Abstract

Background: Hispanic males have the highest rates of overweight and obesity compared to men of all other racial/ethnic groups. While weight loss can significantly reduce obesity related health risks, there is limited research examining effective gender- and culturally-tailored behavioral weight loss programs for Hispanic men.

Objective: To assess the feasibility of and preliminary efficacy of a 12-week gender- and culturally-sensitive weight loss intervention (GCSWLI) as compared to a waist-list control (WLC) in sedentary, Hispanic males with overweight/obesity.

Methods: Fifty Hispanic males (age: 43 years (SD 11); BMI: 34 ± 5 kg/m^2; 58% Spanish monolingual) were randomized to one of two groups: GCSWLI (n=25) or WLC (n=25). GCSWLI participants attended weekly in-person individual sessions with a bilingual, bicultural Hispanic male lifestyle coach, and were prescribed a daily reduced calorie goal and 225 minutes of moderate-intensity physical activity per week. The WLC were asked to maintain their usual diet and physical activity habits for 12 weeks. GCSWLI participants continued with 12 additional weeks of follow-up including bi-weekly phone calls with lifestyle coaches.

Results: At week 12, the mean weight loss in the GCSWLI was -6.3 kg (95% CI [-8.1, -4.4]) compared to -0.8 kg (95% CI [-2.5, 0.9]) for the WLC (difference = -5.5 kg, 95% CI (-8.0, -2.9), $p < 0.01$). At week 24, weight loss in the GCSWLI was maintained.

Conclusions: The GCSWLI appears to be a feasible strategy to engage Hispanic males in short-term weight loss. Our pilot study indicates preliminary evidence of efficacy, though confirmation of these findings are needed in a larger study.

Introduction

Hispanics are the largest and fastest growing racial/ethnic subgroup in the U.S., comprising nearly 17% of the total population (Colby & Ortman, 2014). Significant health disparities exist for this population, particularly in the areas of obesity and obesity-related comorbidities (Forrest, Leeds, & Ufelle, 2017). In fact, Hispanic men have the highest prevalence (78.6%) of overweight or obesity compared to non-Hispanic black men (69.2%) and non-Hispanic white (NHW) men (71.4%) (Ogden, Carroll, Kit, & Flegal, 2014). This prevalence is second only to non-Hispanic black women (82%) among all gender and racial/ethnic subgroups. Consequently, Hispanic men are at higher risk of developing obesity-related diseases such as hypercholesterolemia, non-alcoholic fatty liver disease (NAFLD), and type 2 diabetes (Ford, Maynard, & Li, 2014; Go et al., 2014; Lazo et al., 2013). Behavioral weight loss interventions are the cornerstone treatment for individuals with overweight or obesity (Jensen et al., 2014). Despite the urgent need for Hispanic men to engage in weight management efforts to improve health outcomes, it is estimated Hispanic men represent approximately 1% of males in U.S. study populations (Pagoto et al., 2012). To our knowledge, few weight loss interventions have been specifically designed for Hispanic men (Garcia et al., 2018).

Divergent patterns observed for incidence of obesity by gender are likely due to Hispanic men having a stronger tendency to adopt unhealthy lifestyle behaviors (e.g., physical inactivity and sugar-sweetened beverage consumption) compared to NHWs (Arredondo et al., 2016; Yang et al., 2014). In addition, Hispanic men face social and

cultural barriers to adopting healthy behaviors. Culture is a group phenomenon of situationally-based beliefs, practices, and behaviors that are differentially shared and distributed (Kagawa Singer, Dressler, George, & Panel, 2016). Cultural factors influencing Hispanic men's health include acculturation status (Ahluwalia, Ford, Link, & Bolen, 2007; Delavari, Sonderlund, Swinburn, Mellor, & Renzaho, 2013; Power, O'Connor, Orlet Fisher, & Hughes, 2015), physically-demanding jobs (Garcia, Valdez, & Hooker, 2017; Valdez, Amezquita, Hooker, & Garcia, 2017), dietary cultural norms (Power et al., 2015; Santiago-Torres et al., 2015), and access to health services (Timmins, 2002). Given these factors, efforts to tailor weight loss interventions more specifically to the needs of Hispanic men are warranted.

To date, studies examining the effectiveness of tailored weight loss interventions for Hispanics have primarily focused on women (Lindberg et al., 2012; Rosas et al., 2015). In one of the limited studies exploring the effectiveness of culturally-tailored weight loss strategies among a Latino immigrant population, Rosas et al. (2015) compared the effects of a case-management (CM) community-based intervention with and without community health workers (CHWs). At six months, weight loss in the CM + CHW group was significantly higher than the exclusive CM group; however, this weight loss was not maintained by the end of the two-year intervention. Notably, only 23% of the study population were men (Rosas et al., 2015). Lindberg et al. (2012) assessed the feasibility of a weight-loss intervention designed specifically for Spanish-speaking Mexican women. Development for this culturally- and gender-sensitive pilot intervention was informed by formative qualitative work, and the program included important adaptations

(e.g., the use of female interventionists, focus on group activities and traditional Mexican beliefs, etc.) (Lindberg & Stevens, 2011). Importantly, women achieved an average weight loss of -5.7% and -7.6% from baseline after 6 and 12 months, respectively (Lindberg et al., 2012). To our knowledge, this work has not yet been paralleled in Hispanic men.

Gender, as a result of its socially-constructed characteristics for men and women (Vlassoff & Garcia Moreno, 2002) and traditionally dichotomized gender identities, has been found to interact with various health-related factors and intersects with culturally-bound factors to influence general health behaviors (Garcia et al., 2017; Griffith, Gunter, & Allen, 2011; Griffith, King, & Ober Allen, 2013). Consideration of gender- and culturally related perceptions and attitudes surrounding weight management behaviors may provide an opportunity to inform interventions and deepen adaptations beyond common, superficial adaptations (e.g., translation of study materials, use of low-literacy materials) to improve the effectiveness of weight loss interventions. For example, tailoring interventions to reflect cultural beliefs and perception of gender roles has been demonstrated as a way to engage middle-aged and older African American men in physical activity interventions (Griffith, Allen, Johnson-Lawrence, & Langford, 2014). A recent systematic review examined cultural tailoring and adaptations of diabetes prevention programs for Hispanic individuals in the U.S. (McCurley, Gutierrez, & Gallo, 2017). The authors found there was a wide variety of tailoring variables; however, none were related to gender. In addition, a large gender bias was observed with eight of 12 studies comprised of ≥70% females. It was concluded that more studies are needed

which utilize randomized controlled designs, recruit Hispanic men, report intervention content, and utilize tailoring strategies.

Previous work by our team has examined Hispanic male's perspectives of health behaviors related to weight management (Garcia et al., 2017; Valdez et al., 2017). A variety of interpersonal, sociocultural, and environmental factors were identified by Hispanic men suggesting weight loss programs should be tailored to meet their unique needs. Based on these findings, we developed a pilot gender- and culturally-sensitive weight loss intervention for Hispanic men with overweight and obesity (Garcia et al., 2018). The purpose of the current study was to assess the feasibility, acceptability and preliminary efficacy of a gender- and culturally-sensitive weight loss intervention in 50 overweight/obese Hispanic males.

Methods

Study design, participants, and research setting

Details of the Animo (a Spanish term for motivation or encouragement) recruitment, retention, study design, protocol, participant baseline characteristics and measures can be found in previously published material (Garcia et al., 2018). Briefly, the Animo pilot study was a 24-week randomized controlled trial conducted July 2016-February 2017 that investigated feasibility and tested the effects of a gender- and culturally-sensitive weight loss intervention (GCSWLI) on body weight in Hispanic men compared to a wait-list control (WLC) group. Study participants met the following criteria: 1) 18-64 years of age; 2) body mass index (BMI) 25 to 50 kg/m^2; 3) self-identify as Hispanic; 4) ability to

provide informed consent and complete a health risk assessment before participation; and 5) speak, read, and write English or Spanish. In city, state (omitted for submission), nearly 36% of the population is Hispanic and 18.5% of persons live below the Federal Poverty Level (citation omitted for submission).

Randomization and blinding

Stratified block randomization was used to assign participants to intervention arm using random numbers generated by statistical software, Variable block sizes, where BMI category (overweight or obese) and diabetes status (yes/no) were used as strata. A statistician who had no contact with participants completed the randomization using a computer system. After randomization, two clinical assessment coordinators blinded to the treatment arm assignment assessed study outcomes measures.

Gender and Cultural Tailoring Framework

The GCSWLI was developed using the Diabetes Prevention Program lifestyle intervention as a template (Diabetes Prevention Program Research Group, 2002). To guide the tailoring process, we chose a framework developed by Bernal and Saez-Santigao which recommends focusing on eight elements to "culturally center" an intervention (Bernal & Sáez-Santiago, 2006). These elements include the following: (1) *language,* (2) *persons,* (3) *metaphors,* (4) *content,* (5) *concepts,* (6) *goals,* (7) *methods,* and (8) *context.* Given the extent of interactions between gender and cultural factors in our sample (Garcia et al., 2017; Valdez et al., 2017), a great deal of the tailoring for gender and culture occurred simultaneously. For example, within the element of

context, which considers a participants broader social, economic, and political reality, discussions were held during intervention sessions related to gender role strain and perceived challenges providing healthy foods for family members. Within the element of *goals*, discussions on dietary recommendations centered on culturally appropriate alterations to participants' current diets (e.g., substitution of corn tortillas for flour tortillas). Together, lifestyle coaches and participants brainstormed strategies to overcome these barriers on a weekly basis.

Intervention

The Animo study was conducted in two phases. In phase one, WLC participants were asked to maintain their usual diet and physical activity habits for 12 weeks. GCSWLI participants met with their trained bilingual, bicultural Hispanic male lifestyle coach in-person, one to one, once a week for 12 weeks. Lifestyle coaches were public health graduate students who received formal training by the principal investigator using a facilitator guide. Examples of weekly topics included the following: *using food labels*, *eating out in restaurants*, and *smart snacking*. During these individual counseling sessions, lifestyle coaches assisted participants in setting diet and physical activity goals and reminded participants to continue self-monitoring. Tailored materials were also provided, which focused primarily on developing and maintaining successful behavioral strategies for adopting and maintaining healthy eating and physical activity behaviors. Session materials were grounded in the Social Cognitive Theory (SCT) (Bandura, 2001) and Problem Solving Theory (D'Zurilla & Goldfried, 1971) with constitutive behavior change techniques shown to be successful in weight loss

interventions (e.g. self-monitoring, goal setting, self-instruction, self-efficacy) (Michie, West, Sheals, & Godinho, 2018). For example, problem solving exercises were used to support adherence to study goals and improve self-efficacy. Consistent with SCT, self-regulation was promoted through self-monitoring behaviors. Participants were required to bring completed self-reported written diaries, including dietary and physical activity behaviors, to individual counseling sessions wherein challenges to meeting goals were discussed. During these sessions, coaches worked with participants to identify and overcome perceived barriers (e.g., unhealthy traditional foods, familial influence, strenuous work schedules, etc.) to engaging in healthy diet and physical activity behaviors. In phase two, GCSWLI participants completed a 12-week follow-up. This consisted of bi-weekly phone calls lasting approximately ten minutes. Lifestyle coaches reviewed body weight status, barriers for eating and physical activity behaviors, and barriers for weight loss and weight maintenance. After 12 weeks of receiving no intervention, WLC participants received the GCSWLI plus mobile Health (mHealth) technology support.

Outcome Measures

Assessments for the GCSWLI and WLC were conducted at baseline, 12, and 24 weeks, including anthropometrics, and self-reported behaviors (e.g., dietary intake and physical activity).

Anthropometrics

Study personnel performed measurements of height (baseline only) using a wall-mounted stadiometer, weight using a calibrated digital scale (Seca 876), waist circumference using a flexible tape measure (Gulick), and resting blood pressure using an automated blood pressure cuff (Omron HEM-907XL). Measurements were taken twice for consistency and the average was recorded for data collection. Body composition was measured using the whole-body dual-energy X-ray absorptiometry (DXA, Lunar Prodigy; Lunar, Madison, WI, USA).

Dietary Intake

Diet was assessed using the validated Southwestern Food Frequency Questionnaire (SWFFQ) (R. Garcia, Taren, & Teufel, 1999). The SWFFQ is a bilingual FFQ adapted from the Arizona FFQ which includes over 150 food items commonly consumed by Mexican-Americans. Examples of these foods include corn/flour tortillas, *nopalitos*, traditional Mexican soups, machaca, and chorizo. Data retrieved from the SWFFQ allowed for the calculation of total daily energy intake and percentage of daily energy intake.

Physical Activity

Physical activity was assessed using the validated Global Physical Activity Questionnaire (GPAQ) (Cleland et al., 2014) in a self-administered format. It asks participants to describe their physical activity participation in three settings: activity at work, travel to and from places, and recreational activities in addition to sedentary

behavior. The questionnaire is available in both English and Spanish and provides duration (minutes per week) and intensity of physical activity.

Acculturation

Acculturation has been shown to impact attitudes, perceptions, and behaviors surrounding health-related activities and outcomes (Allen et al., 2014). Therefore, for descriptive purposes only, we assessed the level of acculturation related to language, ethnic identity, and ethnic interaction in study participants using the validated Acculturation Rating Scale for Mexican Americans-II (ARSMA-II) (Cuellar, Arnold, & Maldonado, 1995), available in both English and Spanish. The ARSMA-II contains two scales: a 30-item Anglo Orientation Scale (AOS) and a 17-item Mexican orientation scale (MOS). Scales are scored on a Likert scale from 1 (not all all) to 5 (extremely often or almost always). A mean AOS and MOS is calculated by summing the scores of the items and dividing by the number of items for each scale (e.g., 30 and 17). The MOS mean is subtracted from the AOS mean to obtain an acculturation score along a continuum from very Mexican oriented (mean < -1.33), Mexican Oriented to Approximately Bicultural (mean ≥ -1.33 and ≤ -.07) to very Anglo oriented (mean > 2.45).

Treatment Satisfaction

Satisfaction with the GCSWLI was assessed at 12 weeks using four questions rated on a Likert scale, with higher scores indicating greater program favorability (VanWormer, Martinez, Cosentino, & Pronk, 2010). Questions asked participants whether they would

recommend the program to others and prompted participants to rate their overall satisfaction with their progress toward changing dietary and physical activity behaviors and weight (Baldwin, Rothman, & Jeffery, 2009).

Statistical Analyses

Feasibility Outcomes

The primary feasibility outcomes were recruitment and retention. We aimed to recruit approximately two participants per week; a recruitment rate less than this was an indication of lack of feasibility. Retention rate was determined by the number of participants who remained in the study at 12 and 24 weeks divided by the total number enrolled. Because average retention rates in published weight loss interventions are reported between 60 and 80% (Lindberg et al., 2012; Wadden, Crerand, & Brock, 2005), we deemed the intervention not feasible if the retention rate was less than 60% . Additionally, we examined process measures including attendance at weekly counseling sessions, physical activity, self-monitoring of dietary intake, self-weighing, and treatment satisfaction using descriptive analyses.

Preliminary Efficacy

Weight loss was the primary efficacy outcome. Weight was assessed at baseline, 12 weeks, 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, are consistent with intention-to-treat analysis, and yield unbiased estimates for certain types of missing data (Bell & Fairclough, 2014). Weight loss at 12 weeks and 24 weeks for each group was estimated using contrasts within this model and was reported with 95% confidence intervals, as was the differences between intervention arms at week 12 (mHealth technology was integrated into the WLC at week 12, so comparisons at week 24 were not appropriate). Similar models were used to analyze the secondary outcomes of eating behaviors, physical activity patterns, and cardiometabolic biomarkers. The distribution of leisure time physical activity was right skewed with many participants reporting no activity, so a Wilcoxon rank sum test (comparing the change from baseline between groups) and Wilcoxon signed rank tests (comparing change from baseline within each group) were performed as a sensitivity analysis.

Results

Baseline Characteristics

Full demographic and clinical characteristics of participants have been published elsewhere (Garcia et al., 2018). The mean age of GCSWLI participants was 45.5 years (SD 10.4) compared to 41.0 years (12.1) in WLC participants. There were no statistically significant differences in body weight (GCSWLI: 102.1 kg (18.4); WLC: 103.1 kg (9.1)) and BMI (GCSWLI: 33.9 kg/m^2 (5.1); WLC: 34.3 kg/m^2 (5.6). Eleven GCSWLI participants and 14 WLC participants were born outside the U.S. Ethnic heritage was predominantly identified as Mexican (64%) and Mexican-American (34%), with 58% reporting Spanish as the primary language used at home (GCSWLI, n=13;

WLC, n=16). On the ARSMA-II MOS scale, 69.4% fell within the Very Mexican Oriented or Mexican Oriented to Approximately Bicultural categories (GCSWLI, n=19; WLC=15). Seventy percent held the equivalent of a high school diploma or greater (GCSWLI, n= 18; WLC=17).

Study recruitment and retention

Recruitment occurred over three months in which 143 men expressed interest in participating in the study. The most salient recruitment strategy was face-to-face at a swap meet (i.e. outdoor marketplace), which yielded 101 out of the 115 men who completed eligibility screening. Additional recruitment efforts included family and friend referrals (n=6), printed flyers (n=3), and social media posts (n=5). After completing eligibility screening, 52 men were enrolled and completed baseline measures, however, two men withdrew prior to randomization. In total, 50 men were randomized to the GCSWLI or WLC. Recruitment exceeded the predetermined target with approximately 4 participants enrolled per week. Forty-three of 50 participants completed the 12-week assessments, an overall attrition rate of 14%, 95% CI (4, 24%) (GCSWLI: n = 5, 20% vs. WLC: n = 2, 8%). Among participants who did not complete assessments, all were lost to follow-up for reasons unknown (**Figure 1**).

Program Utilization

Overall attendance at weekly individual counseling sessions was 77% among GCSWLI completers. In addition, 70% (8.4±3.9 diaries/participant) of self-monitoring diaries were completed across the 12 weeks (**Table 1**). Based on food and exercise journals,

participants self-reported 3.4±3.3 diet days/week, with an average self-reported calorie intake of 1337±410. Physical activity was reported 3.9±2.6 days/week for an average 214.5±173.8 mins/week during the 12-week intervention. In addition, participants reported self-weighing 3.6±3.3 days/week.

Treatment Satisfaction

GCSWLI participants who completed 12-week assessments were asked to rate their overall satisfaction with the intervention they received (**Table 2**). Overall, 94.7% reported they were satisfied or very satisfied with the weight management program. In addition, 94.7% reported they would recommend the program to others. On a scale of -4 "very dissatisfied" to 4 "very satisfied," GCSWLI participants said they were satisfied with their overall progress on changing body weight (median 4.0, IQR: 3.0 - 4.0), dietary habits (median 4.0, IQR; 3.0 - 4.0), and physical activity habits (median 4.0, IQR 2.5 - 4.0).

Weight loss, physical activity, and dietary change

As shown in **Table 3**, mean weight loss in the GCSWLI group was 6.3 kg (95% CI (4.4, 8.1)) from baseline to week 12 compared to 0.8 kg (95% CI (0.94, 2.5)) for the WLC group over the same period (difference = -5.5 kg, 95% CI (-8.0, -2.9)). Mean waist circumference and mean percent body fat both decreased significantly from baseline to week 12 in the GCSWLI group (waist circumference: 4.7 cm decrease, 95% CI (3.1, 6.2); percent body fat: 1.6% decrease, 95% CI (0.89, 2.4)), and these changes were significantly greater in the GCSWLI group than in the WLC group (waist circumference:

4.3 cm greater decrease in GCSWLI, 95% CI (2.1, 6.4); body fat percentage: 1.1% greater decrease in GCSWLI, 95% CI (0.08, 2.2)). Mean leisure time physical activity for GCSWLI participants increased by 183 minutes/week (95% CI (-26, 392)) from baseline to week 12, a 144.5 minutes/week (95% CI (-145, 433)) greater increase than in the WLC group over the same period. The results of sensitivity analyses agreed with results of the primary analysis described above. Mean caloric dietary intake in the GCSWLI group decreased by 51.3% (95% CI (36.7, 62.6)) from baseline to week 12, a 38.3% (95% CI (11.4, 57.1)) greater decrease relative to the baseline in the GCSWLI than the WLC group. All mean changes from baseline to week 12 for the above outcomes were maintained through week 24 in the GCSWLI group.

Discussion

Despite Hispanic men carrying a disproportionate burden of obesity compared to other racial/ethnic subgroups, no intervention to date has specifically targeted this population in a gender- and culturally-sensitive manner for weight loss. The Animo pilot study helps to fill this gap by providing important feasibility, preliminary efficacy, and parameter estimates to inform the development of larger scale, adequately-powered randomized controlled trials. Recruitment was perhaps the largest success of the study. In total, 115 individuals were screened and 50 participants recruited within a 3-month period equating to approximately 4 participants per week (Garcia et al., 2018). A large reason for this success was the utilization of in-person recruitment efforts at a local swap meet (outdoor marketplace). The swap meet was suggested by participants in our formative

research (Garcia et al., 2017), and highlights the importance of face-to-face interactions within community settings when engaging this population in clinical research.

Currently, limited evidence exists examining the success of recruitment strategies targeting Hispanic men for weight loss interventions (Pagoto et al., 2012), preventing the ability to make direct comparisons to the current study's recruitment findings. However, community-based recruitment efforts for weight loss lifestyle interventions among the general Hispanic/Latino populations have been reported by Rosas et al. (2015), who specifically recruited 207 low-income Latino participants within a 25-month time period (i.e., approximately 2 participants per week). Other community-based recruitment efforts include Vincent et al. (2014) who reported the recruitment of 58 Mexican-American adults at high-risk for type 2 diabetes mellitus using community-centered sites, specifically presenting at churches and community health events. Additionally, Lindberg et al. (2012) reported recruiting 47 Mexican-American women using bilingual flyers in community-serving businesses and radio and television media outlets. However, the previous two studies mentioned failed to report the duration of recruitment efforts. The current study demonstrates an effective strategy for engaging Hispanic men in clinical weight loss research.

Retention of all study participants was 86%, which compares favorably to other behavioral weight loss interventions developed for the Hispanic/Latino population. For example, *Vivimos Activos*, a Latino community weight loss intervention testing the effectiveness of culturally-tailored intervention through utilization of community health

workers, observed an 87% retention rate among the treatment arm participants (Rosas et al., 2015). In another culturally-sensitive lifestyle intervention targeting 47 Mexican-American women for weight loss, Lindberg et al. (2012) reported a lower retention rate of 55% in a 12-month weight loss program; however, this was likely due to their study design which sought to mirror a real-life setting.

One possible explanation for our retention success is the culturally-sensitive retention strategies implemented, which were informed by previous qualitative research, in order to increase participant engagement. Previous work by Reidy et al. (2012) evaluated the importance of 15 culturally responsive recruitment and retention strategies, of which the use of bicultural, bilingual, and experienced study staff emerged as critical components. In our study, researchers conducted individual semi-structured interviews with Hispanic men prior to developing the study, which identified several viable gender- and culturally-tailored recruitment and intervention strategies (e.g. face-to-face individual counseling sessions, inviting spouses to attend sessions) (Garcia et al., 2017). These strategies were then incorporated into the design of the current pilot study. Upon the completion of the study, participant utilization and satisfaction with the GCSWLI were assessed in order to evaluate the success and acceptability of specific intervention components. Among GCSWLI completers, intervention attendance was 77% and 70% of self-monitoring diaries were completed during the 12-week intervention. Overall, participant satisfaction with the intervention and individual progress towards changing weight management-related behaviors was high. Further, a majority of the GCSWLI

participants who completed the treatment satisfaction surveys reported that they would definitely recommend the program to others, which is promising for future efforts.

Our pilot study resulted in significant and clinically meaningful weight loss in GCSWLI participants at 12 weeks, and it was maintained by week 24. To our knowledge, no data currently exists to provide a meaningful comparison to a weight loss intervention tailored for Hispanic men. However, our weight loss figures compare favorably to other community-based interventions developed for the Hispanic/Latino population targeting weight loss and prevention of obesity-related chronic diseases. In a pilot *promotora*-led diet and physical activity workplace intervention among a group of immigrant farmworkers, Mitchell et al. (2015) observed significant weight loss after 10 weekly educational sessions. However, interestingly, men did not achieve significant weight loss compared to women (Mitchell et al., 2015). In contrast, Rosas et al. (2015) reported greater weight loss in men compared to women at each time point in a 2-year randomized-controlled trial evaluating the effectiveness of a 12-month intensive case management intervention with and without the use of community health workers. However, at 24 months differences were no longer significant, highlighting the need for further examination of long-term weight maintenance strategies.

Strengths and Limitations

One strength of the study was our comprehensive framework used to develop the intervention taking into consideration factors related to gender and culture(Garcia et al., 2018). Another strength was our study's contribution to the limited research examining

effective culturally-tailored behavioral weight loss programs for Spanish-speaking Hispanic men. This study also had several limitations. First, our small sample size and focus on Hispanic male adults primarily from Mexican-origin decent precludes generalizability to other Hispanic or Latino racial/ethnic subgroups. For example, in the Hispanic Community Health Study/Study of Latinos, rates of obesity and prevalence of three or more cardiovascular disease risk factors were reported to be highest among men and women of Puerto Rican background (Daviglus, Pirzada, & Talavera, 2014). Future research efforts should continue to acknowledge the heterogeneity of the Hispanic/Latino population and focus on addressing these disparities in a culturally-sensitive manner. It is also important to recognize the relatively short duration of the study which precludes the assessment of long-term weight management behaviors. Further, while attendance, adherence to self-monitoring, and overall treatment satisfaction were favorable, the study was not designed to assess the relative contributions of individual behavior change techniques, making it difficult to determine which strategies were most effective in eliciting the observed behavior changes. A final limitation was our use of self-reported measures for diet and physical activity outcomes. The potential bias resulting from the use of these measures may be minimized in future, larger trials with the use of alternative measures of diet and physical activity (e.g. dietary biomarkers and accelerometers for physical activity).

Research and Practical Implications

As efforts continue to be made towards obesity prevention and treatment, it is critical that culturally relevant factors belonging to racial/ethnic subgroups that may affect key

intervention components in weight loss behavioral research are identified, garnered, and used to inform intervention design and implementation. Although feasibility, acceptability, and preliminary efficacy of the current pilot intervention are promising, future research should determine if these improvements can be sustained beyond 24 weeks.

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Table 1. Intervention attendance and self-monitoring adherence during the GCSWLI among completers

Characteristics	GCSWLI (N=20) mean (SD)
Attendance at Individual Sessions (%)	77
Diaries Completed (%)	70
Diaries Completed Per Person (total # diaries)	8.4 (3.9)
Diet Days Recorded (days/week)[a]	3.4 (3.3)
Self-Reported Calorie Intake (kcal/day)[a]	1337 (410)
Self-Reported Physical Activity[a]	
● Days/Week[a]	3.9 (2.6)
● Minutes/Week[a]	214.5 (173.8)
Self-Weighed (days/week)[a]	3.6 (3.3)

SD = standard deviation
GCSWLI = gender- and culturally-sensitive weight loss intervention
[a] Data obtained from paper diary logging

Table 2. GCSWLI Participant Reponses (n=19) to Treatment Satisfaction Survey

How satisfied are you overall with the weight management program?[a]	
Somewhat Dissatisfied	1 (4.0%)
Somewhat Satisfied	2 (8.0%)
Very Satisfied	16 (64.0%)
Would you recommend the weight management program you received to others?[b]	
Probably Not	1 (4.0%)
Definitely Would	18 (72.0%)
Given the effort you put into following the weight management program, how satisfied are you with your overall progress over the past 12 weeks?[c]	3.0 (3.0 - 4.0)
Given the effort you put into following the weight management program for the past 12 weeks, how satisfied are you overall with your progress on…[c]	
Changing your weight:	4.0 (3.0 - 4.0)
Changing your dietary habits:	4.0 (3.0 - 4.0)
Changing your physical activity habits:	4.0 (2.5 - 4.0)
Missing	6 (24.0%)

Responses are n (%) or median (interquartile range)

[a] (1 = very dissatisfied and 4 = very satisfied)

[b] (1 = definitely not and 4 = definitely would)

[c] (-4 = very dissatisfied and 4 = very satisfied)

Table 3. Weight, body composition, physical activity, and daily caloric intake by treatment group

	Mean[a] (SD)			Mean change from baseline (95% CI), p-value	Mean differences between groups (95% CI), p-value
	Baseline	Week 12	Week 24	Week 12 - Baseline	Week 12[b]
Weight (kg)					
GCSWLI	103 (19.1)	96.9 (17.8)	96.7 (18.4)	-6.3 (-8.1, -4.4), p < 0.01	-5.5 (-8.0, -2.9), p < 0.01
WLC	102 (18.4)	101 (19.5)		-0.8 (-2.5, 0.9), p = 0.37	
Percent weight change					
GCSWLI				-5.8 (-7.5, -4.0), p < 0.01	-5.0 (-7.4, -2.5), p < 0.01
WLC				-0.8 (-2.5, 0.9), p = 0.34	
Waist circumference (cm)					
GCSWLI	115 (13.4)	110 (14.1)	110 (14.2)	-4.7 (-6.2, -3.1), p < 0.01	-4.3 (-6.4, -2.1), p < 0.01
WLC	113 (13.1)	113 (13.3)		-0.39 (-1.9, 1.1), p = 0.60	
Percent body fat					
GCSWLI	37.2 (5.42)	35.5 (6.15)	34.8 (6.68)	-1.6 (-2.4, -0.89), p < 0.01	-1.1 (-2.2, -0.08), p = 0.035
WLC	37 (5.98)	36.4 (4.86)		-0.5 (-1.2, 0.2), p = 0.16	
Leisure Time Physical Activity (minutes/week)					
GCSWLI	92 (260)	275 (495)	228 (439)	183 (-26, 392), p = 0.087	144.5 (-145, 433), p = 0.33
WLC	56.4 (137)	94.9 (184)		38.5 (-162, 239), p = 0.71	
Average caloric intake[c] (kcal/day)					
GCSWLI	2825 (3087)	1375 (852)	1477 (1143)	-51.3 (-62.6, -36.7), p < 0.01	-38.3 (-57.1, -11.4), p < 0.01
WLC	2729 (3292)	2152 (3758)		-21.1 (-38.5, 1.1), p = 0.061	
Number of observations[d] (% of observations at baseline)					
GCSWLI	25 (100)	20 (80)	19 (76)		
WLC	25 (100)	23 (92)			

SD = standard deviation; GCSWLI = gender- and culturally-sensitive weight loss intervention; WLC = wait-list control

[a]Geometric means, estimated by contrasts in the model

[b]Difference in change from baseline between groups at week 12

[c]Differences in caloric intake are percent differences, and (for the last column) percent difference in ratio of mean week 12 to mean baseline measurements

[d]The number of observations available for some outcomes were one below or above the values given

NOTE: mHealth technology was integrated for the WLC at week 12. Outcome data at week 24 is not presented in the table as comparisons between groups would not be appropriate.