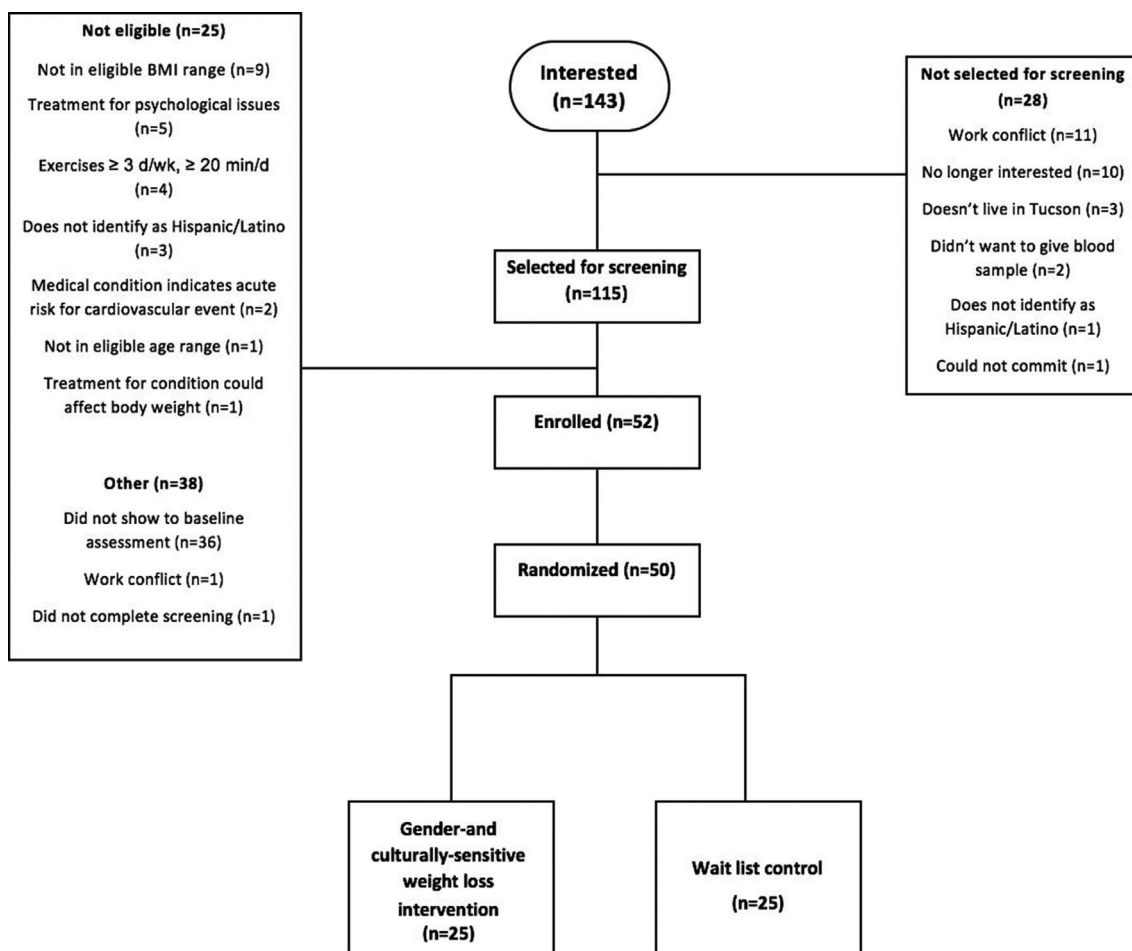


Fig. 2. Screening and recruitment process for the ANIMO pilot study.

6. Results

6.1. Recruitment outcomes

Fig. 2 shows results of the screening and recruitment process. Between June–August 2016, 143 men expressed interest in participation. Twenty-eight men elected not to complete eligibility screening due to the following reasons: work conflicts prohibiting participation (n = 11); were no longer interested in the study (n = 10); limited access to the study site (n = 3); did not want to provide a blood sample (n = 2); did not identify as Hispanic/Latino (n = 1); and could not commit to study requirements (n = 1). Of the 115 that were screened, face-to-face recruitment at the swap meet yielded the most men (n = 101), followed by referrals (n = 6), social media posts (n = 5), and printed flyers (n = 3). In total, 90 men were eligible, and 25 ineligible for study inclusion. Common reasons for ineligibility, after completing the eligibility screening, included not meeting the BMI criterion (n = 9), treatment for psychological issues (n = 5), high amounts of self-reported physical activity (n = 4), did not identify as Hispanic/Latino (n = 3), medical condition that indicated an acute risk for cardiovascular event (n = 2), not in eligible age range (n = 1), and treatment for condition that could affect body weight (n = 1). Of those who were eligible to participate, 36 men did not show for baseline assessments, 1 cited a work conflict and declined participation, and 1 did not complete the initial telephone screening. Fifty-two enrolled and completed baseline measures. Two men withdrew prior to randomization citing time commitment issues. Overall, 50 men were randomized into the study, exceeding our target recruitment. Further, since recruitment lasted approximately 12-weeks, approximately 4 participants

were enrolled per week, exceeding the target of 2 per week.

6.2. Characteristics of study participants

Participants randomized to the GCSWLI were slightly older on average than those randomized to the WLC (45.5 years versus 41.0 years, respectively); though the average baseline weight, BMI, and waist circumference were similar between groups. Participants randomized to the GCSWLI group were more acculturated on average than the WLC. A greater proportion of the GCSWLI group also primarily spoke English at home (48% vs 28%), identified themselves as Mexican-American (44% vs 24%), and were employed (84% vs 72%). Fewer participants in the GCSWLI were married than in the WLC (64% vs 84%). The GCSWLI also had more participants with some college or higher (56% vs 40%), but also more participants without any high school education (24% vs 8%). Differences in baseline characteristics were not statistically significant (Table 4).

7. Conclusion

Given the Hispanic population is the fastest growing in the U.S., efforts to identify strategies to promote weight control among Hispanic males, a population at high-risk of obesity and type 2 diabetes, has potential to significantly impact public health. The expected outcome of the proposed project is the identification of feasible and appropriate weight loss intervention strategies to improve engagement and weight management in this vulnerable and underserved population. This addition to the literature holds great promise in moving forward obesity prevention and treatment programs for Hispanic men. Notably, our

Table 4
Baseline characteristics of enrolled participants by randomized group.

	Total	WLC n = 25	GCSWLI n = 25	P-value
Age				
Mean (SD)	43.3 (11.4)	41.0 (12.1)	45.5 (10.4)	0.16
Weight (kg)				
Mean (SD)	102.6 (18.6)	102.1 (18.4)	103.1 (19.1)	0.96
BMI (kg/m²)				
Mean (SD)	34.1 (5.3)	33.9 (5.1)	34.3 (5.6)	0.86
Waist circumference (cm)				
Mean (SD)	114.1 (13.2)	113.4 (13.1)	114.9 (13.4)	0.95
Employed				
Nov	11 (22.0%)	7 (28.0%)	4 (16.0%)	0.50
Yes	39 (78.0%)	18 (72.0%)	21 (84.0%)	
Highest education completed				
Grades 1 through 8	8 (16.0%)	2 (8.0%)	6 (24.0%)	0.12
Attended some high school	7 (14.0%)	6 (24.0%)	1 (4.0%)	
Graduated high school or GED	11 (22.0%)	7 (28.0%)	4 (16.0%)	
Some college	14 (28.0%)	5 (20.0%)	9 (36.0%)	
Bachelor's, Graduate degree or higher	10 (20.0%)	5 (20.0%)	5 (20.0%)	
Married or lives with domestic partner				
No	13 (26.0%)	4 (16.0%)	9 (36.0%)	0.20
Yes	37 (74.0%)	21 (84.0%)	16 (64.0%)	
Birthplace				
Foreign Born	25 (50.0%)	14 (56.0%)	11 (44.0%)	0.57
U.S. Born	25 (50.0%)	11 (44.0%)	14 (56.0%)	
Racial Heritage				
Mexican	32 (64.0%)	18 (72.0%)	14 (56.0%)	0.23
Mexican-American	17 (34.0%)	6 (24.0%)	11 (44.0%)	
Puerto Rican	1 (2.0%)	1 (4.0%)	0 (0.0%)	
Primary language spoken at home				
English	19 (38.0%)	7 (28.0%)	12 (48.0%)	0.16
Spanish	29 (58.0%)	16 (64.0%)	13 (52.0%)	
Both equally	2 (4.0%)	2 (8.0%)	0 (0.0%)	
Mexican Orientation Subscale (MOS) of ARSMA-II				
Mean (SD)	3.9 (0.8)	4.0 (0.9)	3.8 (0.7)	0.35
Acculturation Level (ARSMA-II)^a				
Very Mexican oriented	21 (42.9%)	12 (50.0%)	9 (36.0%)	0.53
Mexican oriented to approximately balanced bicultural	13 (26.5%)	7 (29.2%)	6 (24.0%)	
Slightly Anglo oriented bicultural	11 (22.4%)	4 (16.0%)	7 (28.0%)	
Strongly Anglo oriented	3 (6.1%)	0 (0.0%)	3 (12.0%)	
Very assimilated; Anglicized	1 (2.0%)	1 (4.2%)	0 (0.0%)	
Total	50 (100.0%)	25 (100.0%)	25 (100.0%)	

^a One participant in the WLC group was not included in this section because the scale was designed for Mexican Americans.

research design also will allow us to examine participant characteristics and process measures related to the uptake of mHealth technology. This will inform the development of a future highly-scalable weight loss intervention that could be disseminated to a broader proportion of Hispanic males (and other populations) in settings where on-site weight loss delivery efforts may be a challenge (such as clinics, rural settings, or worksites in which access to facilities and services is limited). Further, we will use the variance estimates of this pilot study to design future adequately-powered studies to test the efficacy of the GCSWLI, with the intent of developing strategies and practice recommendations to expand the reach and impact of the intervention approach. However, it is important to recognize our study is limited to Hispanic men, primarily of Mexican-origin descent living in Southwest Arizona, which may limit the generalizability of our findings.

Conflicts of interest

The authors declare that they have no competing interests.

Ethics approval and consent to participate

All participants were informed about the potential benefits and risk of the weight loss intervention. All participants signed an informed consent prior to enrollment. The experimental design and study procedures were approved by the University of Arizona Institutional Review Board (IRB approval # 1604536275).

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.conctc.2018.01.010>.

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